Ruxolitinib for the Treatment of Chronic Graft-Versus-Host Disease

Summary of key data

Ruxolitinib/Ruxolitinib XR Indication and Dosing

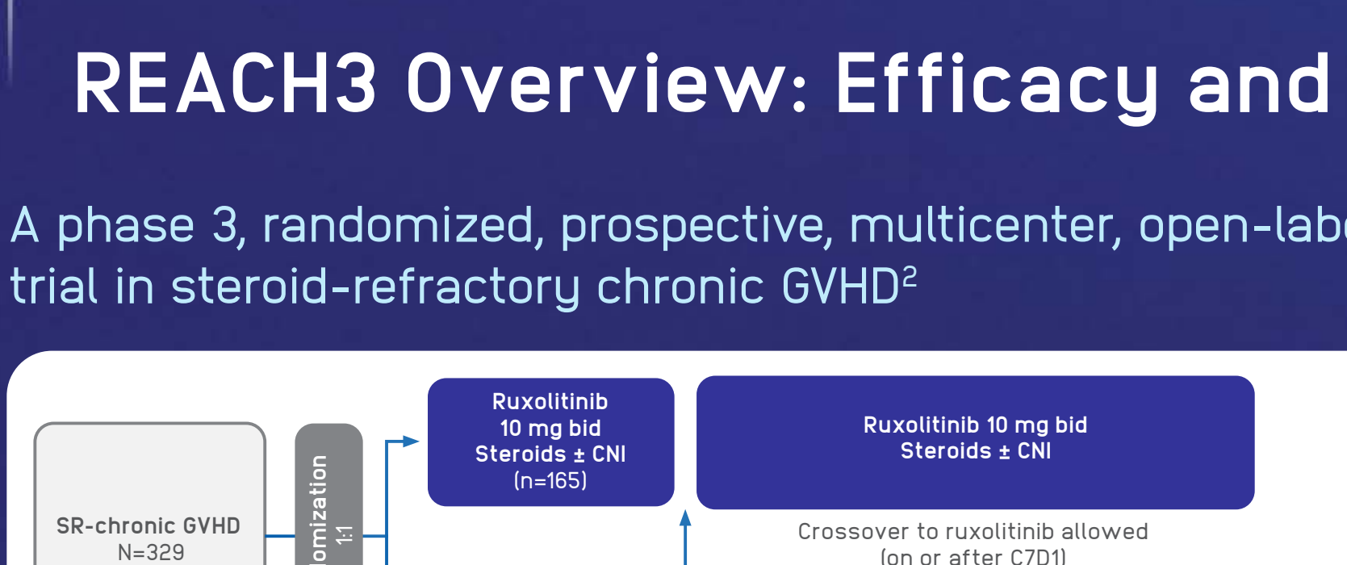
Indication[1]	Dosing[1]
Ruxolitinib/Ruxolitinib XR is a kinase inhibitor indicated for treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years of age and older[a]	Recommended starting dose of ruxolitinib is: **10 mg** **ruxolitinib** given orally twice daily OR **22 mg** **ruxolitinib XR** given orally once daily

GVHD, graft-versus-host disease; XR, extended release.

[a] The safety and effectiveness of ruxolitinib XR has been established from adequate and well-controlled studies of ruxolitinib in adult patients with myelofibrosis, polycythemia vera, and adult and pediatric patients with acute and chronic graft-versus-host-disease.

REACH3 Overview: Efficacy and Safety[2]

A phase 3, randomized, prospective, multicenter, open-label trial in steroid-refractory chronic GVHD[2]


SR-chronic GVHD
N=329
Randomization 1:1
Ruxolitinib 10 mg bid Steroids ± CNI (n=165)
Ruxolitinib 10 mg bid Steroids ± CNI
Crossover to ruxolitinib allowed (on or after C7D1)
BAT Steroids ± CNI (n=164)
BAT Steroids ± CNI
Stratified by chronic GVHD grade
Primary efficacy period
Extension period
Safety follow-up (+30 days)
Day 1 (C1D1)
Week 24 (C7D1)
Enter long-term survival follow-up if treatment is discontinued
Week 156 (EOT)

