2024 Annual Congress:

Hematologic Malignancies™

New York Marriott Marquis • New York, NY

EXHIBIT GUIDE

In-Person and Virtual Exhibits

Exhibit Hall

Astor Ballroom (7th Floor)

FRIDAY, SEPTEMBER 20, 2024

12:00 – 1:00 PM

3:05 – 3:25 PM

5:30 – 7:00 PM Welcome Reception

SATURDAY, SEPTEMBER 21, 2024

7:00 – 8:00 AM

10:20 – 10:40 AM

11:40 AM – 12:40 PM

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- Friday, September 20 | 12:25 – 12:55 PM
  Learn About an Alternative Treatment for Certain B-cell Malignancies*
  Sponsored by Eli Lilly and Company
- Saturday, September 21 | 7:25 – 7:55 AM
  Learn More About the Library of NCCN Compendia
  Presented by NCCN
- Saturday, September 21 | 11:50 AM – 12:25 PM
  COLUMVI (glofitamab-gxbm): The First and Only FDA-approved Fixed-duration Bispecific Antibody for 3L+ Diffuse Large B-cell Lymphoma*
  Presented by Genentech

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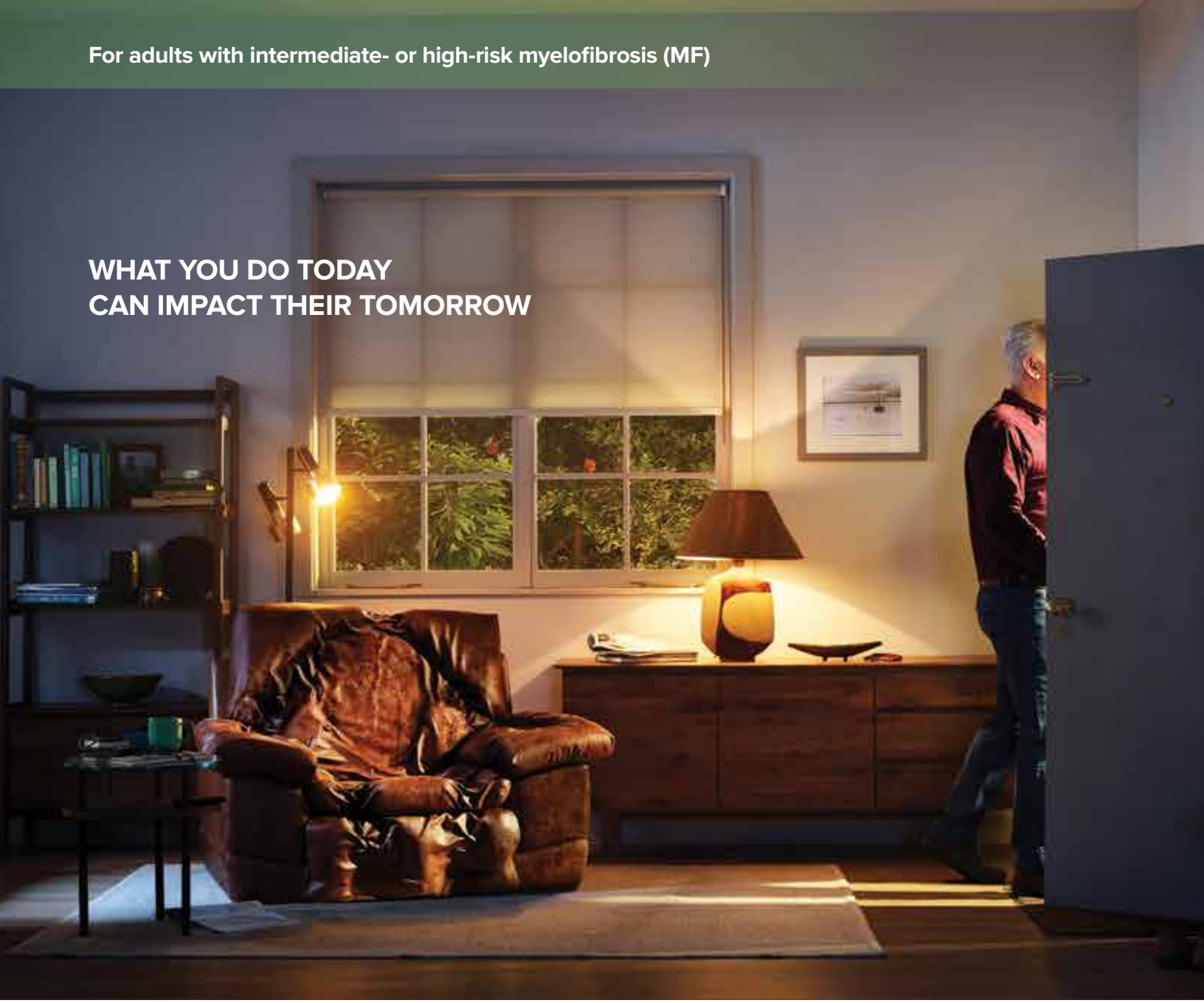
For adults with intermediate- or high-risk myelofibrosis (MF)



WHAT YOU DO TODAY CAN IMPACT THEIR TOMORROW

Indications and Usage

Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF in adults.

Important Safety Information

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia (ANC $<0.5 \times 10^9$/L) was generally reversible by withholding Jakafi until recovery
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination
- Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate
- Herpes zoster infection has been reported in patients receiving Jakafi. Advise patients about early signs and symptoms of herpes zoster and to seek early treatment. Herpes simplex virus reactivation and/or dissemination has been reported in patients receiving Jakafi. Monitor patients for the development of herpes simplex infections. If a patient develops evidence of dissemination of herpes simplex, consider interrupting treatment with Jakafi; patients should be promptly treated and monitored according to clinical guidelines
- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections. Monitor and treat patients with chronic HBV infection according to clinical guidelines
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation
- Non-melanoma skin cancers (NMSC) including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations

INTERVENE WITH JAKAFI AT DIAGNOSIS

COMFORT-I Primary Endpoint*

42% of patients receiving Jakafi achieved a ≥35% reduction in spleen volume at week 24 vs 0.7% of patients receiving placebo ($P < 0.0001$)[1,2]

- 4.4-year median duration of spleen response among primary responders (n = 65)[3†]

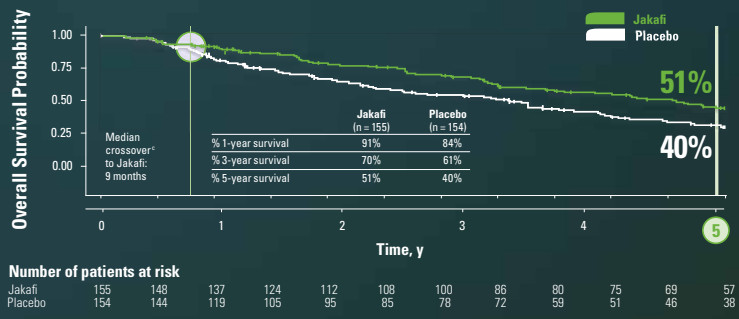
COMFORT-I Secondary Endpoint‡

46% of patients receiving Jakafi achieved a ≥50% improvement in Total Symptom Score (TSS) at week 24 vs 5% of patients receiving placebo ($P < 0.0001$)[1,2]

- Median time to symptom response was <4 weeks for patients receiving Jakafi[1]

COMFORT-I 5-year analysis: Jakafi and placebo

Overall Survival Kaplan-Meier Curves by Treatment Group in COMFORT-I[1,3,4,a,b]



- At 3 years, survival probability was 70% for patients originally randomized to Jakafi and 61% for those originally randomized to placebo[1]
- Overall survival was a prespecified secondary endpoint in COMFORT-I[1]

Jakafi 5-year overall survival probability was 51%[3]

- All patients in the placebo group either crossed over to Jakafi at a median of 9 months or discontinued[1]

Intervene with Jakafi at diagnosis in appropriate patients with MF
STARTWITHJAKAFI.COM

CT, computed tomography; MRI, magnetic resonance imaging.
*COMFORT-I (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-I) was a randomized, double-blind, placebo-controlled phase 3 study with 309 patients with intermediate-2–risk or high-risk MF. The primary endpoint was the proportion of patients achieving a ≥35% reduction in spleen volume from baseline to week 24 as measured by CT or MRI.[1,2]
†Duration of spleen response was defined as the interval between the first spleen response measurement that was a ≥35% reduction from baseline and the date of the first measurement that was no longer a ≥35% reduction from baseline that was also a >25% increase from nadir.[3]
‡A secondary endpoint was the proportion of patients with a ≥50% reduction in TSS from baseline to week 24 as measured by the daily patient diary, the modified Myelofibrosis Symptom Assessment Form. TSS encompasses core symptoms of MF: abdominal discomfort, early satiety, pain under left ribs, pruritus, night sweats, and bone/muscle pain. Symptom scores ranged from 0 to 10, with 0 representing symptoms "absent" and 10 representing symptoms "worst imaginable." These scores were added to create the daily total score, which has a maximum of 60. At baseline, mean TSS was 18.0 in the group receiving Jakafi and 16.5 in the group receiving placebo.[1,2]
[a]The 5-year overall survival analysis is not included in the Full Prescribing Information for Jakafi. Although the 3-year overall survival analysis is presented in the Full Prescribing Information, *P* values and hazard ratios are omitted from the overall survival Kaplan-Meier curves.[1,3]
[b]COMFORT-I was not designed to compare survival probabilities between Jakafi and placebo at 3 or 5 years.[3]
[c]Patients randomized to placebo were eligible to crossover to receive Jakafi because of progression-driven events or at the physician's discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.[3]

Jakafi® ruxolitinib (tablets)
5mg • 10mg • 15mg • 20mg • 25mg

- Treatment with Jakafi has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiating Jakafi. Monitor and treat according to clinical guidelines for the management of hyperlipidemia
- Another JAK-inhibitor has increased the risk of major adverse cardiovascular events (MACE), including cardiovascular death, myocardial infarction, and stroke (compared to those treated with tumor TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur
- Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis (DVT), pulmonary embolism (PE), and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. In patients with myelofibrosis (MF) and polycythemia vera (PV) treated with Jakafi in clinical trials, the rates of thromboembolic events were similar in Jakafi and control treated patients. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately
- Another JAK-inhibitor has increased the risk of lymphoma and other malignancies excluding NMSC (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Patients who are current or past smokers are at additional increased risk. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi, particularly in patients with a known secondary malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers
- In myelofibrosis and polycythemia vera, the most common nonhematologic adverse reactions (incidence ≥15%) were bruising, dizziness, headache, and diarrhea. In acute graft-versus-host disease, the most common nonhematologic adverse reactions (incidence >50%) were infections (pathogen not specified) and edema. In chronic graft-versus-host disease, the most common nonhematologic adverse reactions (incidence >20%) were infections (pathogen not specified) and viral infections
- Avoid concomitant use with fluconazole doses greater than 200 mg. Dose modifications may be required when administering Jakafi with fluconazole doses of 200 mg or less, or with strong CYP3A4 inhibitors, or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breastfeed during treatment and for 2 weeks after the final dose

Please see Brief Summary of Full Prescribing Information for Jakafi on the following pages. To learn more about Jakafi, visit **HCP.Jakafi.com**

References: 1. Jakafi Prescribing Information. Wilmington, DE: Incyte Corporation. **2.** Verstovsek S, et al. *N Engl J Med.* 2012;366(9):799-807. **3.** Data on file. Incyte Corporation. Wilmington, DE. **4.** Verstovsek S, et al. *J Hematol Oncol.* 2017;10(1):55.

Jakafi®
ruxolitinib (tablets)
5mg • 10mg • 15mg • 20mg • 25mg

BRIEF SUMMARY: For Full Prescribing Information, see package insert.

