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Important Safety Information

- Treatment with Jakafi 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 × 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.
- 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 ruxolitinib treatment for myelofibrosis. If PML is suspected, stop Jakafi and evaluate.
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment.
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 including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations.

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.

The three most frequent non-hematologic adverse reactions (incidence >10%) were bruising, dizziness and headache. A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or fluconazole 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 breast-feed.

Please see Brief Summary of Full Prescribing Information for Jakafi on the following pages.
**Brief Summary:** For Full Prescribing Information, see package insert.

**Contraindications:** None.

**Warnings and Precautions:**

**Thrombocytopenia, Anemia and Neutropenia**

Treatment with Jakafi can cause thrombocytopenia, anemia, and neutropenia. [See Dosage and Administration (2.1) in Full Prescribing Information]. Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary [see Dosage and Administration (2.1.1) and Adverse Reactions (6.1) in Full Prescribing Information]. Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi. Severe neutropenia (ANC less than 0.5 X 10^9/L) was generally reversible by withholding Jakafi until recovery [see Adverse Reactions (6.1) in Full Prescribing Information]. 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 (2.1.1) and Adverse Reactions (6.1) in Full Prescribing Information].

**Risk of Infection**

Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting therapy with Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. 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. PML Progressive multifocal leukoencephalopathy (PML) has occurred with ruxolitinib treatment for myelofibrosis. If PML is suspected, stop Jakafi and evaluate. *Herpes Zoster* Adverse events such as a rash, fever, headache, fatigue, lymphadenopathy, myalgias, and arthralgias have been reported in patients with chronic HBV infection 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 reappear to pretreatment levels over a period of approximately one week. Some patients with myeloproliferative disorders have experienced one or more of the following adverse events after discontinuing Jakafi: fever, respiratory distress, hypotension, DIC, 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 (2.5) in Full Prescribing Information], consider tapering the dose of Jakafi gradually rather than discontinuing abruptly.

**Non-Melanoma Skin Cancer**

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. 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.

**Adverse Reactions:**

The following serious 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]. 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. Clinical Trials Experience in Myelofibrosis The safety of Jakafi was assessed in 417 patients in six clinical studies with a median duration of follow-up of 10.9 months, including 301 patients with myelofibrosis 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 (treatment plateau counts of 100 to 200 X 10^9/L) and 20 mg twice daily (treatment plateau counts greater than 200 X 10^9/L and 15% to 25% of patients, respectively, required a dose reduction before the starting dose within the first 6 weeks of therapy. In a double-blind, randomized, placebo-controlled study of Jakafi, among the 155 patients treated with Jakafi, the most frequent adverse drug reactions were thrombocytopenia and anemia [see Table 2]. Thrombocytopenia, anemia and neutropenia are dose related effects. The three most frequent non-hematologic 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 adverse reactions occurring in patients who received Jakafi in the double-blind, placebo-controlled study during randomized treatment.

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

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>All Grades (N=1155) (%)</th>
<th>Grade 3 (N=15)</th>
<th>Grade 4 (N=4)</th>
<th>All Grades (N=1151) (%)</th>
<th>Grade 3 (N=15)</th>
<th>Grade 4 (N=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising</td>
<td>23 &lt;1</td>
<td>0</td>
<td>15 0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>18 &lt;1</td>
<td>0</td>
<td>7 0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Headache</td>
<td>15 0</td>
<td>0</td>
<td>5 0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Urinary Tract Infections</td>
<td>9 0</td>
<td>0</td>
<td>5 &lt;1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight Gain</td>
<td>7 &lt;1</td>
<td>0</td>
<td>1 &lt;1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Flatulence</td>
<td>5 0</td>
<td>0</td>
<td>&lt;1 0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Herpes Zoster</td>
<td>2 0</td>
<td>0</td>
<td>&lt;1 0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0

**Laboratory Parameter**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>All Grades (N=1155) (%)</th>
<th>Grade 3 (N=15)</th>
<th>Grade 4 (N=4)</th>
<th>All Grades (N=1151) (%)</th>
<th>Grade 3 (N=15)</th>
<th>Grade 4 (N=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>70 9</td>
<td>4</td>
<td>31 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Anemia</td>
<td>96 34</td>
<td>11</td>
<td>87 16</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>19 5</td>
<td>2</td>
<td>4 &lt;1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Presented values are worst Grade values regardless of baseline

**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 Grade 4 and 4.4% 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 4% Grade 3 and 0% for placebo.