Primary Endpoint

ORR (CR + PR) at week 24

Key Secondary Endpoints

FFS, mLSS response

Secondary Endpoints

Subgroup responses, individual organ response, NRM, BOR, DOR, OS, QOL, CS reduction, safety

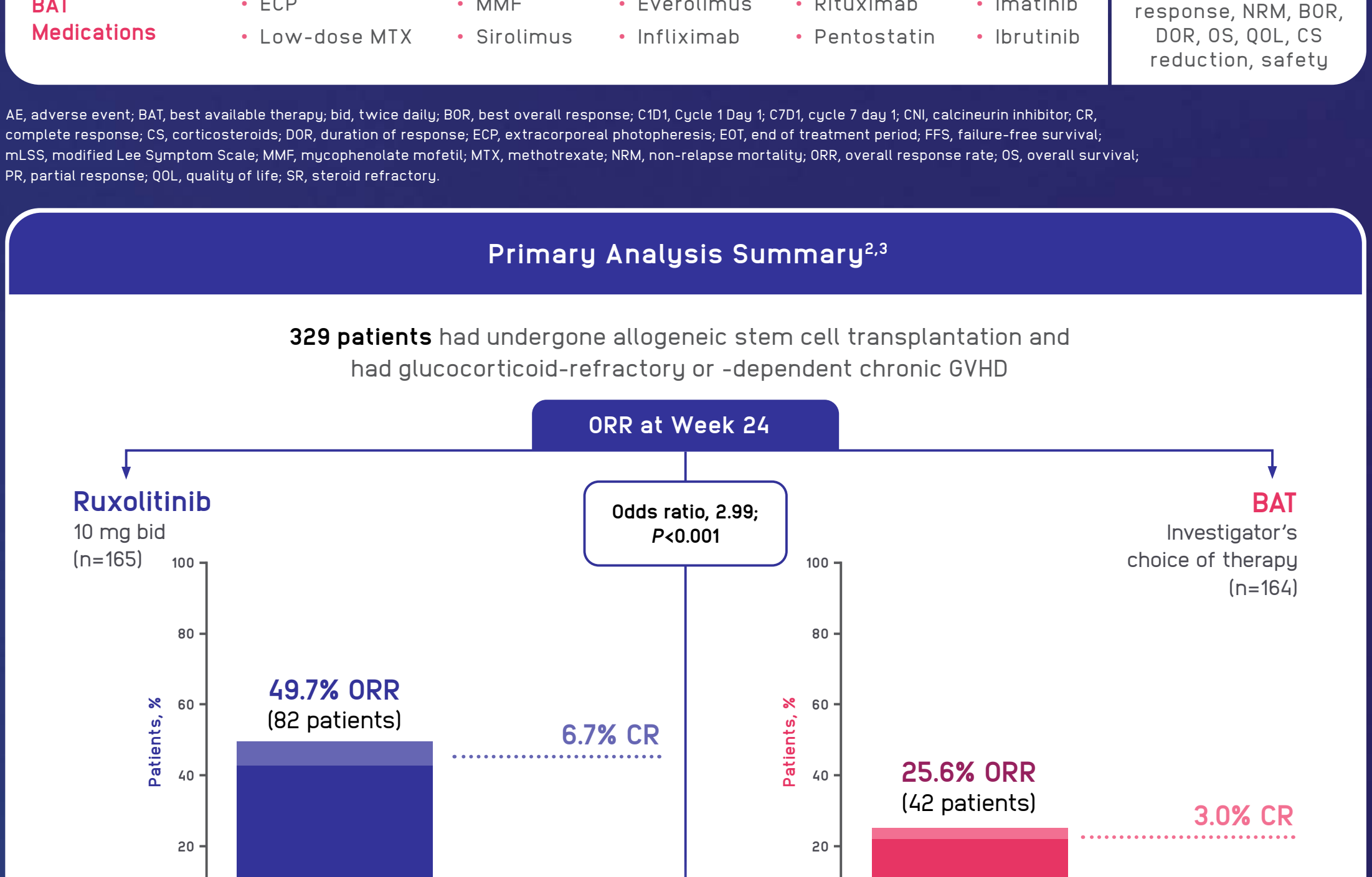
BAT Medications

- ECP
- Low-dose MTX
- MMF
- Sirolimus
- Everolimus
- Infliximab
- Rituximab
- Pentostatin
- Imatinib
- Ibrutinib