INDICATIONS AND USAGE: Myelofibrosis Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults. **Polycythemia Vera** Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft-Versus-Host Disease** Jakafi is indicated for treatment of steroid-refractory acute graft-versus-host disease (aGVHD) in adult and pediatric patients 12 years and older. **Chronic Graft-Versus-Host Disease** Jakafi is indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: Thrombocytopenia, Anemia and Neutropenia Treatment with Jakafi can cause thrombocytopenia, anemia and neutropenia *[see Adverse Reactions (6.1) in Full Prescribing Information]*. Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary *[see Dosage and Administration (2) in Full Prescribing Information]*. Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi. Severe neutropenia (ANC less than 0.5×10^9/L) was generally reversible by withholding Jakafi until recovery. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated *[see Dosage and Administration (2) in Full Prescribing Information]*. **Risk of Infection** Serious bacterial, mycobacterial, fungal and viral infections have occurred *[see Adverse Reactions (6.1) in Full Prescribing Information]*. Delay starting therapy with Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines. *Tuberculosis* Tuberculosis infection has been reported in patients receiving Jakafi. Observe patients receiving Jakafi for signs and symptoms of active tuberculosis and manage promptly. Prior to initiating Jakafi, patients should be evaluated for tuberculosis risk factors, and those at higher risk should be tested for latent infection. Risk factors include, but are not limited to, prior residence in or travel to countries with a high prevalence of tuberculosis, close contact with a person with active tuberculosis, and a history of active or latent tuberculosis where an adequate course of treatment cannot be confirmed. For patients with evidence of active or latent tuberculosis, consult a physician with expertise in the treatment of tuberculosis before starting Jakafi. The decision to continue Jakafi during treatment of active tuberculosis should be based on the overall risk-benefit determination. *Progressive Multifocal Leukoencephalopathy* Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate. *Herpes Zoster and Herpes Simplex* Herpes zoster infection has been reported in patients receiving Jakafi *[see Adverse Reactions (6.1) in Full Prescribing Information]*. Advise patients about early signs and symptoms of herpes zoster and to seek treatment as early as possible if suspected. Herpes simplex virus reactivation and/or dissemination has been reported in patients receiving Jakafi *[see Adverse Reactions (6.2) in Full Prescribing Information]*. Monitor patients for the development of herpes simplex infections. If a patient develops evidence of dissemination of herpes simplex, consider interrupting treatment with Jakafi; patients should be promptly treated and monitored according to clinical guidelines. *Hepatitis B* Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking Jakafi. The effect of Jakafi on viral replication in patients with chronic HBV infection is unknown. Patients with chronic HBV infection should be treated and monitored according to clinical guidelines. **Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi** Following discontinuation of Jakafi, symptoms from myeloproliferative neoplasms may return to pretreatment levels over a period of approximately one week. Some patients with MF have experienced one or more of the following adverse events after discontinuing Jakafi: fever, respiratory distress, hypotension, DIC, or multi-organ failure. If one or more of these occur after discontinuation of, or while tapering the dose of Jakafi, evaluate for and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi therapy without consulting their physician. When discontinuing or interrupting therapy with Jakafi for reasons other than thrombocytopenia or neutropenia *[see Dosage and Administration (2.8) in Full Prescribing Information]*, consider tapering the dose of Jakafi gradually rather than discontinuing abruptly. **Non-Melanoma Skin Cancer (NMSC)** Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred in patients treated with Jakafi. Perform periodic skin examinations. **Lipid Elevations** Treatment with Jakafi has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides *[see Adverse Reactions (6.1) in Full Prescribing Information]*. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined in patients treated with Jakafi. Assess lipid parameters approximately 8-12 weeks following initiation of Jakafi therapy. Monitor and treat according to clinical guidelines for the management of hyperlipidemia. **Major Adverse Cardiovascular Events (MACE)** Another JAK-inhibitor has increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. **Thrombosis** Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis (DVT), pulmonary embolism (PE), and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. In patients with MF and PV treated with Jakafi in clinical trials, the rates of thromboembolic events were similar in Jakafi and control treated patients. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately. **Secondary Malignancies** Another JAK-inhibitor has increased the risk of lymphoma and other malignancies excluding NMSC (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Patients who are current or past smokers are at additional increased risk. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi, particularly in patients with a known secondary malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers. **ADVERSE REACTIONS:** The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling: • Thrombocytopenia, Anemia and Neutropenia *[see Warnings and Precautions (5.1) in Full Prescribing Information]* • Risk of Infection *[see Warnings and Precautions (5.2) in Full Prescribing Information]* • Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi *[see Warnings and Precautions (5.3) in Full Prescribing Information]* • Non-Melanoma Skin Cancer *[see Warnings and Precautions (5.4) in Full Prescribing Information]* • Lipid Elevations *[see Warnings and Precautions (5.5) in Full Prescribing Information]* • Major Adverse Cardiovascular Events (MACE) *[see Warnings and Precautions (5.6) in Full Prescribing Information]* • Thrombosis *[see Warnings and Precautions (5.7) in Full Prescribing Information]* • Secondary Malignancies *[see Warnings and Precautions (5.8) in Full Prescribing Information]*. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. **Myelofibrosis** The safety of Jakafi was assessed in 617 patients in six clinical studies with a median duration of follow-up of 10.9 months, including 301 patients with MF in two Phase 3 studies. In these two Phase 3 studies, patients had a median duration of exposure to Jakafi of 9.5 months (range 0.5 to 17 months), with 89% of patients treated for more than 6 months and 25% treated for more than 12 months. One hundred and eleven (111) patients started treatment at 15 mg twice daily and 190 patients started at 20 mg twice daily. In patients starting treatment with 15 mg twice daily (pretreatment platelet counts of 100 to 200 $\times 10^9$/L) and 20 mg twice daily (pretreatment platelet counts greater than 200 $\times 10^9$/L), 65% and 25% of patients, respectively, required a dose reduction below the starting dose within the first 8 weeks of therapy. In a double-blind, randomized, placebo-controlled study of Jakafi, among the 155 patients treated with Jakafi, the most frequent adverse reactions were thrombocytopenia and anemia *[see Table 2]*. Thrombocytopenia, anemia and neutropenia are dose-related effects. The three most frequent nonhematologic adverse reactions were bruising, dizziness and headache *[see Table 1]*. Discontinuation for adverse events, regardless of causality, was observed in 11% of patients treated with Jakafi and 11% of patients treated with placebo. Table 1 presents the most common nonhematologic adverse reactions occurring in patients who received Jakafi in the double-blind, placebo-controlled study during randomized treatment.

Table 1: Myelofibrosis: Nonhematologic Adverse Reactions Occurring in Patients on Jakafi in the Double-blind, Placebo-controlled Study During Randomized Treatment

	Jakafi (N=155)			Placebo (N=151)		
Adverse Reactions	**All Grades[a] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Bruising[b]	23	< 1	0	15	0	0
Dizziness[c]	18	< 1	0	7	0	0
Headache	15	0	0	5	0	0
Urinary Tract Infections[d]	9	0	0	5	< 1	< 1
Weight Gain[e]	7	< 1	0	1	< 1	0
Flatulence	5	0	0	< 1	0	0
Herpes Zoster[f]	2	0	0	< 1	0	0

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
[b] includes contusion, ecchymosis, hematoma, injection site hematoma, periorbital hematoma, vessel puncture site hematoma, increased tendency to bruise, petechiae, purpura
[c] includes dizziness, postural dizziness, vertigo, balance disorder, Meniere's Disease, labyrinthitis
[d] includes urinary tract infection, cystitis, urosepsis, urinary tract infection bacterial, kidney infection, pyuria, bacteria urine, bacteria urine identified, nitrite urine present
[e] includes weight increased, abnormal weight gain
[f] includes herpes zoster and post-herpetic neuralgia

Description of Selected Adverse Reactions: Anemia In the two Phase 3 clinical studies, median time to onset of first CTCAE Grade 2 or higher anemia was approximately 6 weeks. One patient (< 1%) discontinued treatment because of anemia. In patients receiving Jakafi, mean decreases in hemoglobin reached a nadir of approximately 1.5 to 2.0 g/dL below baseline after 8 to 12 weeks of therapy and then gradually recovered to reach a new steady state that was approximately 1.0 g/dL below baseline. This pattern was observed in patients regardless of whether they had received transfusions during therapy. In the randomized, placebo-controlled study, 60% of patients treated with Jakafi and 38% of patients receiving placebo received red blood cell transfusions during randomized treatment. Among transfused patients, the median number of units transfused per month was 1.2

in patients treated with Jakafi and 1.7 in placebo treated patients. **Thrombocytopenia** In the two Phase 3 clinical studies, in patients who developed Grade 3 or 4 thrombocytopenia, the median time to onset was approximately 8 weeks. Thrombocytopenia was generally reversible with dose reduction or dose interruption. The median time to recovery of platelet counts above 50×10^9/L was 14 days. Platelet transfusions were administered to 5% of patients receiving Jakafi and to 4% of patients receiving control regimens. Discontinuation of treatment because of thrombocytopenia occurred in < 1% of patients receiving Jakafi and < 1% of patients receiving control regimens. Patients with a platelet count of 100×10^9/L to 200×10^9/L before starting Jakafi had a higher frequency of Grade 3 or 4 thrombocytopenia compared to patients with a platelet count greater than 200×10^9/L (17% versus 7%). **Neutropenia** In the two Phase 3 clinical studies, 1% of patients reduced or stopped Jakafi because of neutropenia. Table 2 provides the frequency and severity of clinical hematology abnormalities reported for patients receiving treatment with Jakafi or placebo in the placebo-controlled study.

Table 2: Myelofibrosis: Worst Hematology Laboratory Abnormalities in the Placebo-Controlled Study[a]

	Jakafi (N=155)			Placebo (N=151)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Thrombocytopenia	70	9	4	31	1	0
Anemia	96	34	11	87	16	3
Neutropenia	19	5	2	4	< 1	1

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Additional Data from the Placebo-Controlled Study
• 25% of patients treated with Jakafi and 7% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in alanine transaminase (ALT). The incidence of greater than or equal to Grade 2 elevations was 2% for Jakafi with 1% Grade 3 and no Grade 4 ALT elevations. • 17% of patients treated with Jakafi and 6% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in aspartate transaminase (AST). The incidence of Grade 2 AST elevations was < 1% for Jakafi with no Grade 3 or 4 AST elevations. • 17% of patients treated with Jakafi and < 1% of patients treated with placebo developed newly occurring or worsening Grade 1 elevations in cholesterol. The incidence of Grade 2 cholesterol elevations was < 1% for Jakafi with no Grade 3 or 4 cholesterol elevations.

Polycythemia Vera In a randomized, open-label, active-controlled study, 110 patients with PV resistant to or intolerant of hydroxyurea received Jakafi and 111 patients received best available therapy *[see Clinical Studies (14.2) in Full Prescribing Information]*. The most frequent adverse reaction was anemia. Discontinuation for adverse events, regardless of causality, was observed in 4% of patients treated with Jakafi. Table 3 presents the most frequent nonhematologic adverse reactions occurring up to Week 32.

Table 3: Polycythemia Vera: Nonhematologic Adverse Reactions Occurring in ≥ 5% of Patients on Jakafi in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment

	Jakafi (N=110)		Best Available Therapy (N=111)	
Adverse Reactions	**All Grades[a] (%)**	**Grade 3-4 (%)**	**All Grades (%)**	**Grade 3-4 (%)**
Diarrhea	15	0	7	< 1
Dizziness[b]	15	0	13	0
Dyspnea[c]	13	3	4	0
Muscle Spasms	12	< 1	5	0
Constipation	8	0	3	0
Herpes Zoster[d]	6	< 1	0	0
Nausea	6	0	4	0
Weight Gain[e]	6	0	< 1	0
Urinary Tract Infections[f]	6	0	3	0
Hypertension	5	< 1	3	< 1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
[b] includes dizziness and vertigo
[c] includes dyspnea and dyspnea exertional
[d] includes herpes zoster and post-herpetic neuralgia
[e] includes weight increased and abnormal weight gain
[f] includes urinary tract infection and cystitis

Clinically relevant laboratory abnormalities are shown in Table 4.

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment[a]

	Jakafi (N=110)			Best Available Therapy (N=111)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Hematology						
Anemia	72	< 1	< 1	58	0	0
Thrombocytopenia	27	5	< 1	24	3	< 1
Neutropenia	3	0	< 1	10	< 1	0
Chemistry						
Hypercholesterolemia	35	0	0	8	0	0
Elevated ALT	25	< 1	0	16	0	0
Elevated AST	23	0	0	23	< 1	0
Hypertriglyceridemia	15	0	0	13	0	0

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Acute Graft-Versus-Host Disease In a single-arm, open-label study, 71 adults (ages 18-73 years) were treated with Jakafi for aGVHD failing treatment with steroids with or without other immunosuppressive drugs *[see Clinical Studies (14.3) in Full Prescribing Information]*. The median duration of treatment with Jakafi was 46 days (range, 4-382 days). There were no fatal adverse reactions to Jakafi. An adverse reaction resulting in treatment discontinuation occurred in 31% of patients. The most common adverse reaction leading to treatment discontinuation was infection (10%). Table 5 shows the adverse reactions other than laboratory abnormalities.