**Clinical Trial Experience in Polycythemia Vera**

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

**Table 2: Myelofibrosis: Worst Laboratory Abnormalities in the Placebo-controlled Study**

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>All Grades (N=115) (%)</th>
<th>Grade 3 (N=15)</th>
<th>Grade 4 (N=4)</th>
<th>All Grades (N=115) (%)</th>
<th>Grade 3 (N=15)</th>
<th>Grade 4 (N=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>70 9</td>
<td>4</td>
<td>31 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Anemia</td>
<td>96 34</td>
<td>11</td>
<td>87 16</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>19 5</td>
<td>2</td>
<td>4 &lt;1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0
Table 3: Polycythemia Vera: Treatment Emergent Adverse Events Occurring in ≥ 6% of Patients on Jakafi in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment

<table>
<thead>
<tr>
<th>Jakafi (N=110)</th>
<th>Best Available Therapy (N=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event</td>
<td>All Grades (%)</td>
</tr>
<tr>
<td>Headache</td>
<td>16 &lt;1</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>15 &lt;1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>15 0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>15 0</td>
</tr>
<tr>
<td>Fatigue</td>
<td>15 0</td>
</tr>
<tr>
<td>Pruritus</td>
<td>14 &lt;1</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>13 3</td>
</tr>
<tr>
<td>Muscle Spasms</td>
<td>12 &lt;1</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>9 0</td>
</tr>
<tr>
<td>Constipation</td>
<td>8 0</td>
</tr>
<tr>
<td>Cough</td>
<td>8 0</td>
</tr>
<tr>
<td>Edema</td>
<td>8 0</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>7 0</td>
</tr>
<tr>
<td>Anemia</td>
<td>7 0</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>6 0</td>
</tr>
<tr>
<td>Herpes Zoster</td>
<td>6 &lt;1</td>
</tr>
<tr>
<td>Nausea</td>
<td>6 0</td>
</tr>
</tbody>
</table>

* National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0

Other clinically important treatment emergent adverse events observed in less than 6% of patients treated with Jakafi were: Weight gain, hypertension, and urinary tract infections. 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

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>Jakafi (N=110)</th>
<th>Best Available Therapy (N=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Hematology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>72 &lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>27 5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>3 0</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>35 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Elevated ALT</td>
<td>25 &lt;1</td>
<td>0 0</td>
</tr>
<tr>
<td>Elevated AST</td>
<td>23 0</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td>15 0</td>
<td>0 0</td>
</tr>
</tbody>
</table>

* Presented values are worst Grade values regardless of baseline

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CYP3A4 inducer rifampin in healthy subjects. No dose adjustment is recommended; however, monitor patients frequently and adjust the Jakafi dose based on safety and efficacy [see Pharmacokinetics (12.3) in Full Prescribing Information].

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C: [See Summary]
There are no adequate and well-controlled studies of Jakafi in pregnant women. In embryofetal toxicity studies, treatment with ruxolitinib resulted in an increase in late resorptions and reduced fetal weights at maternally toxic doses. Jakafi should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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 was no evidence of teratogenicity. However, 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 6% 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).

Nursing Mothers: It is not known whether ruxolitinib is excreted in human milk. Ruxolitinib and/or its metabolites were excreted in the milk of lactating rats with a concentration that was >5-fold the maternal plasma. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Jakafi, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Pediatric Use: The safety and effectiveness of Jakafi in pediatric patients have not been established. Geriatric Use: Of the total number of patients with myelofibrosis 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.

Renal Impairment: The safety and pharmacokinetics of single dose Jakafi (25 mg) were evaluated in a study in healthy subjects [C0 72-164 mL/min (N=8)] and in subjects with mild [C0 53-63 mL/min (N=8)], moderate [C0 38-57 mL/min (N=8)], or severe renal impairment (C0 15-51 mL/min (N=8)]. Eight (8) additional subjects with end stage renal disease requiring hemodialysis were also enrolled. The pharmacokinetics of ruxolitinib was similar in subjects with various degrees of renal impairment and in those with normal renal function. However, plasma AUC values of ruxolitinib metabolites increased with increasing severity of renal impairment. This was most marked in the subjects with end stage renal disease requiring hemodialysis. The change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding increase in metabolite exposure. Ruxolitinib is not removed by dialysis; however, the removal of some active metabolites by dialysis cannot be ruled out. When administering Jakafi to patients with myelofibrosis and moderate (C0 30-59 mL/min) or severe renal impairment (C0 15-29 mL/min) with a platelet count between 50 X 10^9 and 150 X 10^9/L, a dose reduction is recommended. A dose reduction is also recommended for patients with polycythemia vera and moderate (C0 30-59 mL/min) or severe renal impairment (C0 15-29 mL/min) in all patients with end stage renal disease on dialysis, a dose reduction is recommended [see Dosage and Administration (2.4) in Full Prescribing Information].

Hepatic Impairment: The safety and pharmacokinetics of single dose Jakafi (25 mg) were evaluated in a study in healthy subjects (N=8) and in subjects with mild [Child-Pugh A (N=8)], moderate [Child-Pugh B (N=8)], or severe hepatic impairment [Child-Pugh C (N=8)]. The mean AUC for ruxolitinib was increased by 67%, 28% and 65%, respectively, in patients with mild, moderate and severe hepatic impairment compared to patients with normal hepatic function. The terminal elimination half-life was prolonged in patients with hepatic impairment compared to healthy controls (4.1-5.0 hours versus 2.8 hours). The change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding increase in ruxolitinib exposure except in the severe (Child-Pugh C) hepatic impairment cohort where the pharmacodynamic activity was more prolonged in some subjects than expected based on plasma concentrations of ruxolitinib. When administering Jakafi to patients with myelofibrosis and any degree of hepatic impairment and with a platelet count between 50 X 10^9 and 150 X 10^9/L, a dose reduction is recommended. A dose reduction is also recommended for patients with polycythemia vera and hepatic impairment [see Dosage and Administration (2.4) 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 ruxolitinib.