AE, adverse event; BAT, best available therapy; bid, twice daily; BOR, best overall response; C1D1, Cycle 1 Day 1; C7D1, cycle 7 day 1; CNI, calcineurin inhibitor; CR, complete response; CS, corticosteroids; DOR, duration of response; ECP, extracorporeal photopheresis; EOT, end of treatment period; FFS, failure-free survival; mLSS, modified Lee Symptom Scale; MMF, mycophenolate mofetil; MTX, methotrexate; NRM, non-relapse mortality; ORR, overall response rate; OS, overall survival; PR, partial response; QOL, quality of life; SR, steroid refractory.

Primary Analysis Summary[2,3]

329 patients had undergone allogeneic stem cell transplantation and had glucocorticoid-refractory or -dependent chronic GVHD



Median dose intensity of ruxolitinib (interquartile range): 19.6 mg/day (4.8-20.5)

Adverse Events up to Week 24 in ≥8% of Patients Treated with Ruxolitinib[2]

AE, n (%)	Ruxolitinib (n=165)		BAT (n=158)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any	161 (97.6)	94 (57.0)	145 (91.8)	91 (57.6)
Hematologic event				
Anemia	48 (29.1)	21 (12.7)	20 (12.7)	12 (7.6)
Thrombocytopenia	35 (21.2)	25 (15.2)	23 (14.6)	16 (10.1)
Neutropenia	18 (10.9)	14 (8.5)	8 (5.1)	6 (3.8)
Gastrointestinal event				
Diarrhea	17 (10.3)	1 (0.6)	21 (13.3)	2 (1.3)
Nausea	15 (9.1)	0	16 (10.1)	2 (1.3)
Infection				
Pneumonia	18 (10.9)	14 (8.5)	20 (12.7)	15 (9.5)
Upper respiratory tract infection	14 (8.5)	0	13 (8.2)	2 (1.3)
Laboratory abnormality				
Alanine aminotransferase increased	25 (15.2)	7 (4.2)	7 (4.4)	0
Creatinine increased	23 (13.9)	0	7 (4.4)	1 (0.6)
Aspartate aminotransferase increased	16 (9.7)	3 (1.8)	4 (2.5)	1 (0.6)
Hypertriglyceridemia	16 (9.7)	8 (4.8)	13 (8.2)	6 (3.8)
γ-glutamyltransferase increased	15 (9.1)	11 (6.7)	5 (3.2)	3 (1.9)
Other				
Hypertension	26 (15.8)	8 (4.8)	20 (12.7)	11 (7.0)
Pyrexia	26 (15.8)	3 (1.8)	15 (9.5)	2 (1.3)
Cough	17 (10.3)	0	11 (7.0)	0
Fatigue	17 (10.3)	1 (0.6)	12 (7.6)	3 (1.9)
Dyspnea	16 (9.7)	3 (1.8)	10 (6.3)	2 (1.3)
Headache	14 (8.5)	2 (1.2)	12 (7.6)	1 (0.6)

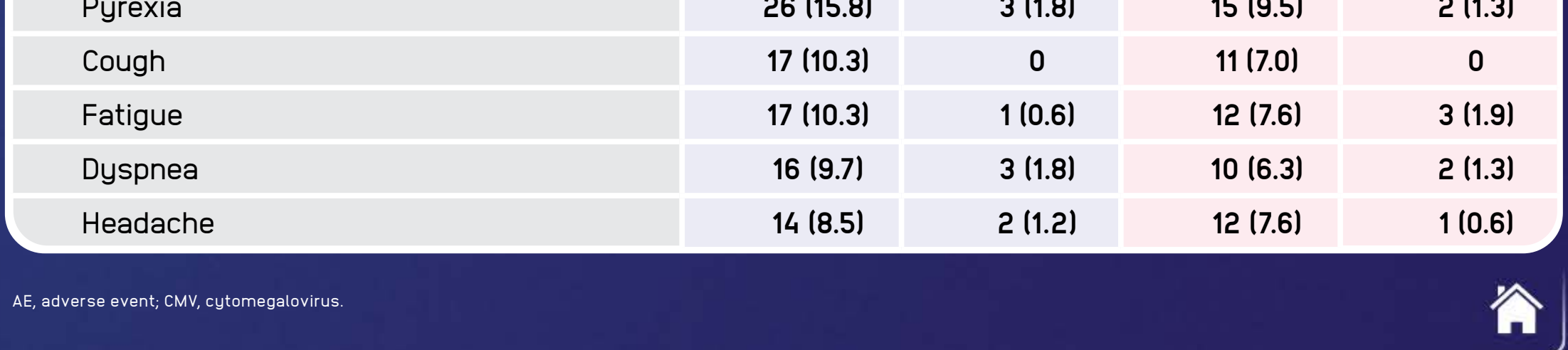
AE, adverse event; CMV, cytomegalovirus.