Table 5: Acute Graft-Versus-Host Disease: Nonhematologic Adverse Reactions Occurring in ≥ 15% of Patients in the Open-Label, Single-Cohort Study

	Jakafi (N=71)	
Adverse Reactions[a]	**All Grades[b] (%)**	**Grade 3-4 (%)**
Infections (pathogen not specified)	55	41
Edema	51	13
Hemorrhage	49	20
Fatigue	37	14
Bacterial infections	32	28
Dyspnea	32	7
Viral infections	31	14
Thrombosis	25	11
Diarrhea	24	7
Rash	23	3
Headache	21	4
Hypertension	20	13
Dizziness	16	0

[a] Selected laboratory abnormalities are listed in Table 6 below
[b] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.03

Selected laboratory abnormalities during treatment with Jakafi are shown in Table 6.

Table 6: Acute Graft-Versus-Host Disease: Selected Laboratory Abnormalities Worsening from Baseline in the Open-Label, Single Cohort Study

	Jakafi (N=71)	
	Worst grade during treatment	
Laboratory Parameter	**All Grades[a] (%)**	**Grade 3-4 (%)**
Hematology		
Anemia	75	45
Thrombocytopenia	75	61
Neutropenia	58	40
Chemistry		
Elevated ALT	48	8
Elevated AST	48	6
Hypertriglyceridemia	11	1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03

Chronic Graft-Versus-Host Disease In a Phase 3, randomized, open-label, multi-center study, 165 patients were treated with Jakafi and 158 patients were treated with best available therapy for cGVHD failing treatment with steroids with or without other immunosuppressive drugs *[see Clinical Studies (14.4) in Full Prescribing Information]*; sixty-five patients crossed over from best available therapy to treatment with Jakafi, for a total of 230 patients treated with Jakafi. The median duration of exposure to Jakafi for the study was 49.7 weeks (range, 0.7 to 144.9 weeks) in the Jakafi arm. One hundred and nine (47%) patients were on Jakafi for at least 1 year. There were five fatal adverse reactions to Jakafi, including 1 from toxic epidermal necrolysis and 4 from neutropenia, anemia and/or thrombocytopenia. An adverse reaction resulting in treatment discontinuation occurred in 18% of patients treated with Jakafi. An adverse reaction resulting in dose modification occurred in 27%, and an adverse reaction resulting in treatment interruption occurred in 23%. The most common hematologic adverse reactions (incidence > 35%) are anemia and thrombocytopenia. The most common nonhematologic adverse reactions (incidence ≥ 20%) are infections (pathogen not specified) and viral infection. Table 7 presents the most frequent nonlaboratory adverse reactions occurring up to Cycle 7 Day 1 of randomized treatment.

Table 7: Chronic Graft-Versus-Host Disease: All-Grade (≥ 10%) and Grades 3-5 (≥ 3%) Nonlaboratory Adverse Reactions Occurring in Patients in the Open-Label, Active-controlled Study up to Cycle 7 Day 1 of Randomized Treatment

	Jakafi (N = 165)		Best Available Therapy (N = 158)	
Adverse Reactions[b]	**All Grades[a] (%)**	**Grade ≥ 3 (%)**	**All Grades (%)**	**Grade ≥ 3 (%)**
Infections and infestations				
Infections (pathogen not specified)	45	15	44	16
Viral infections	28	5	23	5
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain	18	1	13	0
General disorders and administration site conditions				
Pyrexia	16	2	9	1
Fatigue	13	1	10	2
Edema	10	1	12	1
Vascular disorders				
Hypertension	16	5	13	7
Hemorrhage	12	2	15	2
Respiratory, thoracic and mediastinal disorders				
Cough	13	0	8	0
Dyspnea	11	1	8	1
Gastrointestinal disorders				
Nausea	12	0	13	2
Diarrhea	10	1	13	1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.03
[b] Grouped terms that are composites of applicable adverse reaction terms.

Clinically relevant laboratory abnormalities are shown in Table 8.

Table 8: Chronic Graft-Versus-Host Disease: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Cycle 7 Day 1 of Randomized Treatment[a]

	Jakafi (N = 165)		Best Available Therapy (N = 158)	
Laboratory Test	**All Grades[b] (%)**	**Grade ≥ 3 (%)**	**All Grades (%)**	**Grade ≥ 3 (%)**
Hematology				
Anemia	82	13	75	8
Neutropenia	27	12	23	9
Thrombocytopenia	58	20	54	17

	Jakafi (N = 165)		Best Available Therapy (N = 158)	
Laboratory Test	All Grades[b] (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Chemistry				
Hypercholesterolemia	88	10	85	8
Elevated AST	65	5	54	6
Elevated ALT	73	11	71	16
Gamma glutamyltransferase increased	81	42	75	38
Creatinine increased	47	1	40	2
Elevated lipase	38	12	30	9
Elevated amylase	35	8	25	4

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of Jakafi. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: • Infections and Infestations: Herpes simplex virus reactivation and/or dissemination.

DRUG INTERACTIONS: Effect of Other Drugs on Jakafi: Fluconazole Concomitant use of Jakafi with fluconazole increases ruxolitinib exposure *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*, which may increase the risk of exposure-related adverse reactions. Avoid concomitant use of Jakafi with fluconazole doses of greater than 200 mg daily. Reduce the Jakafi dosage when used concomitantly with fluconazole doses of less than or equal to 200 mg *[see Dosage and Administration (2.6) in Full Prescribing Information]*. **Strong CYP3A4 Inhibitors** Concomitant use of Jakafi with strong CYP3A4 inhibitors increases ruxolitinib exposure *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*, which may increase the risk of exposure-related adverse reactions. Reduce the Jakafi dosage when used concomitantly with strong CYP3A4 inhibitors except in patients with aGVHD or cGVHD *[see Dosage and Administration (2.6) in Full Prescribing Information]*. **Strong CYP3A4 Inducers** Concomitant use of Jakafi with strong CYP3A4 inducers may decrease ruxolitinib exposure *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*, which may reduce efficacy of Jakafi. Monitor patients frequently and adjust the Jakafi dose based on safety and efficacy *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*.

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary When pregnant rats and rabbits were administered ruxolitinib during the period of organogenesis adverse developmental outcomes occurred at doses associated with maternal toxicity *(see Data)*. There are no studies with the use of Jakafi in pregnant women to inform drug-associated risks. The background risk of major birth defects and miscarriage for the indicated populations is unknown. Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk in the U.S. general population of major birth defects is 2% to 4% and miscarriage is 15% to 20% of clinically recognized pregnancies. **Data** *Animal Data* Ruxolitinib was administered orally to pregnant rats or rabbits during the period of organogenesis, at doses of 15, 30 or 60 mg/kg/day in rats and 10, 30 or 60 mg/kg/day in rabbits. There were no treatment-related malformations. Adverse developmental outcomes, such as decreases of approximately 9% in fetal weights were noted in rats at the highest and maternally toxic dose of 60 mg/kg/day. This dose results in an exposure (AUC) that is approximately 2 times the clinical exposure at the maximum recommended dose of 25 mg twice daily. In rabbits, lower fetal weights of approximately 8% and increased late resorptions were noted at the highest and maternally toxic dose of 60 mg/kg/day. This dose is approximately 7% the clinical exposure at the maximum recommended dose. In a pre- and post-natal development study in rats, pregnant animals were dosed with ruxolitinib from implantation through lactation at doses up to 30 mg/kg/day. There were no drug-related adverse findings in pups for fertility indices or for maternal or embryofetal survival, growth and development parameters at the highest dose evaluated (34% the clinical exposure at the maximum recommended dose of 25 mg twice daily). **Lactation: Risk Summary** No data are available regarding the presence of ruxolitinib in human milk, the effects on the breast fed child, or the effects on milk production. Ruxolitinib and/or its metabolites were present in the milk of lactating rats *(see Data)*. Because many drugs are present in human milk and because of the potential for thrombocytopenia and anemia shown for Jakafi in human studies, discontinue breastfeeding during treatment with Jakafi and for two weeks after the final dose. **Data** *Animal Data* Lactating rats were administered a single dose of [^{14}C]-labeled ruxolitinib (30 mg/kg) on postnatal Day 10, after which plasma and milk samples were collected for up to 24 hours. The AUC for total radioactivity in milk was approximately 13-fold the maternal plasma AUC. Additional analysis showed the presence of ruxolitinib and several of its metabolites in milk, all at levels higher than those in maternal plasma. **Pediatric Use:** Myelofibrosis The safety and effectiveness of Jakafi for treatment of myelofibrosis in pediatric patients have not been established. Polycythemia Vera The safety and effectiveness of Jakafi for treatment of polycythemia vera in pediatric patients have not been established. Acute Graft-Versus-Host Disease The safety and effectiveness of Jakafi for treatment of steroid-refractory aGVHD has been established for treatment of pediatric patients 12 years and older. Use of Jakafi in pediatric patients with steroid-refractory aGVHD is supported by evidence from adequate and well-controlled trials of Jakafi in adults *[see Clinical Studies (14.3) in Full Prescribing Information]* and additional pharmacokinetic and safety data in pediatric patients. The safety and effectiveness of Jakafi for treatment of steroid-refractory aGVHD has not been established in pediatric patients younger than 12 years old. Chronic Graft-Versus-Host Disease The safety and effectiveness of Jakafi for treatment of cGVHD after failure of one or two lines of systemic therapy has been established for treatment of pediatric patients 12 years and older. Use of Jakafi in pediatric patients with cGVHD after failure of one or two lines of systemic therapy is supported by evidence from adequate and well-controlled trials of Jakafi in adults and adolescents *[see Clinical Studies (14.4) in Full Prescribing Information]* and additional pharmacokinetic and safety data in pediatric patients. The safety and effectiveness of Jakafi for treatment of cGVHD has not been established in pediatric patients younger than 12 years old. Other Myeloproliferative Neoplasms, Leukemias, and Solid Tumors The safety and effectiveness of ruxolitinib were assessed but not established in a single-arm trial (NCT01164163) in patients with relapsed or refractory solid tumors, leukemias, or myeloproliferative neoplasms. The patients included 18 children (age 2 to < 12 years) and 14 adolescents (age 12 to < 17 years). Overall, 19% of patients received more than one cycle. No new safety signals were observed in pediatric patients in this trial. The safety and effectiveness of ruxolitinib in combination with chemotherapy for treatment of high-risk, de novo CRLF2 rearranged or JAK pathway–mutant Ph-like acute lymphoblastic leukemia (ALL) were assessed but not established in a single-arm trial (NCT02723994). The patients included 2 infants (age < 2 years), 42 children (age 2 to < 12 years) and 62 adolescents (age 12 to < 17 years). No new safety signals were observed in pediatric patients in this trial. Juvenile Animal Toxicity Data Administration of ruxolitinib to juvenile rats resulted in effects on growth and bone measures. When administered starting at postnatal day 7 (the equivalent of a human newborn) at doses of 1.5 to 75 mg/kg/day, evidence of fractures occurred at doses ≥ 30 mg/kg/day, and effects on body weight and other bone measures [e.g., bone mineral content, peripheral quantitative computed tomography, and x-ray analysis] occurred at doses ≥ 5 mg/kg/day. When administered starting at postnatal day 21 (the equivalent of a human 2-3 years of age) at doses of 5 to 60 mg/kg/day, effects on body weight and bone occurred at doses ≥ 15 mg/kg/day, which were considered adverse at 60 mg/kg/day. Males were more severely affected than females in all age groups, and effects were generally more severe when administration was initiated earlier in the postnatal period. These findings were observed at exposures that are at least 27% the clinical exposure at the maximum recommended dose of 25 mg twice daily. **Geriatric Use:** Of the total number of patients with MF in clinical studies with Jakafi, 52% were 65 years and older, while 15% were 75 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. Clinical studies of Jakafi in patients with aGVHD did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects. Of the total number of patients with cGVHD treated with Jakafi in clinical trials, 11% were 65 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. **Renal Impairment:** Total exposure of ruxolitinib and its active metabolites increased with moderate (CLcr 30 to 59 mL/min) and severe (CLcr 15 to 29 mL/min) renal impairment, and ESRD (CLcr less than 15 mL/min) on dialysis *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. Modify Jakafi dosage as recommended *[see Dosage and Administration (2.7) in Full Prescribing Information]*. **Hepatic Impairment:** Exposure of ruxolitinib increased with mild (Child-Pugh A), moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. Reduce Jakafi dosage as recommended in patients with MF or PV with hepatic impairment *[see Dosage and Administration (2.7) in Full Prescribing Information]*. Reduce Jakafi dosage as recommended for patients with Stage 4 liver aGVHD. Monitor blood counts more frequently for toxicity and modify the Jakafi dosage for adverse reactions if they occur for patients with Score 3 liver cGVHD *[see Dosage and Administration (2.7) and Clinical Pharmacology (12.3) in Full Prescribing Information]*. **OVERDOSAGE:** There is no known antidote for overdoses with Jakafi. Single doses up to 200 mg have been given with acceptable acute tolerability. Higher than recommended repeat doses are associated with increased myelosuppression including leukopenia, anemia and thrombocytopenia. Appropriate supportive treatment should be given. Hemodialysis is not expected to enhance the elimination of Jakafi.

