Speak with an Incyte representative today:

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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.

In COMFORT-I,† significantly more patients receiving Jakafi achieved a ≥35% reduction in spleen volume from baseline compared with placebo.¹,³

<table>
<thead>
<tr>
<th>Primary endpoint:</th>
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<tr>
<td>Spleen volume reduction ≥35% at week 24³</td>
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<table>
<thead>
<tr>
<th>Jakafi</th>
<th>Placebo</th>
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<tbody>
<tr>
<td>42%</td>
<td>0.7%</td>
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</tbody>
</table>

(²P ≤ 0.0001)

COMFORT-I 5-year analysis: Jakafi and placebo

- 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.³

Adapted with permission from the Journal of Hematology & Oncology.

The 5-year overall survival analysis is not included in the Full Prescribing Information. 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.⁴

Patients randomized to placebo were eligible to cross over 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.⁴

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

In COMFORT-II,‡ significantly more patients receiving Jakafi achieved a ≥35% reduction in spleen volume from baseline compared with best available therapy (BAT).¹,6‡

<table>
<thead>
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<th>Primary endpoint:</th>
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<tr>
<td>Spleen volume reduction ≥35% at week 48⁴</td>
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<table>
<thead>
<tr>
<th>Jakafi</th>
<th>BAT</th>
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<tbody>
<tr>
<td>29%²</td>
<td>0%⁵</td>
</tr>
</tbody>
</table>

(⁶P ≤ 0.0001)

COMFORT-II 5-year analysis: Jakafi and BAT

- At 3 years, survival probability was 79% for patients originally randomized to Jakafi and 59% for those originally randomized to BAT.¹
- Overall survival was a prespecified secondary endpoint in COMFORT-II.¹

Adapted with permission from Leukemia.

The 5-year overall survival analysis is not included in the Full Prescribing Information. 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.⁴

COMFORT-II was not designed to compare survival probabilities between Jakafi and best available therapy at 3 or 5 years.⁴

Patients randomized to best available therapy were eligible to cross over 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.⁴

All patients in the BAT group either crossed over to Jakafi at a median of 17 months or discontinued.¹

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 × 10⁹/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.

Please see related and other Important Safety Information on last slide. Please click here for Full Prescribing Information.
Indications and Usage
Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea.

In the phase 3 RESPONSE* trial, Jakafi demonstrated superior results vs BAT‡

**The RESPONSE (Randomized study of Efficacy and Safety in POlycythemia vera with JAK Inhibitor ruxolitinib verSus bEst available care) trial was a randomized, open-label, active-controlled phase 3 trial comparing Jakafi with BAT in 222 patients with PV. Patients enrolled in the study had been diagnosed with PV for at least 24 weeks, had an inadequate response to or were intolerant of HU, required phlebotomy for Hct control, and exhibited splenomegaly. All patients were required to demonstrate Hct control between 40% and 45% prior to randomization. After week 32, patients were able to cross over to Jakafi treatment.**1,13

* The composite primary endpoint was defined as Hct control without phlebotomy eligibility and a ≥35% spleen volume reduction as measured by CT or MRI. To achieve the Hct control endpoint, patients could not become eligible for phlebotomy between weeks 8 and 32. Phlebotomy eligibility was defined as Hct >45% that is ≥3 percentage points higher than baseline or Hct >48% (lower value).**1,13

‡ BAT included HU (60%), interferon/pegylated interferon (12%), anagrelide (7%), pipobroman (2%), lenalidomide/thalidomide (5%), and observation (15%).**1

[In the RESPONSE trial, Jakafi achieved a higher rate of Hct control vs BAT]

[Exploratory endpoint from the RESPONSE trial: Jakafi symptom data]

- **At week 32, 49% of patients receiving Jakafi and 5% of patients receiving BAT had at least a 50% reduction in the 14-item Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF) Total Symptom Score (TSS)**4,13
- RESPONSE was an open-label trial and, therefore, not designed to evaluate differences in symptoms.
- Patient-reported outcomes were assessed using the MPN-SAF symptom diary. The MPN-SAF diary was administered daily in an electronic diary format to score 14 disease-related symptoms on a scale of 0 (absent) to 10 (worst possible). At baseline, median TSS was 23.4 (range, 0-106) in the group receiving Jakafi and 33.3 (range, 0-118) in the group receiving BAT.**13

**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 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.**

Please see related and other Important Safety Information on page 310. Please **click here** for Full Prescribing Information.
Indications and Usage
Jakafi is indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.

REACH1: an open-label, single-arm, multicenter study of Jakafi in patients with steroid-refractory aGVHD

Patients had Grade II-IV steroid-refractory acute GVHD (aGVHD)* occurring after allogeneic hematopoietic stem cell transplantation; 71 patients were enrolled, of whom 49 were refractory to steroids alone and evaluable for efficacy.1

- 73% (36/49) had Grade III or IV aGVHD
- 84% (41/49) had visceral disease1

Includes patients with upper and lower gastrointestinal and liver involvement.

* Defined using Mount Sinai Acute GVHD International Consortium (MAGIC) criteria.

Day 28 responses were achieved in the majority of patients treated with Jakafi

Primary Endpoint: ORR at Day 28

Day 28 responses with Jakafi were seen across all aGVHD grades

Reachitib in PaEnts With RefAcctory Graft-Versus-Host Disease After Allogeneic Stem Cell Transplantation.

For more information, visit hcp.jakafi.com

Important Safety Information (continued)

- 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.

- 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 and edema.

- Dose modifications may be required 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 breastfeed during treatment and for 2 weeks after the final dose.

Please see related and other Important Safety Information on hcp.jakafi.com. Please click here for Full Prescribing 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 × 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 highest 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.

Advise patients about early signs and symptoms of herpes zoster and to seek early treatment.

Increases in hematopoietic burden, organomegaly and splenomegaly was observed with Jakafi treatment. Evaluate patients after 3 months for development of organomegaly and splenomegaly.

Infections and/or neutropenia, or other signs and symptoms of myelosuppression, suggest the need for dose reduction or discontinuation of Jakafi.

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 click here for Full Prescribing Information for Jakafi.