AUC of ruxolitinib decreased 32% and 61%, respectively, following concomitant administration with the strong CYP3A4 inhibitor, fluconazole at doses of 100 mg to 400 mg once daily, respectively [see Pharmacokinetics (12.3) in Full Prescribing Information].
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Seating is open for NCCN Congress attendees in either the NCCN Exhibit North or South areas.

Saturday, October 1, 2016

**Proteasome Inhibition with NINLARO® (ixazomib)**
*Presented by Takeda Oncology*

7:30 AM – Exhibitor Showcase North
12:05 PM – Exhibitor Showcase South

**NCCN Imaging Appropriate Use Criteria (NCCN Imaging AUC™)**
*Presented by NCCN*

7:30 AM – Exhibitor Showcase South
12:05 PM – Exhibitor Showcase North
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Gilead Sciences, Inc.

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company’s mission is to advance the care of patients suffering from life-threatening diseases worldwide. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

Harborside Press

Harborside Press is a medical publishing company with a specific focus in oncology. Its leadership and management team has more than 50 years of experience in the field, including extensive success in building and leading editorial teams for a number of publications. Harborside Press is the current publisher of *JNCCN—Journal of the National Comprehensive Cancer Network*, the *NCCN Highlights* series, *The ASCO Post*, the *Journal of Oncology Practice (JOP)*, and the *Journal of the Advanced Practitioner in Oncology (JADPRO)*.

Incyte Corporation

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics, primarily for oncology. The company’s first commercial product, Jakafi® (ruxolitinib), an oral JAK1 and JAK2 inhibitor, is approved by the FDA to treat two rare blood disorders—first approved in November 2011 Jakafi received a subsequent U.S. approval in December 2014. For additional information on Incyte, please visit the Company’s web site at www.incyte.com. To learn about Jakafi, please visit www.Jakafi.com.
The Roswell Park Cancer Institute Center for Immunotherapy (CFI) harnesses the power of the immune system to fight cancer!

Roswell Park currently has 38 active immunotherapy studies, including:

- A Phase I Study of Safety, Tolerability and Immunological Effects of SVN53-67/M57-KLH in Patients with Multiple Myeloma Receiving Lenalidomide Maintenance Therapy

- A Phase I/II Dose Escalation Study Evaluating Safety and Feasibility of BPX-501 T Cells after Partially Mismatched, Related T Cell-Depleted HSCT

- A Randomized Phase III Study Comparing Conventional Dose Treatment Using a Combination of Lenalidomide, Bortezomib and Dexamethasone (RVD) to High-Dose Treatment with Peripheral Stem Cell Transplant in the Initial Management of Myeloma in Patients up to 65 Years of Age

To learn about these and other studies, visit RoswellPark.org/Immunotherapy or stop by our exhibit #25.

LEADING THE WAY CANCER IS TREATED TODAY AND TOMORROW

The Stanford Cancer Institute (SCI) is committed to giving patients every clinical and technological advantage in the prevention and treatment of cancer. The SCI leverages the expertise of over 300 physicians and researchers working together to unravel cancer’s secrets. Stanford’s scientific focus includes cancer cell and stem cell biology, immunology, molecular imaging and genetics. Translational medicine is the cornerstone of Stanford’s cancer treatment programs, combining new advances with compassionate care and supportive services.
Janssen
Exhibit # 19

At Janssen Oncology, we’re shaping the future of cancer treatment. Our purpose is driven by an urgency and commitment to bringing transformational cancer solutions to the people who need them. Our goal is to develop and deliver biologics that offer an opportunity for improved outcomes for patients. Janssen is a biopharmaceutical company and a global leader in the development and commercialization of biologic medicines to treat cancer.

Jazz Pharmaceuticals
Exhibit # 8

Jazz Pharmaceuticals plc is an international biopharmaceutical company focused on improving patients’ lives by identifying, developing and commercializing meaningful products that address unmet medical needs. Our core values—integrity, collaboration, passion, pursuit of excellence and innovation—define our corporate practices and demonstrate our commitment to our mission of improving patients’ lives.

We have a diverse portfolio of products and product candidates with a focus in the areas of sleep, hematology/oncology, pain and other. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase Erwinia chrysanthemi) and Prialt® (ziconotide) intrathecal infusion in the U.S., and markets Erwinase® and Defitelio® (defibrotide) in Europe and other countries outside the U.S. For more information, please visit: www.jazzpharma.com.

Kite Pharma, Inc.
Exhibit # 7

Kite Pharma, Inc. is a clinical-stage biopharmaceutical company engaged in the development of novel cancer immunotherapy products, with a primary focus on engineered autologous cell therapy (eACT™) designed to restore the immune system’s ability to recognize and eradicate tumors. Kite is based in Santa Monica, CA. For more information on Kite Pharma, please visit www.kitepharma.com. Sign up to follow @KitePharma on Twitter at http://www.twitter.com/kitepharma.