Revised: January 2023 PLR-JAK-00064

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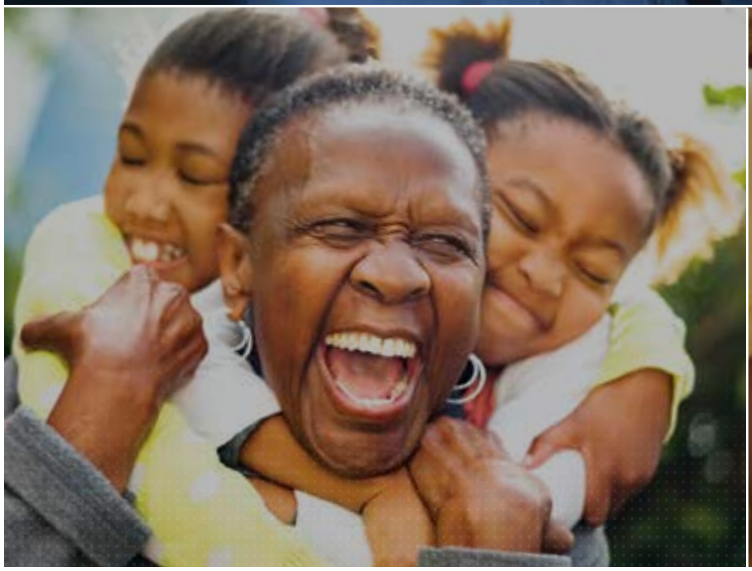

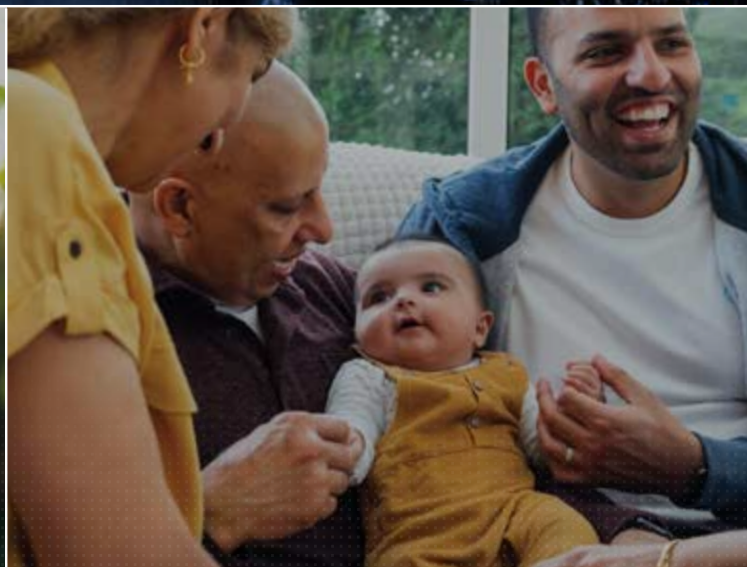

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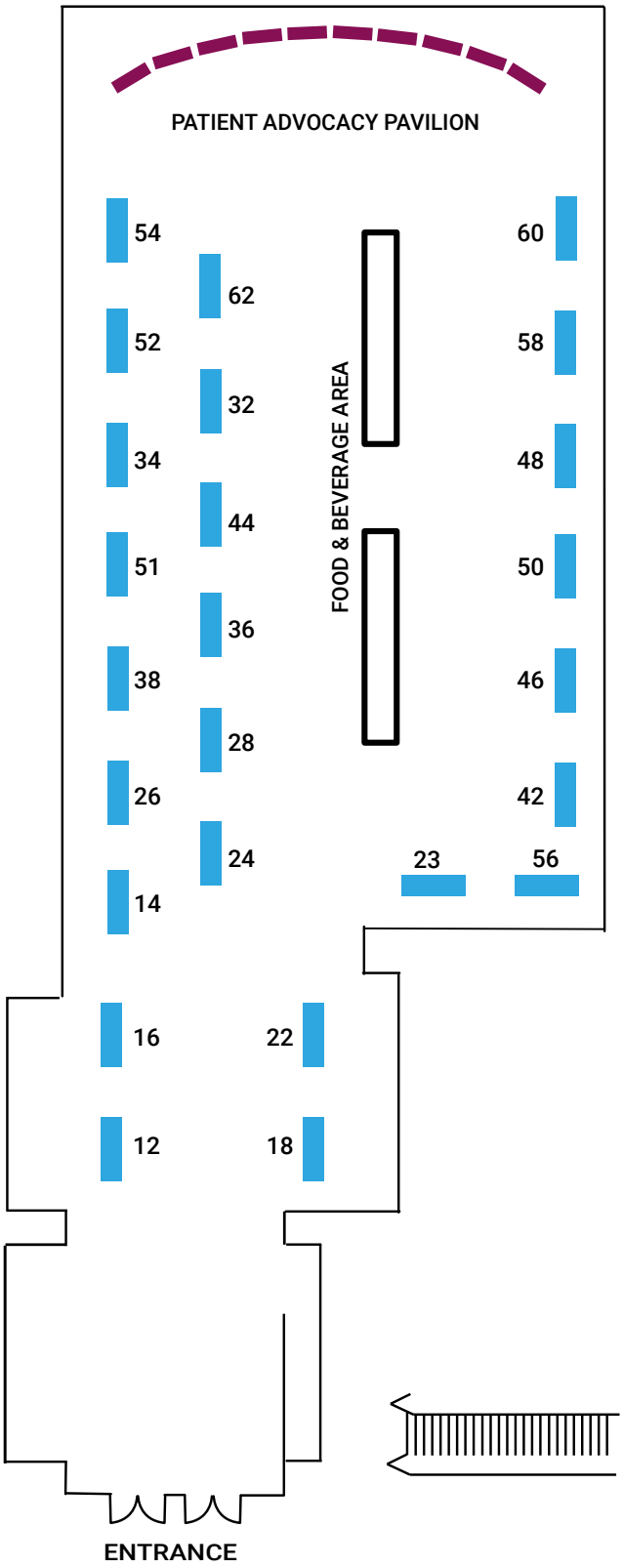

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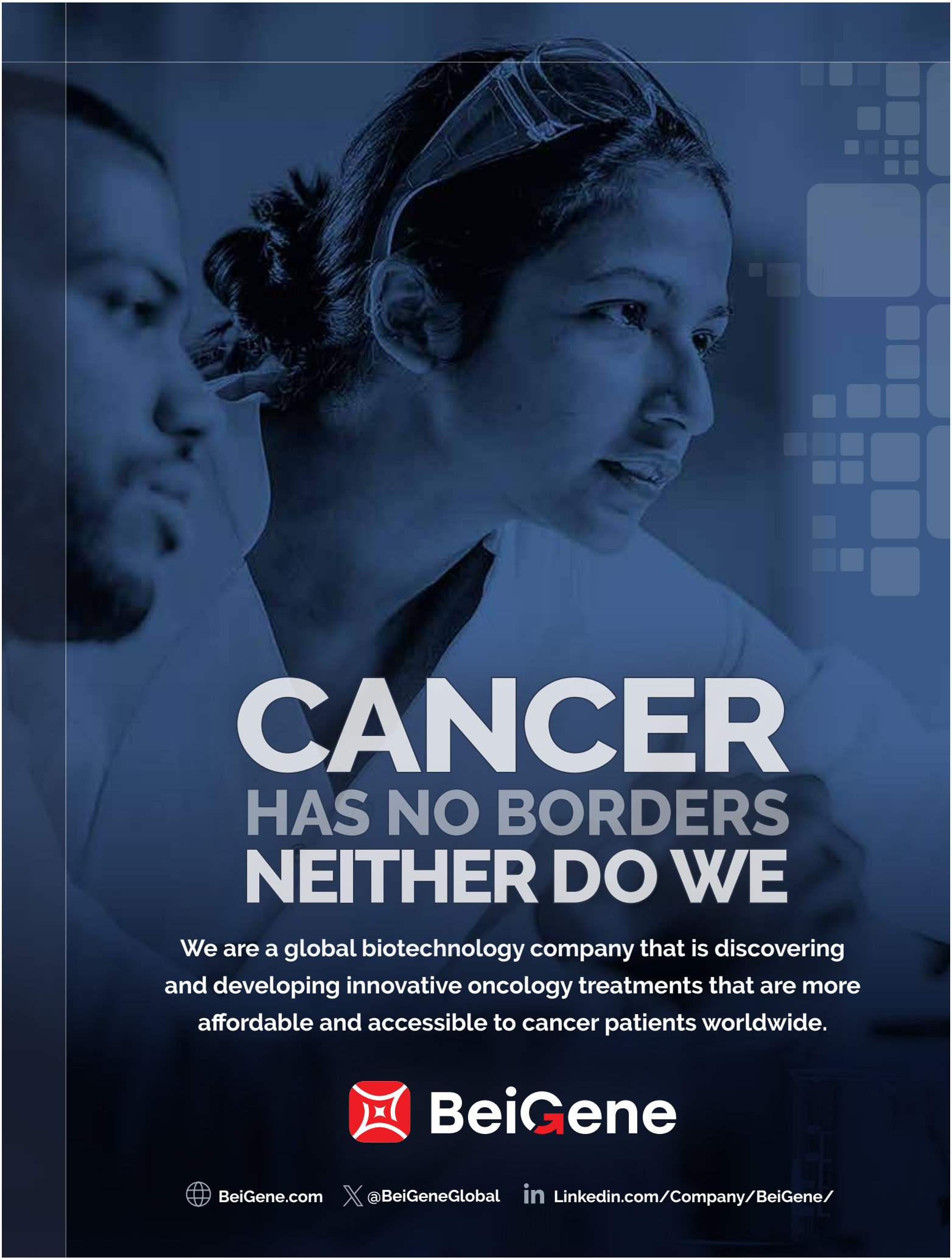
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EVOLVE YOUR STRATEGY WITH TALVEY® (talquetamab-tgvs)

Learn more

INDICATION AND USAGE

TALVEY® (talquetamab-tgvs) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY, including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TALVEY®. Initiate TALVEY® treatment with step-up dosing to reduce the risk of CRS. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS): TALVEY® can cause cytokine release syndrome, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 76% of patients who received TALVEY® at the recommended dosages, with Grade 1 CRS occurring in 57% of patients, Grade 2 in 17%, and Grade 3 in 1.5%. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. Recurrent CRS occurred in 30% of patients. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Initiate therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should be administered prior to the next TALVEY® dose.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity, and consider further management per current practice guidelines. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic Toxicity including ICANS: TALVEY® can cause serious or life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including fatal reactions. In the clinical trial, neurologic toxicity occurred in 55% of patients who received the recommended dosages, with Grade 3 or 4 neurologic toxicity occurring in 6% of patients. The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction (10%).

ICANS was reported in 9% of 265 patients where ICANS was collected and who received the recommended dosages. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Monitor patients for signs and symptoms of neurologic toxicity during treatment and treat promptly. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive care based on severity. Withhold or permanently discontinue TALVEY® based on severity and consider further management per current practice guidelines [see Dosage and Administration (2.5)].

Due to the potential for neurologic toxicity, patients receiving TALVEY® are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during the step-up dosing schedule and for 48 hours after completion of the step-up dosing schedule, and in the event of new onset of any neurological symptoms, until symptoms resolve.

TECVAYLI® and TALVEY® REMS: TALVEY® is available only through a restricted program under a REMS, called the TECVAYLI® and TALVEY® REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Further information about the TECVAYLI® and TALVEY® REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.

TALVEY®
(talquetamab-tgvs) Injection for subcutaneous use
2 mg/mL and 40 mg/mL

Make Your Move

First-in-class GPRC5D × CD3 targeting agent[1,2]

Powerful efficacy demonstrated with TALVEY® monotherapy[1,3,4]

MonumenTAL-1 study design: The efficacy of TALVEY® was evaluated in 219 patients with relapsed or refractory multiple myeloma in the single-arm, open-label, multicenter, phase 1/2 trial. The trial included patients who had received ≥3 prior systemic therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Efficacy was based on ORR and DOR as assessed by an IRC using IMWG criteria.*

Naïve to T-cell redirection therapy†

- **73.6%** ORR‡ with Q2W dosing (95% CI, 63.0%-82.4%) (n=65/87)
- **73%** ORR‡ with QW dosing (95% CI, 63.2%-81.4%) (n=73/100)

Exposed to T-cell redirection therapy†

- **72%** ORR‡ with QW dosing (95% CI, 53%-86%) (n=23/32)§

Versatile treatment option for patients naïve and exposed to T-cell redirection therapy[1]

The MonumenTAL-1 study included patients who were naïve and exposed to T-cell redirection therapy.†§

Flexible dosing: either Q2W or QW dosing schedule right from the start[1]

Q2W and QW dosing begins after the respective step-up dosing schedule.