Early vs Late Treatment

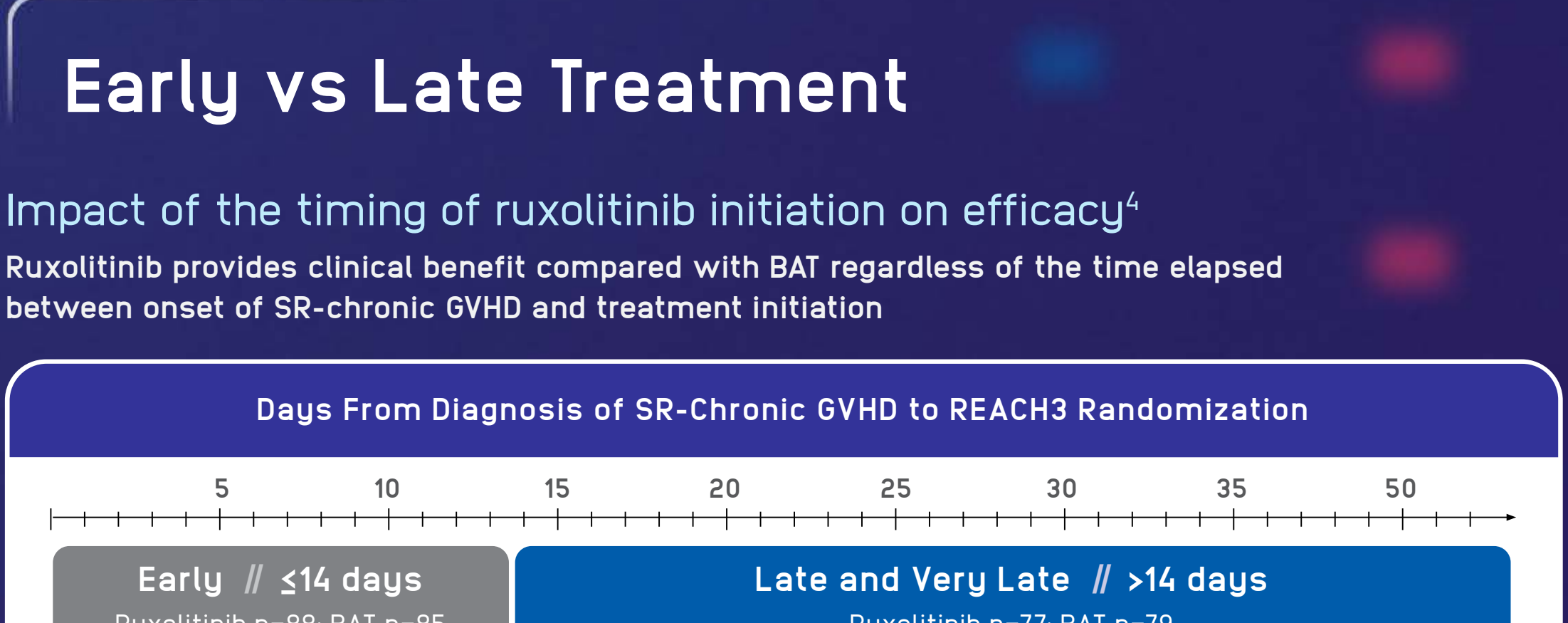
Impact of the timing of ruxolitinib initiation on efficacy[4]