MDS Foundation, Inc.
Exhibit # 21

The MDS Foundation, Inc. is an international organization devoted to the support and education of patients and healthcare providers, with innovative research in the field of MDS and related myeloid neoplasms. Our goal is to accelerate the progress leading to the control and cure of these diseases.

Novartis Oncology
Exhibit # 26

Novartis Oncology is a global leader in improving outcomes for patients. We strive to transform cancer care through distinctive scientific and clinical strategies focused on developing targeted, immuno-oncology and combination therapies to create more effective options for patients. For more information, please visit www.novartis Oncology.com.

Patient Access Network (PAN) Foundation
Exhibit # 22

The Patient Access Network (PAN) Foundation is an independent, national nonprofit organization dedicated to helping federally and commercially insured people living with chronic, life-threatening and rare diseases with the out-of-pocket costs for their prescribed medications.

Pfizer
Exhibit # 28

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time.

Pharmacyclics LLC, an AbbVie Company
Exhibit # 2

Pharmacyclics LLC, a subsidiary of AbbVie, is focused on developing and commercializing innovative small-molecule drugs for the treatment of cancer and immune-mediated diseases. The company’s mission is to improve the quality of life, increase duration of life and resolve serious unmet medical needs. Pharmacyclics markets IMBRUVICA and has two product candidates in clinical development. Pharmacyclics is committed to high standards of ethics, scientific rigor and operational efficiency as it moves each of these programs toward commercialization.

Roswell Park Cancer Institute
Exhibit # 25

Since 1898, Roswell Park Cancer Institute in Buffalo, NY, has forged an exemplary reputation with the combined strength of its basic/translational research, multidisciplinary oncology teams, educational programs and compassionate staff. A seamless interface of scientific inquiry and clinical application, and an aggressive clinical trials program, afford patients access to breakthroughs in cancer diagnostics, technology and therapies. A charter member of the NCCN, Roswell Park is the only NCI-designated comprehensive cancer center in Upstate New York.

Sandoz – a Novartis division
Exhibit # 6

Sandoz, a Novartis company, is a global leader in generic pharmaceuticals and biosimilars, driving access to high-quality healthcare. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable medicines to customers around the globe. Our portfolio comprises approximately 1,100 molecules which accounted for 2014 sales of USD 9.6 billion. Sandoz is headquartered in Holzkirchen, Germany.

Seattle Genetics
Exhibit # 11

Seattle Genetics is a biotechnology company focused on developing and commercializing innovative, empowered antibody-based therapies for the treatment of cancer. We are the industry leader in antibody-drug conjugates (ADCs), a technology designed to harness the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells. ADCs are intended to spare non-targeted cells and thus reduce many of the toxic effects of traditional chemotherapy, while potentially enhancing antitumor activity. In addition to one marketed product, we are advancing a deep product pipeline to address significant unmet medical needs.

Shire
Exhibit # 20

At Shire, we aim to make a difference in the lives of people living with cancer. The oncology market is one of the fastest growing and largest, but the need for new treatment options is clear. We are building an innovative, sustainable and diverse portfolio of new oncology therapies, and are accessing transformational science – and growing our global footprint – through strategic research and development partnerships.
Experience Practical Recommendations in Immuno and Molecular Oncology (PRIMO) Meetings!

PRIMO IS A COLLECTION OF THOUGHTFULLY ORGANIZED MEETINGS AIMED AT EDUCATING PRACTICING PROVIDERS ON THE LATEST ADVANCES IN IMMUNO AND MOLECULARLY TARGETED THERAPIES. THROUGH PLANNED DISCUSSIONS WITH YOUR COLLEAGUES YOU WILL HAVE THE UNIQUE OPPORTUNITY TO INTERACT FACE-TO-FACE WITH WORLD-RENNED CANCER EXPERTS IN THE FACULTY, WHILE EARNING CME CREDITS.

The 2017 Annual PRIMO Meeting is designed to summarize key developments in cancer care over the past 12 months and features expected advances that you will likely see in the upcoming year across multiple tumor types. You will learn how this information can be applied to your practice and how it will benefit your patients. Register now at www.primomeeting.org.

FEBRUARY 9-12, MARRIOTT, WAILEA - MAUI, HI

2016 PRIMO Regional Meetings focus on recent advances specific to hematology. Register for FREE today at www.primomeeting.org/heme to attend a meeting in your area.

OCTOBER 14-15
Alexis Hotel
Seattle, WA

OCTOBER 21-22
Conrad Hotel
Indianapolis, IN

OCTOBER 28-29
JW Marriott
Phoenix, AZ

NOVEMBER 4-5
Thompson Hotel
Nashville, TN

This activity is jointly provided by Postgraduate Institute for Medicine and PRIMO Education. Grant support will be solicited from multiple supporters and support will be acknowledged in course materials.

AMA Credit Designation | These activities have been approved for AMA PRA Category 1 Credit(s)™.

Nursing Credit Designation | These activities are eligible for ANCC credit. See final CNE activity announcement for specific details.