Oral Toxicity and Weight Loss: TALVEY® can cause oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis. In the clinical trial, 80% of patients had oral toxicity, with Grade 3 occurring in 2.1% of patients who received the recommended dosages. The most frequent oral toxicities were dysgeusia (49%), dry mouth (34%), dysphagia (23%), and ageusia (18%). The median time to onset of oral toxicity was 15 (range: 1 to 634) days, and the median time to resolution to baseline was 43 (1 to 530) days. Oral toxicity did not resolve to baseline in 65% of patients.

TALVEY® can cause weight loss. In the clinical trial, 62% of patients experienced weight loss of 5% or greater, regardless of having an oral toxicity, including 28% of patients with Grade 2 (10% or greater) weight loss and 2.7% of patients with Grade 3 (20% or greater) weight loss. The median time to onset of Grade 2 or higher weight loss was 67 (range: 6 to 407) days, and the median time to resolution was 50 (range: 1 to 403) days. Weight loss did not resolve in 57% of patients who reported weight loss.

Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice, including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate clinically significant weight loss further. Withhold TALVEY® or permanently discontinue based on severity.

Infections: TALVEY® can cause infections, including life-threatening or fatal infections. Serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis and COVID-19 (2.7%).

Monitor patients for signs and symptoms of infection prior to and during treatment with TALVEY® and treat appropriately. Administer prophylactic antimicrobials according to local guidelines. Withhold or consider permanent discontinuation of TALVEY® as recommended, based on severity.

Cytopenias: TALVEY® can cause cytopenias, including neutropenia and thrombocytopenia. In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY®. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4 thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during treatment and withhold TALVEY® as recommended, based on severity.

Skin Toxicity: TALVEY® can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash. In the clinical trial, skin reactions occurred in 62% of patients, with grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to grade 1 or less was 33 days.

Monitor for skin toxicity, including rash progression. Consider early intervention and treatment to manage skin toxicity. Withhold TALVEY® as recommended based on severity.

Hepatotoxicity: TALVEY® can cause hepatotoxicity. Elevated ALT occurred in 33% of patients, with grade 3 or 4 ALT elevation occurring in 2.7%; elevated AST occurred in 31% of patients, with grade 3 or 4 AST elevation occurring in 3.3%. Grade 3 or 4 elevations of total bilirubin occurred in 0.3% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TALVEY® or consider permanent discontinuation of TALVEY®, based on severity [see Dosage and Administration (2.5)].

Embryo-Fetal Toxicity: Based on its mechanism of action, TALVEY® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TALVEY® and for 3 months after the last dose.

Adverse Reactions: The most common adverse reactions (≥20%) are pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache.

The most common Grade 3 or 4 laboratory abnormalities (≥30%) are lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

Please see Brief Summary of full Prescribing Information, including Boxed WARNING for TALVEY®, on adjacent pages.

cp-394174v4

*Efficacy results reflect patients who received ≥4 prior lines of therapy.
†T-cell redirection therapy refers to both CAR-T and bispecific antibody therapy.
‡ORR: sCR+CR+VGPR+PR.
§Of 32 patients, 81% had prior CAR-T, 25% had prior bispecific antibody therapy, and 94% had prior BCMA-directed therapy.

BCMA, B-cell maturation antigen; CAR-T, chimeric antigen receptor-T cell; CD, cluster of differentiation; CI, confidence interval; CR, complete response; DOR, duration of response; GPRC5D, G protein-coupled receptor class C group 5 member D; IMWG, International Myeloma Working Group; IRC, Independent Review Committee; ORR, overall response rate; PR, partial response; QW, once weekly; Q2W, every 2 weeks; sCR, stringent complete response; VGPR, very good partial response.

References: 1. TALVEY® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** U.S. FDA approves TALVEY® (talquetamab-tgvs), a first-in-class bispecific therapy for the treatment of patients with heavily pretreated multiple myeloma. News release. Janssen Biotech, Inc.; August 10, 2023. Accessed January 9, 2024. https://www.janssen.com/fda-approves-talveytm-talquetamab-tgvs-first-class-bispecific-therapy-treatment-patients-heavily **3.** Data on file. Janssen Biotech, Inc. **4.** A study of Talquetamab in participants with relapsed or refractory multiple myeloma. ClinicalTrials.gov identifier: NCT04634552. Updated January 3, 2024. Accessed January 9, 2024. https://clinicaltrials.gov/ct2/show/NCT04634552

Johnson&Johnson

01/24 cp-371120v1

Brief Summary of Prescribing Information for TALVEY™ (talquetamab-tgvs)
TALVEY™ (talquetamab-tgvs) injection, for subcutaneous use

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY, including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TALVEY. Initiate TALVEY treatment with step-up dosing to reduce the risk of CRS. Withhold TALVEY until CRS resolves or permanently discontinue based on severity *[see Dosage and Administration (2.2, 2.5) in Full Prescribing Information, Warnings and Precautions]*.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life threatening or fatal reactions, can occur with TALVEY. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY based on severity *[see Dosage and Administration (2.5) in Full Prescribing Information, Warnings and Precautions]*.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY is available only through a restricted program called the TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS) *[see Warnings and Precautions]*.

INDICATIONS AND USAGE

TALVEY is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate and durability of response *[see Clinical Studies (14) in Full Prescribing Information]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS)

TALVEY can cause cytokine release syndrome, including life-threatening or fatal reactions *[see Adverse Reactions]*.

In the clinical trial, CRS occurred in 76% of patients who received TALVEY at the recommended dosages, with Grade 1 CRS occurring in 57% of patients, Grade 2 in 17%, and Grade 3 in 1.5%. Recurrent CRS occurred in 30% of patients. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Initiate TALVEY therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should be administered prior to the next TALVEY dose *[see Dosage and Administration (2.2, 2.3) in Full Prescribing Information]*.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity and consider further management per current practice guidelines. Withhold TALVEY until CRS resolves or permanently discontinue based on severity *[see Dosage and Administration (2.5) in Full Prescribing Information]*.

TALVEY is available only through a restricted program under a REMS *[see Warnings and Precautions]*.

Neurologic Toxicity including ICANS

TALVEY can cause serious, life-threatening, or fatal neurologic toxicity, including ICANS *[see Adverse Reactions]*.

In the clinical trial, neurologic toxicity, including ICANS, occurred in 55% of patients who received TALVEY at the recommended dosages, with Grade 3 or 4 neurologic toxicity occurring in 6% of patients. The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction (10%).

ICANS was reported in 9% of 265 patients where ICANS was collected and who received TALVEY at the recommended dosages *[see Adverse Reactions]*. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive care based on severity; withhold or permanently discontinue TALVEY based on severity and consider further management per current practice guidelines *[see Dosage and Administration (2.5) in Full Prescribing Information]*.

Due to the potential for neurologic toxicity, patients receiving TALVEY are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during the step-up dosing schedule and for 48 hours after completion of the step-up dosing schedule *[see Dosage and Administration (2.2) in Full Prescribing Information]* and in the event of new onset of any neurological symptoms, until symptoms resolve.

TALVEY is available only through a restricted program under a REMS *[see Warnings and Precautions]*.

TECVAYLI and TALVEY REMS

TALVEY is available only through a restricted program under a REMS called the TECVAYLI and TALVEY REMS because of the risks of CRS and neurologic toxicity, including ICANS *[see Warnings and Precautions]*.

Notable requirements of the TECVAYLI and TALVEY REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Prescribers must counsel patients receiving TALVEY about the risk of CRS and neurologic toxicity, including ICANS and provide patients with Patient Wallet Card.
- Pharmacies and healthcare settings that dispense TALVEY must be certified with the TECVAYLI and TALVEY REMS program and must verify prescribers are certified through the TECVAYLI and TALVEY REMS program.
- Wholesalers and distributers must only distribute TALVEY to certified pharmacies.

Further information about the TECVAYLI and TALVEY REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.

Oral Toxicity and Weight Loss

TALVEY can cause oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis *[see Adverse Reactions]*.

In the clinical trial, 80% of patients had oral toxicity, with Grade 3 occurring in 2.1% of patients who received TALVEY at the recommended dosages. The most frequent oral toxicities were dysgeusia (49%), dry mouth (34%), dysphagia (23%), and ageusia (18%). The median time to onset of oral toxicity was 15 (range: 1 to 634) days, and the median time to resolution to baseline was 43 (1 to 530) days. Oral toxicity did not resolve to baseline in 65% of patients.

TALVEY can cause weight loss *[see Adverse Reactions]*. In the clinical trial, 62% of patients experienced weight loss, regardless of having an oral toxicity, including 29% of patients with Grade 2 (10% or greater) weight loss and 2.7% of patients with Grade 3 (20% or greater) weight loss. The median time to onset of Grade 2 or higher weight loss was 67 (range: 6 to 407) days, and the median time to resolution was 50 (range: 1 to 403) days. Weight loss did not resolve in 57% of patients who reported weight loss.

Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate clinically significant weight loss further. Withhold TALVEY or permanently discontinue based on severity *[see Dosage and Administration (2.5) in Full Prescribing Information]*.

Infections

TALVEY can cause serious infections, including life-threatening or fatal infections *[see Adverse Reactions]*.

In the clinical trial, serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis, and COVID-19 (2.7%).

Monitor patients for signs and symptoms of infection prior to and during treatment with TALVEY and treat appropriately. Administer prophylactic antimicrobials according to local guidelines. Withhold or consider permanent discontinuation of TALVEY as recommended based on severity *[see Dosage and Administration (2.5) in Full Prescribing Information]*.

Cytopenias

TALVEY can cause cytopenias, including neutropenia and thrombocytopenia *[see Adverse Reactions]*.

In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4 thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during treatment and withhold TALVEY as recommended based on severity *[see Dosage and Administration (2.5) in Full Prescribing Information]*.

Skin Toxicity

TALVEY can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash *[see Adverse Reactions]*.

In the clinical trial, skin reactions occurred in 62% of patients, with Grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to Grade 1 or less was 33 days.

Monitor for skin toxicity, including rash progression. Consider early intervention and treatment to manage skin toxicity. Withhold TALVEY as recommended based on severity *[see Dosage and Administration (2.5) in Full Prescribing Information]*.

Hepatotoxicity

TALVEY can cause hepatoxicity. In the clinical trial, elevated ALT occurred in 33% of patients, with Grade 3 or 4 ALT elevation occurring in 2.7%; elevated AST occurred in 31% of patients, with Grade 3 or 4 AST elevation occurring in 3.3%. Grade 3 or 4 elevations of total bilirubin occurred in 0.3% of patients *[see Adverse Reactions]*. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TALVEY or consider permanent discontinuation of TALVEY based on severity *[see Dosage and Administration (2.5) in Full Prescribing Information]*.

Embryo-Fetal Toxicity

Based on its mechanism of action, TALVEY may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TALVEY and for 3 months after the last dose *[see Use in Specific Populations]*.

ADVERSE REACTIONS

The following adverse reactions are also described elsewhere in the labeling:

- Cytokine Release Syndrome *[see Warnings and Precautions]*
- Neurologic Toxicity, including ICANS *[see Warnings and Precautions]*
- Oral Toxicity and Weight Loss *[see Warnings and Precautions]*
- Infections *[see Warnings and Precautions]*
- Cytopenias *[see Warnings and Precautions]*
- Skin Toxicity *[see Warnings and Precautions]*
- Hepatotoxicity *[see Warnings and Precautions]*

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Relapsed/Refractory Multiple Myeloma

MonumenTAL-1

The safety of TALVEY was evaluated in 339 adult patients with relapsed or refractory multiple myeloma. Patients treated with the weekly dosing schedule received step-up doses of 0.01 mg/kg and 0.06 mg/kg of TALVEY followed by TALVEY 0.4 mg/kg subcutaneously weekly thereafter. Patients treated with the biweekly (every 2 weeks) dosing schedule received step-up doses of 0.01 mg/kg, 0.06 mg/kg, and 0.3 mg/kg (0.75 times the recommended step-up dose 3) followed by TALVEY 0.8 mg/kg subcutaneously every 2 weeks thereafter. The duration of exposure for the 0.4 mg/kg weekly regimen was 5.9 (range: 0.0 to 25.3) months (N=186) and for the 0.8 mg/kg biweekly (every 2 weeks) regimen, it was 3.7 (range: 0.0 to 17.9) months (N=153).