Ruxolitinib provides clinical benefit compared with BAT regardless of the time elapsed between onset of SR-chronic GVHD and treatment initiation

Days From Diagnosis of SR-Chronic GVHD to REACH3 Randomization


5
10
15
20
25
30
35
50
Early // ≤14 days
Ruxolitinib n=88; BAT n=85
Late and Very Late // >14 days
Ruxolitinib n=77; BAT n=79
Very Late // >28 days
Ruxolitinib n=47; BAT n=46

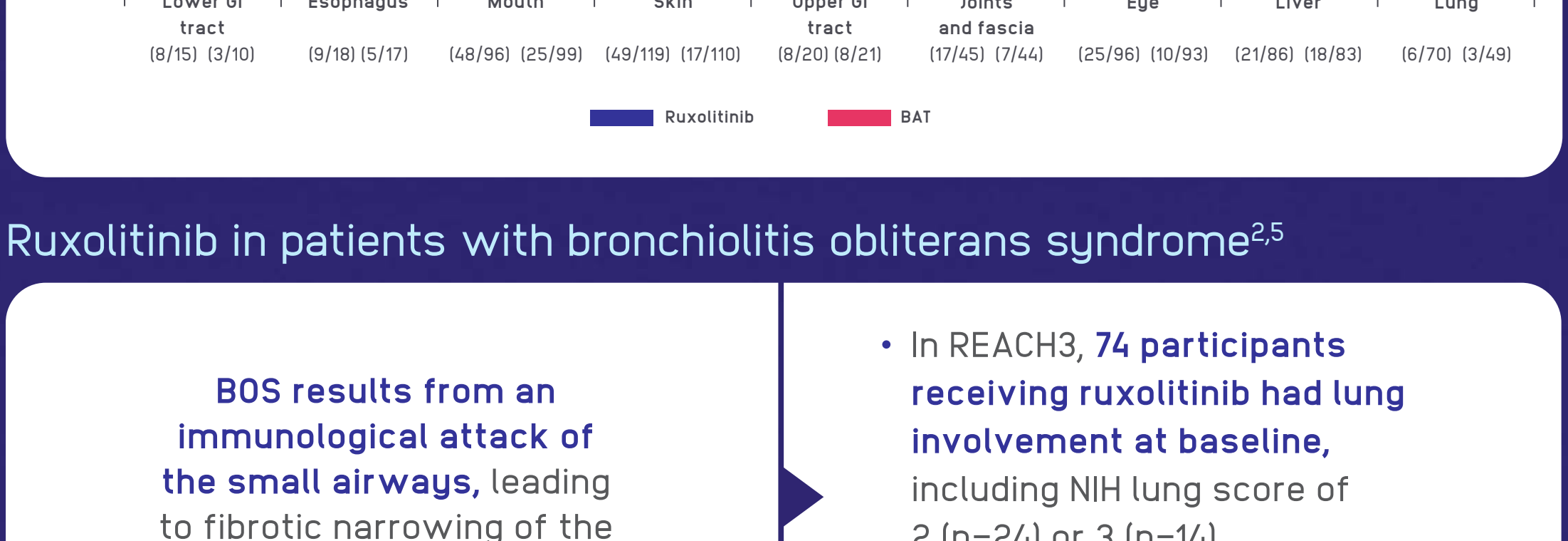
Greater ORR at Week 24 With Ruxolitinib vs BAT



- Week 24 ORR was higher with ruxolitinib vs BAT in all 3 time-to-treatment subgroups
- Ruxolitinib provides clinical benefit compared with BAT regardless of the time elapsed between onset of SR-chronic GVHD and treatment initiation

Organ Specific Outcomes

Response by Organ at Week 24[2]