For questions, please call 1-855-dPRIMO8 (1-855-677-4668) or email support@primomeeting.org.
At Shire, we challenge ourselves to apply our patient-centric and forward-thinking culture to develop innovative therapies that address the complexities of rare cancers.

**Sigma-Tau Pharmaceuticals, Inc.**
Exhibit # 27

Sigma-Tau Pharmaceuticals, Inc. is a rare corporation dedicated to creating novel medicines for the unmet needs of patients with rare diseases. Truly unique in its field, Sigma-Tau places its considerable scientific resources behind the discovery of compounds that benefit the few. Simply because it’s the right thing to do. By maintaining an environment based on integrity, commitment, and placing the patient first, Sigma-Tau is able to consider what may be a small commercial success nothing less than a human triumph.

**Takeda Oncology**
Exhibit # 15

At Takeda Oncology, the oncology business unit brand of Takeda Pharmaceutical Company Limited, we endeavor to deliver novel medicines to patients with cancer worldwide through our commitment to science, breakthrough innovation and passion for improving the lives of patients. By concentrating the power of leading scientific minds and the vast resources of a global pharmaceutical company, we are finding innovative ways to improve the treatment of cancer.

**Spectrum Pharmaceuticals, Inc.**
Exhibit # 30

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in Hematology and Oncology. Spectrum currently markets six hematology/oncology drugs, and expects an FDA decision on another drug in the second half of 2016. More information at www.sppirx.com.

**Teva Oncology**
Exhibit # 16

People are at the heart of what drives Teva Oncology. As a top oncology company in the US, we strive to improve the lives of people affected by cancer. Our focus is to provide solutions in hematologic malignancies, solid tumors and supportive care. At Teva Oncology, our vision is to change the course of cancer care one patient at a time.

**The Leukemia & Lymphoma Society (LLS)**
Exhibit # 23

The mission of The Leukemia & Lymphoma Society (LLS) is: Cure leukemia, lymphoma, Hodgkin’s disease and myeloma, and improve the quality of life of patients and their families. LLS exists to find cures and ensure access to treatments for blood cancer patients. We are the voice for all blood cancer patients and we work to ensure access to treatments for all blood cancer patients.

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**GENERAL POSTER SESSION**

**NCCN 22nd Annual Conference 2017**

**IMPROVING THE QUALITY, EFFECTIVENESS, AND EFFICIENCY OF CANCER CARE™**

NCCN will hold its fifth annual General Poster Session at the NCCN 22nd Annual Conference: Improving the Quality, Effectiveness, and Efficiency of Cancer Care™ in Orlando, Florida. The poster session will take place on March 23 & 24, 2017.

NCCN welcomes original abstracts from investigators in the oncology community. Submissions will be accepted from academic institutions, teaching and community hospitals, and industry. Both NCCN and non-NCCN institutions may participate.

The deadline for abstract submission is Sunday, November 6, 2016. NCCN.org/AC2017
INDICATION

NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

IMPORTANT SAFETY INFORMATION FOR NINLARO

WARNINGS AND PRECAUTIONS

• Thrombocytopenia has been reported with NINLARO. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines. Adjust dosing as needed. Platelet nadirs occurred between Days 14-21 of each 28-day cycle and recovered to baseline by the start of the next cycle.

• Gastrointestinal Toxicities, including diarrhea, constipation, nausea and vomiting, were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for severe symptoms.

• Peripheral Neuropathy (predominantly sensory) was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Monitor patients for symptoms of peripheral neuropathy and adjust dosing as needed.

• Peripheral Edema was reported with NINLARO. Monitor for fluid retention. Investigate for underlying causes when appropriate and provide supportive care as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.

• Cutaneous Reactions: Rash, most commonly maculopapular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification.

• Hepatotoxicity has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported in < 1% of patients treated with NINLARO. Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.

• Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic, and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported in < 1% of patients treated with NINLARO. Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.

• Renal Impairment: Reduce the NINLARO starting dose according to the degree of renal impairment (see the NINLARO full Prescribing Information). Renal impairment has been reported in 2% of patients included in clinical trials. In the NINLARO regimen, 24% of patients had creatinine clearance (CrCl) < 60 mL/min at baseline, compared with 16% and 7% in the lenalidomide and dexamethasone regimens, respectively.

• Cancer Pain: The use of opioids is recommended for the management of cancer pain.

• Hepatic Impairment: Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment. In patients with moderate or severe hepatic impairment, 8% and 0% of patients in the NINLARO regimen and placebo regimen, respectively, experienced Grade 3 or 4 hepatic impairment (mixed model for analysis; see the NINLARO full prescribing information). NINLARO is not recommended for use in patients with end-stage renal disease requiring dialysis. NINLARO is contraindicated in patients with severe renal impairment. In patients with severe renal impairment (CrCl < 30 mL/min), 78% and 54% (pooled from adverse events and laboratory data) of patients in the NINLARO regimen and placebo regimen, respectively, experienced Grade 3 or 4 renal impairment (mixed model for analysis).