Serious adverse reactions occurred in 47% of patients who received TALVEY. Serious adverse reactions in ≥ 2% of patients included CRS (13%), bacterial infection (8%) including sepsis, pyrexia (4.7%), ICANS (3.8%), COVID-19 (2.7%), neutropenia (2.1%), and upper respiratory tract infection (2.1%).

Fatal adverse reactions occurred in 3.2% of patients who received TALVEY, including COVID-19 (0.6%), dyspnea (0.6%), general physical health deterioration (0.6%), bacterial infection (0.3%) including sepsis, basilar artery occlusion (0.3%), fungal infection (0.3%), infection (0.3%), and pulmonary embolism (0.3%).

Permanent discontinuation of TALVEY due to an adverse reaction occurred in 9% of patients. Adverse reactions which resulted in permanent discontinuation of TALVEY in > 1% of patients included ICANS.

Dosage interruptions of TALVEY due to an adverse reaction occurred in 56% of patients. Adverse reactions which required dosage interruption in > 5% of patients included pyrexia (15%), CRS (12%), upper respiratory tract infection (9%), COVID-19 (9%), bacterial infection (7%) including sepsis, neutropenia (6%), and rash (6%).

The most common adverse reactions (≥ 20%) were pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache. The most common Grade 3 or 4 laboratory abnormalities (≥ 30%) were lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

Table 1 summarizes the adverse reactions in MonumenTAL-1.

Table 1: Adverse Reactions (≥10%) in Patients with Relapsed or Refractory Multiple Myeloma Who Received TALVEY in MonumenTAL-1

	TALVEY N=339	
System Organ Class Adverse Reaction	**Any Grade (%)**	**Grade 3 or 4 (%)**
General disorders and administration site conditions		
Pyrexia*	83	4.7†
Fatigue*	37	3.5†
Chills	19	0
Pain*	18	1.8†
Edema*	14	0
Injection site reaction*	13	0
Immune system disorders		
Cytokine release syndrome	76	1.5†
Gastrointestinal disorders		
Dysgeusia[1] ‡	70	0
Dry mouth ‡	34	0
Dysphagia	23	0.9†
Diarrhea	21	0.9†
Stomatitis[2]	18	1.2†
Nausea	18	0
Constipation	16	0
Oral disorder[3]	12	0
Skin and subcutaneous tissue disorders		
Nail disorder[4]	50	0
Skin disorder[5]	41	0.3†
Rash[6]	38	3.5†
Xerosis[7]	30	0
Pruritus	19	0.3†
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain*	43	3.2†
Investigations		
Weight decreased	35	1.5†
Infections and infestations		
Upper respiratory tract infection*	22	2.7†
Bacterial infection including sepsis[8 #]	19	9
COVID-19*[#]	11	2.7
Fungal infection[9 #]	10	0.6
Vascular disorders		
Hypotension*	21	2.9
Nervous system disorders		
Headache*	21	0.6†
Encephalopathy[10]	15	1.8†
Sensory neuropathy[11]	14	0
Motor dysfunction[12]	10	0.6†
Metabolism and nutrition disorders		
Decreased appetite	19	1.2†
Respiratory, thoracic and mediastinal disorders		
Cough*	17	0
Dyspnea*[#]	11	1.8
Hypoxia*	10	1.5†
Cardiac disorders		
Tachycardia*	11	0.6†

Adverse reactions were graded based on CTCAE Version 4.03, with the exception of CRS, which was graded per ASTCT 2019 criteria.

* Includes other related terms.

[#] Includes fatal outcome(s): COVID-19 (N=2), dyspnea (N=2), bacterial infection including sepsis (N=1), fungal infection (N=1).

† Only grade 3 adverse reactions occurred.

‡ Per CTCAE v4.03, maximum toxicity grade for dysgeusia is 2 and maximum toxicity grade for dry mouth is 3.

[1] Dysgeusia: ageusia, dysgeusia, hypogeusia and taste disorder.
[2] Stomatitis: cheilitis, glossitis, glossodynia, mouth ulceration, oral discomfort, oral mucosal erythema, oral pain, stomatitis, swollen tongue, tongue discomfort, tongue erythema, tongue edema and tongue ulceration.
[3] Oral disorder: oral disorder, oral dysesthesia, oral mucosal exfoliation, oral toxicity and oropharyngeal pain.
[4] Nail disorder: koilonychia, nail bed disorder, nail cuticle fissure, nail discoloration, nail disorder, nail dystrophy, nail hypertrophy, nail pitting, nail ridging, nail toxicity, onychoclasis, onycholysis and onychomadesis.
[5] Skin disorder: palmar-plantar erythrodysesthesia syndrome, palmoplantar keratoderma, skin discoloration, skin exfoliation and skin fissures.
[6] Rash: dermatitis, dermatitis acneiform, dermatitis contact, dermatitis exfoliative, dermatitis exfoliative generalized, erythema, exfoliative rash, rash, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pruritic, rash pustular, rash vesicular and stasis dermatitis.
[7] Xerosis: dry eye, dry skin and xerosis.
[8] Bacterial infection including sepsis: bacteremia, bacterial prostatitis, carbuncle, cellulitis, citrobacter infection, clostridium difficile colitis, clostridium difficile infection, cystitis escherichia, cystitis klebsiella, diverticulitis, enterobacter bacteremia, escherichia pyelonephritis, escherichia sepsis, folliculitis, gastroenteritis escherichia coli, helicobacter gastritis, human ehrlichiosis, klebsiella bacteremia, klebsiella sepsis, moraxella infection, otitis media acute, pitted keratolysis, pneumococcal sepsis, pneumonia, pneumonia streptococcal, pseudomonal bacteremia, pyuria, renal abscess, salmonella sepsis, sepsis, septic shock, skin infection, staphylococcal bacteremia, staphylococcal infection, staphylococcal sepsis, streptococcal bacteremia, tooth abscess, tooth infection, urinary tract infection enterococcal, and urinary tract infection pseudomonal.
[9] Fungal infection: body tinea, candida infection, ear infection fungal, esophageal candidiasis, fungal infection, fungal sepsis, fungal skin infection, genital candidiasis, onychomycosis, oral candidiasis, oral fungal infection, oropharyngeal candidiasis, tinea pedis, vulvovaginal candidiasis, and vulvovaginal mycotic infection.
[10] Encephalopathy: agitation, altered state of consciousness, amnesia, aphasia, bradyphrenia, confusional state, delirium, depressed level of consciousness, disorientation, encephalopathy, hallucination, lethargy, memory impairment, mood altered, restlessness, sleep disorder and somnolence.
[11] Sensory neuropathy: dysesthesia, hyperesthesia, hypoesthesia, hypoesthesia oral, immune-mediated neuropathy, neuralgia, neuropathy peripheral, paresthesia, peripheral sensory neuropathy, polyneuropathy, sciatica and vestibular neuronitis.
[12] Motor dysfunction: dysarthria, dysgraphia, dysmetria, dysphonia, gait disturbance, muscle atrophy, muscle spasms, muscular weakness and tremor.

Clinically relevant adverse reactions reported in <10% of patients who received TALVEY included ICANS and viral infection.

Table 2 summarizes select laboratory abnormalities in MonumenTAL-1.

Table 2: Select Laboratory Abnormalities (≥30%) That Worsened from Baseline in Patients with Relapsed or Refractory Multiple Myeloma Who Received TALVEY in MonumenTAL-1

	TALVEY[1]	
Laboratory Abnormality	**Any Grade (%)**	**Grade 3 or 4 (%)**
Hematology		
Lymphocyte count decreased	90	80
White blood cell decreased	73	35
Hemoglobin decreased	67	30
Neutrophil count decreased	64	35
Platelet count decreased	62	22
Chemistry		
Albumin decreased	66	2.1
Alkaline phosphatase increased	49	1.5
Phosphate decreased	44	13
Gamma-glutamyl transferase increased	38	7
Alanine aminotransferase increased	33	2.7
Potassium decreased	31	4.4
Sodium decreased	31	6
Aspartate aminotransferase increased	31	3.3

[1] The denominator used to calculate the rate varied from 326 to 338 based on the number of patients with a baseline value and at least one post-treatment value.

Laboratory toxicity grades are derived based on the NCI CTCAE (National Cancer Institute Common Terminology Criteria for Adverse Events) Version 4.03.

DRUG INTERACTIONS

For certain cytochrome P450 (CYP) substrates, minimal changes in the substrate concentration may lead to serious adverse reactions. Monitor for toxicity or drug concentrations of such CYP substrates when co-administered with TALVEY.

TALVEY™ (talquetamab-tgvs) injection

Talquetamab-tgvs causes release of cytokines *[see Clinical Pharmacology (12.2) in Full Prescribing Information]* that may suppress activity of CYP enzymes, resulting in increased exposure of CYP substrates. Increased exposure of CYP substrates is more likely to occur from initiation of the TALVEY step-up dosing schedule up to 14 days after the first treatment dose and during and after CRS *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on the mechanism of action, TALVEY may cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1) in Full Prescribing Information]*. There are no available data on the use of TALVEY in pregnant women to evaluate for a drug associated risk. No animal reproductive or developmental toxicity studies have been conducted with talquetamab-tgvs.

Talquetamab-tgvs causes T-cell activation and cytokine release; immune activation may compromise pregnancy maintenance. Human immunoglobulin G (IgG) is known to cross the placenta; therefore, TALVEY has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to the fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Lactation

Risk Summary

There is no information regarding the presence of talquetamab-tgvs in human milk, the effect on the breastfed child, or the effect on milk production. Maternal IgG is known to be present in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed child to TALVEY are unknown. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with TALVEY and for 3 months after the last dose.

Females and Males of Reproductive Potential

TALVEY may cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations]*.

Pregnancy Testing

Verify pregnancy status of females of reproductive potential prior to initiating TALVEY.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with TALVEY and for 3 months after the last dose.

Pediatric Use

The safety and efficacy of TALVEY have not been established in pediatric patients.

Geriatric Use

There were 339 patients in the clinical trial for relapsed or refractory multiple myeloma. Of the total number of TALVEY-treated patients in the study, 178 (53%) patients were 65 years of age and older, while 57 (17%) patients were 75 years of age and older. No overall differences in safety or effectiveness were observed in patients 65 to less than 74 years of age compared to younger patients. There was a higher rate of fatal adverse reactions in patients 75 years of age or older compared to younger patients *[see Adverse Reactions]*. Clinical studies did not include sufficient numbers of patients 75 years of age or over to determine whether they respond differently from younger patients.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Cytokine Release Syndrome (CRS)

Discuss the signs and symptoms associated with CRS including, but not limited to, pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Counsel patients to seek medical attention should signs or symptoms of CRS occur. Advise patients that they should be hospitalized for 48 hours after administration of all doses within the TALVEY step-up dosing schedule *[see Dosage and Administration (2.1, 2.5) in Full Prescribing Information, Warnings and Precautions]*.

Neurologic Toxicity, including ICANS

Discuss the signs and symptoms associated with neurologic toxicity, including ICANS including headache, encephalopathy, sensory neuropathy, motor dysfunction, ICANS, confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia. Counsel patients to seek medical attention should signs or symptoms of ICANS occur. Advise patients to refrain from driving or operating heavy or potentially dangerous

machinery during the step-up dosing schedule and for 48 hours after completion of the step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms, until symptoms resolve *[see Dosage and Administration (2.2, 2.5) in Full Prescribing Information, Warnings and Precautions]*.

TECVAYLI and TALVEY REMS

TALVEY is available only through a restricted program called the TECVAYLI and TALVEY REMS. Inform patients that they will be given a Patient Wallet Card that they should carry with them at all times and show to all of their healthcare providers. This card describes signs and symptoms of CRS and neurologic toxicity, including ICANS which, if experienced, should prompt the patient to immediately seek medical attention *[see Warnings and Precautions]*.

Oral Toxicity and Weight Loss

Discuss the signs and symptoms of oral toxicities including dysgeusia, dry mouth, dysphagia, and stomatitis. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur. Advise patients that they may experience weight loss and to report weight loss. Advise patients that they may be referred to a nutritionist for consultation *[see Dosage and Administration (2.5) in Full Prescribing Information, Warnings and Precautions]*.

Infections

Discuss the signs and symptoms of serious infections *[see Dosage and Administration (2.5) in Full Prescribing Information, Warnings and Precautions]*.

Cytopenias

Discuss the signs and symptoms associated with neutropenia and thrombocytopenia *[see Dosage and Administration (2.5) in Full Prescribing Information, Warnings and Precautions]*.

Skin Toxicity

Discuss the signs and symptoms of skin reactions *[see Dosage and Administration (2.5) in Full Prescribing Information, Warnings and Precautions]*.

Hepatotoxicity

Advise patients that liver enzyme elevations may occur and that they should report symptoms that may indicate liver toxicity, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice *[see Warnings and Precautions]*.

Embryo-Fetal Toxicity

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to inform their healthcare provider if they are pregnant or become pregnant. Advise females of reproductive potential to use effective contraception during treatment with TALVEY and for 3 months after the last dose *[see Warnings and Precautions, Use in Specific Populations]*.

Lactation

Advise women not to breastfeed during treatment with TALVEY and for 3 months after the last dose *[see Use in Specific Populations]*.

Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044, USA
U.S. License Number 1864

For patent information: www.janssenpatents.com

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About Our Exhibitors

ADC Therapeutics..... #26

ADC Therapeutics is a leading, commercial-stage global pioneer in the field of antibody drug conjugates (ADCs). Our goal is to be a leading ADC company that transforms the lives of those impacted by cancer. We are a pioneer in the ADC field with specialized end-to-end capabilities unique to ADCs including a validated technology platform, a growing next-generation research & development toolbox and a proven track record that includes an approved and marketed product.

Agios Pharmaceuticals..... #48

Agios is the pioneering leader in PK activation and dedicated to developing transformative therapies for patients living with rare diseases. In the U.S., Agios markets a first-in-class PK activator for adults with PK deficiency, a lifelong, debilitating hemolytic anemia. Building on its scientific expertise in classical hematology and cellular metabolism, Agios is advancing a robust pipeline of investigational medicines in alpha- and beta-thalassemia, sickle cell disease, pediatric PK deficiency, MDS-associated anemia and phenylketonuria.

Amgen ..... #60

While science continues to explore potential cures, every cancer journey is full of challenges from many angles. We can do more. Amgen Oncology advances All Angles of Care by delivering a spectrum of cancer treatment options, from transformative medicines to outcome-enabling solutions such as supportive care and biosimilars.

Astellas..... #24

Astellas is committed to turning innovative science into medical solutions that bring value and hope to patients and their families. Keeping our focus on addressing unmet medical needs and conducting our business with ethics and integrity enables us to improve the health of people throughout the U.S. and around the world.

AstraZeneca..... #32

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines, primarily for the treatment of diseases in three therapeutic areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory & Immunology. For more information, please visit http://www.astrazeneca-us.com and follow us on Twitter @AstraZenecaUS.

GOLD

BeiGene..... #23

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Bristol Myers Squibb ..... #46

Bristol Myers Squibb is a leading global biopharma company focused on discovering, developing and delivering innovative medicines for patients with serious diseases in areas including oncology, hematology, immunology, cardiovascular, fibrosis and neuroscience. Our employees work every day to transform patients' lives through science.

Conexiant Oncology ..... #52

Conexiant empowers oncology professionals with cutting-edge resources, including award-winning clinical content, breaking news, and educational media. Our 25+ years of expertise and robust network foster knowledge sharing and professional growth. We offer integrated advertising solutions through physical and digital publications for clients in the pharmaceutical, research, hospital, and medical services sectors. Conexiant connects clients with an engaged healthcare provider audience using advanced targeting capabilities. Conexiant Oncology—where expertise meets innovation.

SILVER

Eli Lilly and Company..... #16

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism.

GSK..... #58

GSK is a focused, global biopharma company. Our purpose is to unite science, technology and talent to get ahead of disease together and positivity impact the health of billions of people.

About Our Exhibitors

GOLD

Incyte ..... #12

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

BRONZE

Jazz Pharmaceuticals. . . . . #18

Jazz Pharmaceuticals is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases — often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience.

GOLD

Johnson & Johnson . . . . . #14

The Janssen Pharmaceutical Companies of Johnson & Johnson is now J&J Innovative Medicine. Our new brand truly reflects the best of who we are and what we do to lead where medicine is going. Our diverse portfolio spans multiple therapeutic areas—Cardiovascular, Metabolism & Retina, Immunology, Infectious Diseases, Neuroscience, Oncology, and Pulmonary Hypertension.

BRONZE

Karyopharm Therapeutics, Inc. . . . . #22

Karyopharm Therapeutics is a commercial-stage pharmaceutical company pioneering novel first-in-class cancer therapies and dedicated to the discovery, development, and commercialization of drugs to treat cancer. We believe in the extraordinary – in the dedication to positively impact patient lives and treat cancer. We are recognized leaders in XPO1 inhibition, which has the potential to engage the cell's innate ability to fight cancer. Patients embody extraordinary and deserve the same from those in their communities. That is why we choose to spend our time where it has the most significant impact: Multiple Myeloma, Endometrial Cancer, Myelofibrosis, and Diffuse Large B-Cell Lymphoma.

Kite Pharma. . . . . #44

Kite, a Gilead Company, is a global biopharmaceutical company based in Santa Monica, California, focused on cell therapy to treat and potentially cure cancer. As the global cell therapy leader, Kite has treated more patients with CAR T cell therapy than any other company. Kite has the largest in-house cell therapy manufacturing network in the world, spanning process development, vector manufacturing, clinical trial production and commercial product manufacturing.

Menarini Stemline . . . . . #51

Stemline Therapeutics, Inc., a subsidiary of Menarini Group, is focused on the development and commercialization of novel oncology treatments. Stemline commercializes ORSERDU® in the U.S. and Europe, an oral treatment for postmenopausal women or adult men with ER+, HER2-, ESR1-mutated advanced or metastatic breast cancer with disease progression, following at least one line of endocrine therapy. Stemline also commercializes ELZONRIS®, a targeted treatment for patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), an aggressive hematologic malignancy, which is the only approved treatment for BPDCN in the U.S. and E.U. to date. Stemline has an extensive clinical pipeline in various stages of development for a host of cancers.

Merck & Co., Inc. ..... #34

At Merck, our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer. The potential to bring new hope to people with cancer drives our purpose and our commitment. As part of our focus on cancer, Merck is committed to clinical research with one of the largest development programs in the industry across more than 30 tumor types.

Novartis ..... #42

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide. Reimagine medicine with us: Visit us at https://www.novartis.com and connect with us on LinkedIn, Facebook, X/Twitter and Instagram.

Sanofi. . . . . #50

Sanofi is an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our teams across the world strive to transform the practice of medicine, turning the impossible into the possible for patients. Our approach is shaped by our experience developing highly specialized treatments and learning from healthcare professionals and patient communities. We are dedicated to discovering and advancing potential therapies, providing hope to patients and their families around the world.

Servier Pharmaceuticals. . . . . #36

Servier is a global leader in oncology focused on delivering meaningful therapeutic progress for the patients it serves. Governed by a non-profit foundation, Servier approaches innovation with a long-term vision, free of influence from investors and outside pressure to chase short-term monetary targets. Servier's commitment to therapeutic progress guides its collaboration strategy. While many companies across the industry are scaling

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Association-specific verbiage, if applicable; must not contain disease state language.

About Our Exhibitors

back investments, Servier is actively building alliances, completing acquisitions, conducting licensing deals and entering new partnerships that can help to accelerate access to therapies for patients in need. With the company's commercial expertise, global reach, scientific expertise and commitment to clinical excellence, Servier is dedicated to bringing the promise of tomorrow to the patients it serves.

Taiho Oncology, Inc. ..... #28

The mission of Taiho Oncology, Inc. is to improve the lives of patients with cancer, their families and their caregivers. The company specializes in the development and commercialization of orally administered anti-cancer agents for various tumor types. Taiho Oncology has a robust pipeline of small molecule clinical candidates targeting solid tumor and hematological malignancies, with additional candidates in pre-clinical development. Taiho Oncology is a subsidiary of Taiho Pharmaceutical Co., Ltd. which is part of Otsuka Holdings Co., Ltd. Taiho Oncology is headquartered in Princeton, New Jersey and oversees its parent company's European and Canadian operations, which are located in Zug, Switzerland and Oakville, Ontario, Canada. For more information, visit https://www.taihooncology.com/, and follow us on LinkedIn and Twitter.

Thermo Fisher Scientific..... #62

Thermo Fisher Scientific is the world leader in serving science. Our Mission is to enable our customers to make the world healthier, cleaner, and safer. Whether customers are accelerating research, solving complex challenges, improving diagnostics and therapies, or increasing productivity in their laboratories, we are here to support them. Our global team of more than 100,000 colleagues delivers an unrivaled combination of innovative technologies, purchasing convenience, and pharmaceutical services. We are committed to enabling advancements in precision oncology through our Ion Torrent next-generation sequencing (NGS) instrumentation and Oncomine assays, democratizing access to molecular profiling through fast, automated, and reliable solutions.

Patient Advocacy Pavilion

BMT InfoNet..... Virtual Only

BMT InfoNet is a not-for-profit organization that supports transplant and CAR T-cell therapy recipients before, during and after treatment. Our goal is to empower patients with credible information and emotional support so they can take a more active role in decisions affecting health and treatment options. Since 1990, our network of medical experts and transplant and CAR T-cell recipients and care partners have helped thousands of families navigate their treatment experience.

Bone Marrow & Cancer Foundation..... A4

The Bone Marrow & Cancer Foundation founded in 1992 is a national organization dedicated to improving the quality of life for pediatric and adult cancer and transplant patients and their families by providing vital financial assistance, comprehensive resources, educational information, physician referrals and emotional support programs.

Cancer Hope Network..... Virtual Only

Cancer Hope Network's mission is to empower cancer patients and their loved ones with hope through one-on-one peer mentorship support from survivors and caregivers who have faced a similar experience. Through our HopeConnect: One-On-One Peer Mentorship Program, we provide free personalized, supportive connections for patients and caregivers based on their diagnosis and treatment, as well as their mental, emotional, social, cultural, and spiritual needs, individual lifestyle choices, and other personal circumstances.

Cancer Support Community..... A5

The Cancer Support Community is a global nonprofit that uplifts and strengthens people impacted by cancer. We are dedicated to fostering a community where people find connection, compassion, and knowledge. We provide professionally led support and navigation services, along with social connections and award-winning education— *when, where, and how impacted individuals prefer throughout their cancer experience.* We break down barriers to care through education, research, and advocacy.
www.cancersupportcommunity.org

CLL Society ..... Virtual Only

CLL Society is an inclusive, patient-centric, physician-curated nonprofit organization that addresses the unmet needs of the chronic lymphocytic leukemia and

Patient Advocacy Pavilion

small lymphocytic lymphoma (CLL / SLL) community through patient education, advocacy, support, and research. We envision a world in which the entire CLL / SLL community can equitably access quality education, support, and care, to lead healthier and richer lives.

HealthTree Foundation A6

HealthTree is a nonprofit organization using innovation to save lives. We provide lifetime personalized support and education to patients and caregivers, meaningful patient-to-patient connections, and a powerful patient data portal. Our cutting-edge technology empowers blood cancer patients and helps them become active contributors to lifesaving research. Visit healthtree.org.

MPN Research Foundation ..... Virtual Only

For more than 20 years, MPN Research Foundation has been dedicated to identifying and pursuing research to find answers to the prevention, progression - and eventual cure - for rare blood cancers known collectively as myeloproliferative neoplasms (MPN). MPN serves as a convener of researchers, patients, and industry leaders working together to align around a shared mission to address the unmet needs of patients with the most common types of MPNs, which include essential thrombocythemia (ET), polycythemia vera (PV), and myelofibrosis (MF). To learn more, visit www.mpnresearchfoundation.org and connect with us on Twitter, Facebook, Instagram and LinkedIn.

National Marrow Donor Program/Be the Match..... A1

At NMDP, we believe each of us holds the key to curing blood cancers and disorders. As a global nonprofit leader in cell therapy, NMDP creates essential connections between researchers and supporters to inspire action and accelerate innovation to find life-saving cures. With the help of blood stem cell donors from the world's most diverse registry and our extensive network of transplant partners, physicians and caregivers, we're expanding access to treatment so that every patient can receive their life-saving cell therapy. NMDP. Find cures. Save lives.

Oncology Nutrition - Dietetic Practic Group (ON-DPG) A9

Oncology Nutrition Dietetic Practice Group (ON-DPG) of the Academy of Nutrition and Dietetics (AND) fosters excellence in oncology nutrition via an evidence-based nutrition care process. The ON-DPG also promotes advocacy, education and research through its publications, symposiums, and webinars. Attendees will gain education materials on nutrition screening and malnutrition diagnosing as up to 80% of cancer patients become malnourished during their cancer continuum. The ON-DPG endorses the vital role of a Registered Dietitian Nutritionist (RDN) as the nutrition expert on the multidisciplinary care team.