• Other Special Populations: The use of NINLARO as a single agent was not evaluated in patients with severe renal impairment, hepatic impairment, or who are older than 75 years.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend
• The approval of the NINLARO® (ixazomib) regimen (NINLARO+lenalidomide+dexamethasone) was based on a statistically significant ~6 month improvement in median PFS vs the placebo regimen (placebo+lenalidomide+dexamethasone) — Median PFS: 20.6 vs 14.7 months (95% CI, 17.0-NE and 95% CI, 12.9-17.6, respectively) - HR=0.74 (95% CI, 0.587-0.939); P=0.012

ADVERSE REACTIONS
The most common adverse reactions (≥ 20%) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in ≥ 2% of patients included thrombocytopenia (2%) and diarrhea (2%).

SPECIAL POPULATIONS
• Hepatic Impairment: Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment.
• Renal Impairment: Reduce the NINLARO starting dose to 3 mg in patients with severe renal impairment or end-stage renal disease requiring dialysis. NINLARO is not dialyzable.
• Lactation: Advise women to discontinue nursing while on NINLARO.

DRUG INTERACTIONS: Avoid concomitant administration of NINLARO with strong CYP3A inducers.

TOURMALINE-MM1: a global, phase 3, randomized (1:1), double-blind, placebo-controlled study that evaluated the safety and efficacy of NINLARO (an oral proteasome inhibitor) vs placebo, both in combination with lenalidomide and dexamethasone, until disease progression or unacceptable toxicity in 722 patients with relapsed and/or refractory multiple myeloma who received 1-3 prior therapies. NE=not evaluable; PFS=progression-free survival.

Please see adjacent Brief Summary.
BRIEF SUMMARY OF PRESCRIBING INFORMATION
NINLARO (ixazomib) capsules, for oral use

1 INDICATION
NINLARO (ixazomib) is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

5 WARNINGS AND PRECAUTIONS
5.1 Thrombocytopenia: Thrombocytopenia has been reported with NINLARO with platelet nadirs typically occurring between Days 14-21 of each 28-day cycle and recovery to baseline by the start of the next cycle. Three percent of patients in the NINLARO regimen and 1% of patients in the placebo regimen had a platelet count ≤ 10,000/mm² during treatment. Less than 1% of patients in both regimens had a platelet count ≤ 5000/mm² during treatment. Discontinuations due to thrombocytopenia were similar in both regimens (< 1% of patients in the NINLARO regimen and 2% of patients in the placebo regimen discontinued one or more of the three drugs). The rate of platelet transfusions was 6% in the NINLARO regimen and 5% in the placebo regimen.

Monitor platelet counts at least monthly during treatment with NINLARO. Consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines.

5.2 Gastrointestinal Toxicities: Diarrhea, constipation, nausea, and vomiting, have been reported with NINLARO, occasionally requiring use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea was reported in 42% of patients in the NINLARO regimen and 36% in the placebo regimen, respectively. Grade 3 adverse reactions of peripheral neuropathy were reported at 2% in both regimens; there were no Grade 4 or serious adverse reactions.

The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimen, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for Grade 3 or 4 symptoms.

5.3 Peripheral Neuropathy: The majority of peripheral neuropathy adverse reactions were Grade 1 (18% in the NINLARO regimen and 14% in the placebo regimen) and Grade 2 (8% in the NINLARO regimen and 5% in the placebo regimen). Grade 3 adverse reactions of peripheral neuropathy were reported at 2% in both regimens; there were no Grade 4 or serious adverse reactions.

The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimen, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Patients should be monitored for symptoms of neuropathy. Patients experiencing new or worsening peripheral neuropathy may require dose modification.

5.4 Peripheral Edema: Peripheral edema was reported in 25% and 18% of patients in the NINLARO and placebo regimens, respectively. The majority of peripheral edema adverse reactions were Grade 1 (16% in the NINLARO regimen and 13% in the placebo regimen) and Grade 2 (7% in the NINLARO regimen and 4% in the placebo regimen).

Grade 3 peripheral edema was reported in 2% and 1% of patients in the NINLARO and placebo regimens, respectively. There was no Grade 4 peripheral edema reported. There were no discontinuations reported due to peripheral edema.

Evaluate for underlying causes and provide supportive care, as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.

5.5 Cutaneous Reactions: Rash was reported in 19% of patients in the NINLARO regimen and 11% of patients in the placebo regimen. The majority of the rash adverse reactions were Grade 1 (10% in the NINLARO regimen and 7% in the placebo regimen) or Grade 2 (6% in the NINLARO regimen and 3% in the placebo regimen). Grade 3 rash was reported in 3% of patients in the NINLARO regimen and 1% of patients in the placebo regimen. There were no Grade 4 or serious adverse reactions of rash reported. The most common type of rash reported in both regimens included maculo-papular and macular rash. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification if Grade 2 or higher.

5.6 Hepatotoxicity: Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly and adjust dosing for Grade 3 or 4 symptoms.

5.7 Embryo-Fetal Toxicity: NINLARO can cause fetal harm when administered to a pregnant woman based on the mechanism of action and findings in animals. There are no adequate and well-controlled studies in pregnant women using NINLARO. Ixazomib caused embryo-fetal toxicity in pregnant rats and rabbits at doses resulting in exposures that were slightly higher than those observed in patients receiving the recommended dose.