The Leukemia & Lymphoma Society (LLS) A7

The Leukemia & Lymphoma Society (LLS) is the world's largest voluntary (nonprofit) health organization dedicated to funding blood cancer research, support and advocacy. The LLS mission is to cure leukemia, lymphoma, Hodgkin's disease, and myeloma, and improve the quality of life of patients and their families. The mission is carried out through research, patient and professional education and services, and advocating for cures and access to care. For more information, please visit www.LLS.org/CE.

The MDS Foundation, Inc. A8

The MDS Foundation is a global non-profit advocacy organization that for over 30 years has supported patients and their families as well as healthcare providers in the fields of MDS and its related diseases. The MDS Foundation supports and educates patients, their communities, and healthcare providers, and contributes to innovative research in the fields of MDS and its related continuum of diseases to better diagnose, control and ultimately cure these diseases.

Triage Cancer A3

Triage Cancer® is a national, nonprofit organization that provides free education on the legal and practical issues that may impact individuals diagnosed with cancer and their caregivers, through events, materials, and resources.

Young Adult Survivors United A2

Young Adult Survivors United (YASU) provides emotional, social, and financial support to young adult cancer patients & survivors (18-45 when diagnosed), as well as their caregivers. In-person programs are offered in Pittsburgh, PA where YASU is headquartered. Virtual programming is offered to all YAs and caregivers in the U.S. Supportive chats, uplifting social activities, financial assistance, free respite trips, educational workshops, and more are available. For more information, please visit www.yasurvivors.org.


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Navigating a cancer journey is hard.

Connecting with someone who understands is easy.

Cancer Hope Network connects patients and their loved ones with trained Peer Mentors. This one-on-one program is free and confidential.

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We understand.
We're here.

Call or visit us online to be matched:
1-877-HOPENET - **cancerhopenetwork.org**

CANCER HOPE NETWORK

CREATING A WORLD IN WHICH NO ONE HAS TO FACE CANCER ALONE

Cancer Hope Network is a 501(C)(3) Nonprofit registered in the US under EIN: 22-2647316

About Us

YASU offers emotional, social, and financial support to enhancing the quality of lives for YA cancer survivors and their caregivers/co-survivors.

Because Young Adult Cancer is Different.

yasu
Young Adult Survivors United

Contact Us

724-719-2273

www.yasurvivors.org

Programs

(Hybrid Programming)

- Supportive Chats
- Self-Love Workshops
- Financial Assistance
- Free Respite Trips
- Social Activities
- Educational Seminars
- Free Counseling (regional)
- Caregiver/Co-Survivor Support

BMTinfonet.org

30 YEARS EMPOWERING PATIENTS

Resources Available:

Patient Friendly Publications

Directories for:

- Transplant Centers
- CAR T -cell Therapy
- GVHD Specialists
- Mental Health Care Providers

Peer Support

Webinars

Supporting transplant and CAR T-cell therapy patients before, during and after treatment

Since 1990, our network of medical experts and transplant and CAR T-cell recipients has helped thousands of families navigate their treatment

Visit us online: bmtinfonet.org

Email: help@bmtinfonet.org

Phone: 847-433-3313

FREE RESOURCES & MATERIALS FROM TRIAGE CANCER

Legal & Financial Navigation Program

Free, one-on-one help for health care professionals, individuals diagnosed with cancer, and caregivers, in the areas of:

- Health & Disability Insurance
- Employment
- Finances
- Medical Decision-Making
- Estate Planning
- And More!

Contact us:
TriageCancer.org/GetHelp

Practical Guide to Cancer Rights

Four comprehensive Cancer Rights Guides introduce you to the cancer rights law topics that most people encounter in some way after a cancer diagnosis.

- Cancer Rights: Navigating Employment, Insurance, & Finances
- For Caregivers
- For Young Adults
- For Seniors

Download now:
TriageCancer.org/CancerRightsGuides

ONCOLOGY NUTRITION RESOURCES

Optimizing the health of persons with cancer and cancer survivors and contributing to cancer prevention efforts through food and nutrition.

PATIENT SCREENING AND ASSESSMENT TOOLS

Malnutrition Screening Tool

Validated screening tool for inpatient and outpatient oncology populations

Patient Generated Subjective Global Assessment

This scored tool is helpful to triage nutrition interventions

PRACTICE RESOURCES

Educational Handouts and Resources

Over 60 patient handouts covering a variety of disease states, symptoms, and more!

AT A GLANCE

MEMBERS

More than 2000 practicing, retired, and student members spanning clinical, industry, community, educational, management and research practice settings

CPT BILLING CODES FOR MEDICAL NUTRITION THERAPY

97802 - Initial assessment and intervention, face-to-face, each 15 minutes
97803 - Reassessment and intervention, face-to-face, each 15 minutes
97804- Group (2+ individuals), each 30 minutes

COLLABORATORS

- Association of Community Cancer Centers
- Oncology Nursing Society
- Pancreatic Cancer Action Network
- American Cancer Society
- Leukemia and Lymphoma Society
- Cholangiocarcinoma Foundation
- Hope for Stomach Cancer

Oncology Nutrition
a dietetic practice group of the
eat right. Academy of Nutrition and Dietetics

Making cancer a little less lonely.

Bone Marrow & Cancer FOUNDATION

Offering a range of free services designed to help support cancer and transplant patients and their families through treatment and recovery.

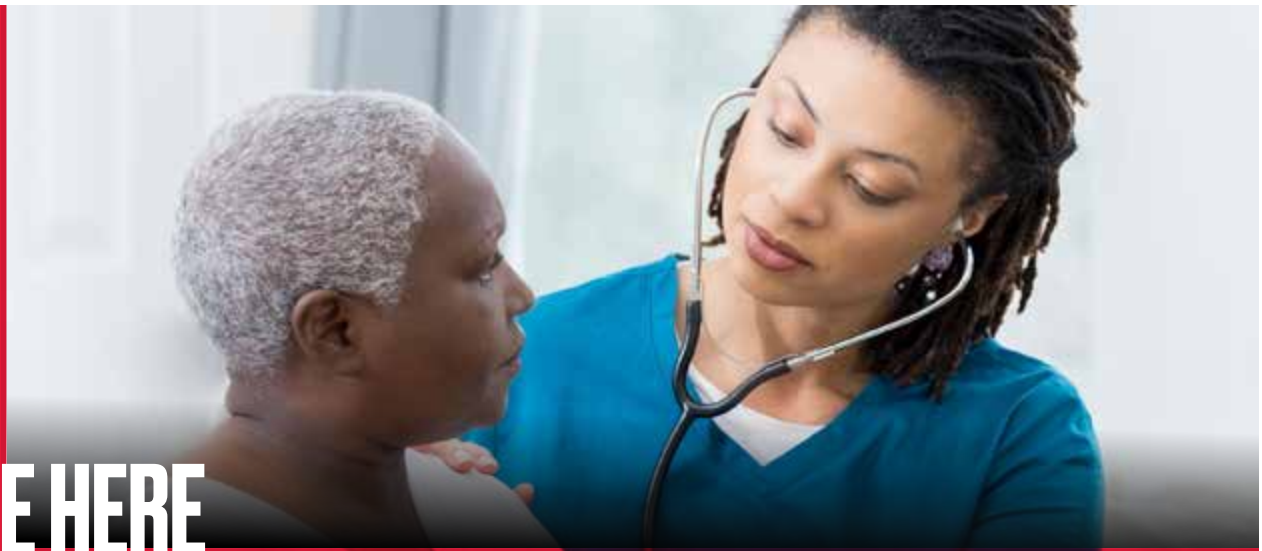
Carelines is a fundraising platform specifically for cancer and transplant patients and their families to raise tax-deductible support for treatment and related expenses, that will not affect a patient's medical insurance or benefits.

Clinical Care Counseling provides confidential individual and family supportive counseling and resource referrals for cancer and transplant patients and family members.

CancerBuddy is a social support network that helps cancer patients, survivors and caregivers find resources, emotional support and a new community of peers going through similar experiences. Download the free app.

Download on the App Store GET IT ON Google Play

Learn more about these and our other services at **bonemarrow.org** or **800-365-1336**



WE'RE HERE TO HELP YOUR PATIENTS.

LEUKEMIA & LYMPHOMA SOCIETY®

A blood cancer diagnosis can be overwhelming for your patients. Blood cancer patients, including those with leukemia, lymphoma, myeloma, myelodysplastic syndromes and myeloproliferative neoplasms can find hope, education, guidance and support from The Leukemia & Lymphoma Society (LLS).

Our Information Specialists complement the care you provide with FREE, in-depth personalized services that connect patients to financial assistance, patient education (including booklets, podcasts and webinars), online and in-person support, nutrition consultations and the LLS Clinical Trial Support Center for assistance with clinical trials.
Please contact us at **800.955.4572** or go to **www.LLS.org/resources-healthcare-professionals**.

National Comprehensive Cancer Network®

NCCN FOUNDATION
Guiding Treatment. Changing Lives.

Support provided by NCCN Foundation

NCCN Guidelines for Patients®

Access 70+ FREE cancer resources

- Acute Lymphoblastic Leukemia (adult)
- Acute Lymphoblastic Leukemia (pediatric)
- Acute Myeloid Leukemia
- Adolescent and Young Adult Cancer
- Adrenal Tumors
- Anal Cancer
- Anemia and Neutropenia: Low Red and White Blood Cell Counts
- Basal Cell Skin Cancer
- B-Cell Lymphomas: Diffuse Large B-Cell Lymphomas
- B-Cell Lymphomas: Follicular Lymphoma
- B-Cell Lymphomas: Mantle Cell Lymphoma
- B-Cell Lymphomas: Marginal Zone Lymphomas
- Bladder Cancer
- Blood Clots and Cancer
- Bone Cancer
- Brain Cancer: Glioma
- Breast Cancer: DCIS Breast Cancer
- Breast Cancer: Inflammatory Breast Cancer
- Breast Cancer: Invasive Breast Cancer
- Breast Cancer: Metastatic Breast Cancer
- Breast Cancer Screening and Diagnosis
- Cervical Cancer
- Chronic Lymphocytic Leukemia
- Chronic Myeloid Leukemia
- Colon Cancer
- Colorectal Cancer Screening
- Distress During Cancer Care
- Esophageal Cancer
- Fatigue and Cancer
- Gallbladder and Bile Duct Cancers
- Gastrointestinal Stromal Tumors (GIST)
- Graft-Versus-Host Disease
- Head and Neck Cancers: Mouth Cancer
- Head and Neck Cancers: Nasopharyngeal Cancer
- Head and Neck Cancers: Throat Cancer
- Hodgkin Lymphoma
- Hodgkin Lymphoma in Children
- Immunotherapy Side Effects: CAR T-Cell Therapy
- Immunotherapy Side Effects: Immune Checkpoint Inhibitors
- Kidney Cancer
- Liver Cancer
- Lung Cancer Screening
- Malignant Pleural Mesothelioma
- Melanoma
- Multiple Myeloma
- Mycosis Fungoides/Sézary Syndrome
- Myelodysplastic Syndromes
- Myeloproliferative Neoplasms
- Nausea and Vomiting
- Neuroendocrine Tumors
- Non-Small Cell Lung Cancer: Early and Locally Advanced
- Non-Small Cell Lung Cancer: Metastatic
- Ovarian Cancer
- Palliative Care
- Pancreatic Cancer
- Peripheral T-Cell Lymphoma
- Primary Central Nervous System Lymphoma
- Primary Cutaneous Lymphomas
- Prostate Cancer: Advanced Stage
- Prostate Cancer: Early Stage
- Rectal Cancer
- Small Bowel Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Squamous Cell Skin Cancer
- Stomach Cancer
- Survivorship Care for Cancer-Related Late and Long-Term Effects
- Survivorship Care for Healthy Living
- Systemic Mastocytosis
- Thyroid Cancer
- Uterine Cancer
- Waldenström Macroglobulinemia

NCCN.org/patientguidelines

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Jazz Pharmaceuticals is proud to support the NCCN 2024 Annual Congress: Hematologic Malignancies ™

Jazz Pharmaceuticals is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases — often with limited or no therapeutic options.

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www.jazzpharmaceuticals.com

Mark Your Calendars

Friday, March 28 – Sunday, March 30, 2025

NCCN Annual Conference 2025

New Location!

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NCCN.org/conference

NCCN 30th Anniversary

2025 Annual Congress: NCCN Hematologic Malignancies™

Fall 2025 – Dates to post soon

New Location!

San Diego, CA

NCCN.org/hem