Females of reproductive potential should be advised to avoid becoming pregnant while being treated with NINLARO. If NINLARO is used during pregnancy or if the patient becomes pregnant while taking NINLARO, the patient should be apprised of the potential hazard to the fetus. Advise females of reproductive potential that they must use effective contraception during treatment with NINLARO and for 90 days following the final dose.

6 ADVERSE REACTIONS
The following adverse reactions are described in detail in other sections of the prescribing information:

• Thrombocytopenia [see Warnings and Precautions (5.1)]
• Gastrointestinal Toxicities [see Warnings and Precautions (5.2)]
• Peripheral Neuropathy [see Warnings and Precautions (5.3)]
• Peripheral Edema [see Warnings and Precautions (5.4)]
• Cutaneous Reactions [see Warnings and Precautions (5.5)]
• Hepatotoxicity [see Warnings and Precautions (5.6)]

6.1 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.

The safety population from the randomized, double-blind, placebo-controlled clinical study included 720 patients with relapsed and/or refractory multiple myeloma, who received NINLARO in combination with lenalidomide and dexamethasone (NINLARO regimen; N=360) or placebo in combination with lenalidomide and dexamethasone (placebo regimen; N=360).

The most frequently reported adverse reactions (≥ 20%) in the NINLARO regimen and greater than the placebo regimen were diarrhea, constipation, thrombocytopenia, peripheral neuropathy, nausea, peripheral edema, vomiting, and back pain. Serious adverse reactions reported in ≥ 2% of patients included thrombocytopenia (2%) and diarrhea (2%). For each adverse reaction, one or more of the three drugs was discontinued in ≤ 1% of patients in the NINLARO regimen.

Table 4: Non-Hematologic Adverse Reactions Occurring in ≥ 5% of Patients with a ≥ 5% Difference Between the NINLARO Regimen and the Placebo Regimen (All Grades, Grade 3 and Grade 4)

<table>
<thead>
<tr>
<th>System Organ Class / Preferred Term</th>
<th>NINLARO + Lenalidomide and Dexamethasone N=360</th>
<th>Placebo + Lenalidomide and Dexamethasone N=360</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Grade 3</td>
<td>Grade 4</td>
<td>All Grade 3</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>69 (19)</td>
<td>0</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral neuropathies*</td>
<td>100 (28)</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>151 (42)</td>
<td>0</td>
</tr>
<tr>
<td>Nausea</td>
<td>122 (34)</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>92 (26)</td>
<td>0</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash*</td>
<td>68 (19)</td>
<td>0</td>
</tr>
<tr>
<td>Radiculitis and sciatic nerve pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>68 (19)</td>
<td>0</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>91 (25)</td>
<td>0</td>
</tr>
</tbody>
</table>

*Represents a pooling of preferred terms

Note: Adverse reactions included as preferred terms are based on MedDRA version 16.0.

(Continued on next page)
Brief Summary (cont’d)

Table 5: Thrombocytopenia and Neutropenia (poled adverse event and laboratory data)

<table>
<thead>
<tr>
<th>Condition</th>
<th>NINLARO + Lenalidomide and Dexamethasone N=360</th>
<th>Placebo + Lenalidomide and Dexamethasone N=360</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Any Grade</td>
<td>Grade 3-4</td>
<td>Any Grade</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>281 (78) 93 (26)</td>
<td>196 (54) 39 (11)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>240 (67) 93 (26)</td>
<td>239 (66) 107 (30)</td>
</tr>
</tbody>
</table>

Eye Disorders

Eye disorders were reported with many different preferred terms but in aggregate, the frequency was 26% in patients in the NINLARO regimen and 16% of patients in the placebo regimen. The most common adverse reactions were blurred vision (6% in the NINLARO regimen and 3% in the placebo regimen), dry eye (5% in the NINLARO regimen and 1% in the placebo regimen), and conjunctivitis (6% in the NINLARO regimen and 1% in the placebo regimen). Grade 3 adverse reactions were reported in 2% of patients in the NINLARO regimen and 1% in the placebo regimen.

The following serious adverse reactions have each been reported at a frequency of < 1%: acute febrile neutrophilic dermatosis (Sweet’s syndrome), Stevens-Johnson syndrome, toxic epidermal necrolysis, posterior reversible encephalopathy syndrome, tumor lysis syndrome, and thrombotic thrombocytopenic purpura.

7 DRUG INTERACTIONS

7.1 Strong CYP3A Inducers: Avoid concomitant administration of NINLARO with strong CYP3A inducers (such as rifampin, phenytoin, carbamazepine, and St. John’s Wort).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Women should avoid becoming pregnant while being treated with NINLARO.

Risk Summary: NINLARO can cause fetal harm when administered to a pregnant woman. There are no human data available regarding the potential effect of NINLARO on pregnancy or development of the embryo or fetus. Isoazomib caused embryo-fetal toxicity in pregnant rats and rabbits at doses resulting in exposures that were slightly higher than those observed in patients receiving the recommended dose. Advise women of the potential risk to a fetus and to avoid becoming pregnant while being treated with NINLARO. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. Animal Data: In an embryo-fetal development study in pregnant rabbits there were increases in fetal skeletal variations/abnormalities (caudal vertebrae, number of lumbar vertebrae, and full supernumerary ribs) at doses that were maternally toxic (≥ 0.3 mg/kg). Exposures in the rabbit at 0.3 mg/kg were 1.9 times the clinical time-averaged exposures at the recommended dose of 4 mg. In a rat dose range-finding embryo-fetal development study, at doses that were maternally toxic, there were decreases in fetal weights, a trend towards decreased fetal viability, and increased post-implantation losses at 0.6 mg/kg. Exposures in rats at the dose of 0.6 mg/kg was 2.5 times the clinical time averaged exposures at the recommended dose of 4 mg.

8.2 Lactation: It is not known whether NINLARO or its metabolites are present in human milk. Many drugs are present in human milk and as a result, there could be a potential for adverse events in nursing infants. Advise women to discontinue nursing.

8.3 Females and Males of Reproductive Potential: Contraception - Male and female patients of childbearing potential must use effective contraceptive measures during and for 90 days following treatment. Infertility - Fertility studies were not conducted with NINLARO; however there were no effects on reproductive organs in either males or females in nonclinical studies in rats and dogs.

8.4 Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

8.5 Geriatric Use: Of the total number of subjects in clinical studies of NINLARO, 55% were 65 and over, while 17% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Hepatic Impairment: In patients with moderate or severe hepatic impairment, the mean AUC increased by 20% when compared to patients with normal hepatic function. Reduce the starting dose of NINLARO in patients with moderate or severe hepatic impairment.

8.7 Renal Impairment: In patients with severe renal impairment or ESRD requiring dialysis, the mean AUC increased by 39% when compared to patients with normal renal function. Reduce the starting dose of NINLARO in patients with severe renal impairment or ESRD requiring dialysis. NINLARO is not dialyzable and therefore can be administered without regard to the timing of dialysis.

10 OVERDOSAGE: There is no known specific antidote for NINLARO overdose. In the event of an overdose, monitor the patient for adverse reactions and provide appropriate supportive care.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Dosing Instructions

- Instruct patients to take NINLARO exactly as prescribed.
- Advise patients to take NINLARO once a week on the same day and at approximately the same time for the first three weeks of a four week cycle.
- Advise patients to take NINLARO at least one hour before or at least two hours after food.
- Advise patients that NINLARO and dexamethasone should not be taken at the same time, because dexamethasone should be taken with food and NINLARO should not be taken with food.
- Advise patients to swallow the capsule whole with water. The capsule should not be crushed, chewed or opened.
- Advise patients that direct contact with the capsule contents should be avoided. In case of capsule breakage, avoid direct contact of capsule contents with the skin or eyes. If contact occurs with the skin, wash thoroughly with soap and water. If contact occurs with the eyes, flush thoroughly with water.
- If a patient misses a dose, advise them to take the missed dose as long as the next scheduled dose is ≥ 72 hours away. Advise patients not to take a missed dose if it is within 72 hours of their next scheduled dose.
- If a patient vomits after taking a dose, advise them not to repeat the dose but resume dosing at the time of the next scheduled dose.
- Advise patients to store capsules in original packaging, and not to remove the capsule from the packaging until just prior to taking NINLARO.

Thrombocytopenia: Advise patients that they may experience low platelet counts (thrombocytopenia). Signs of thrombocytopenia may include bleeding and easy bruising.

Gastrointestinal Toxicities: Advise patients they may experience diarrhea, constipation, nausea and vomiting and to contact their physician if these adverse reactions persist.

Peripheral Neuropathy: Advise patients to contact their physicians if they experience new or worsening symptoms of peripheral neuropathy such as tingling, numbness, pain, a burning feeling in the feet or hands, or weakness in the arms or legs.

Peripheral Edema: Advise patients to contact their physicians if they experience unusual swelling of their extremities or weight gain due to swelling.

Cutaneous Reactions: Advise patients to contact their physicians if they experience any other medication they are currently taking and before starting any new medications.

Please see full Prescribing Information for NINLARO at NINLARO-hcp.com.

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MORE THREATENING THAN IT APPEARS

Some risk factors that may help identify patients at increased risk of treatment failure include:$^{1,2}$

- Primary or secondary resistance
- Mutations
- Stage of disease
- Number of prior therapies
- Nonadherence

RESPOND TO POTENTIAL FAILURE$^{1,3}$

- Monitor for response
- Check for patient compliance and drug interactions
- Conduct mutational analysis

For more information go to www.CMLrisks.com

References:
Huntsman Cancer Institute
Seventh Annual Hematology Review

A review of advances in benign and malignant hematology

Keynote Speaker: Jerald Radich, MD
Fred Hutchinson Cancer Research Center

February 11, 2017

For more information, please contact: abby.rooney@hsc.utah.edu or paul.shami@utah.edu
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