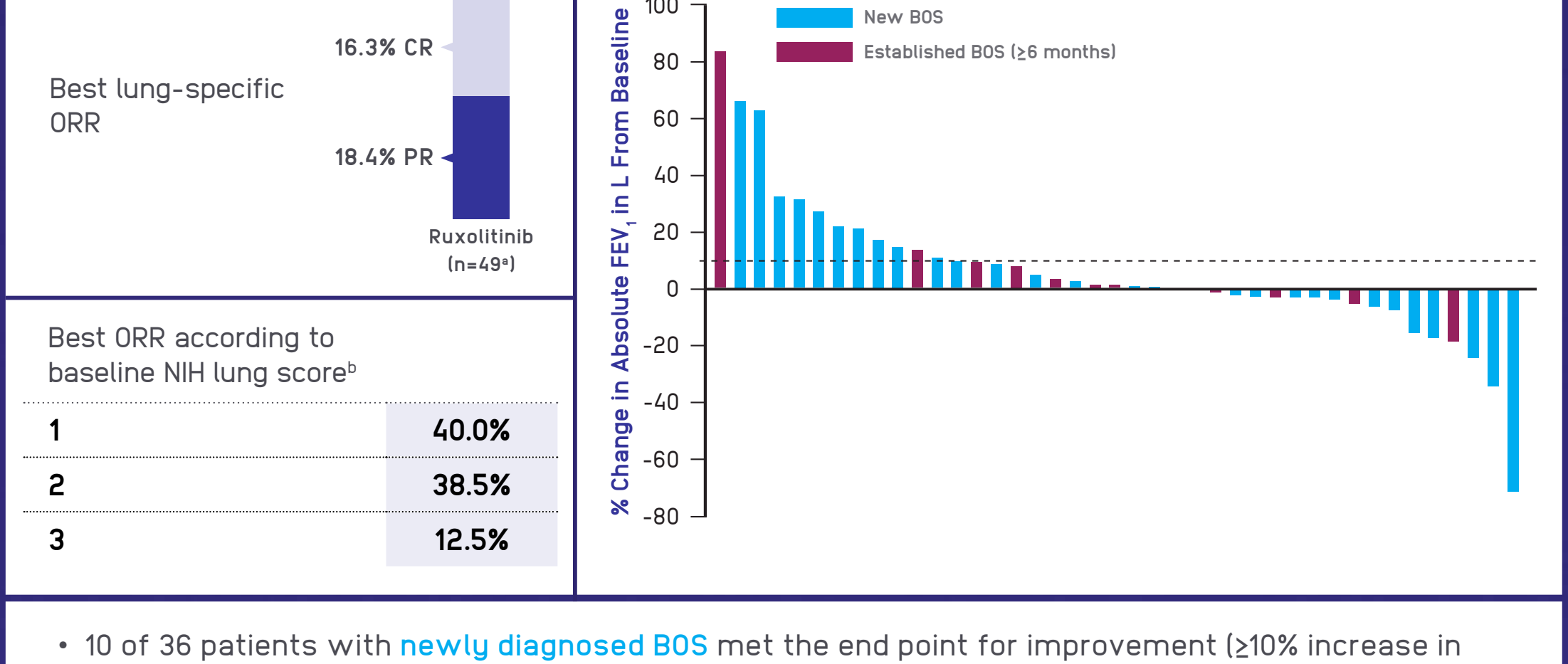


Ruxolitinib in patients with bronchiolitis obliterans syndrome[2,5]

BOS results from an immunological attack of the small airways, leading to fibrotic narrowing of the respiratory bronchioles and subsequent obliteration

- In REACH3, **74 participants receiving ruxolitinib had lung involvement at baseline,** including NIH lung score of 2 (n=24) or 3 (n=14)
- At week 24, the lung-specific response rate was 8.6% (6/70)

Ruxolitinib (10 mg bid) was investigated in a phase 2 multicenter study of patients who developed bronchiolitis obliterans syndrome after allogeneic HCT[5]



Best ORR according to baseline NIH lung score[b]	
1	40.0%
2	38.5%
3	12.5%

- 10 of 36 patients with newly diagnosed BOS met the end point for improvement (≥10% increase in FEV_1) after 3 months of ruxolitinib
- 12 of 13 patients with established BOS met the end point of stabilization of disease (absence of ≥10% decline in FEV_1) after 3 months of ruxolitinib

[a] One participant with a %FEV_1 of 80% was mistakenly enrolled and treated; this participant is included in the safety and survival analyses but excluded from the efficacy analyses. [b] NIH lung score is defined as 1 for mild symptoms (eg, shortness of breath after climbing one flight of steps), 2 for moderate symptoms (eg, shortness of breath after walking on flat ground), and 3 for severe symptoms (eg, shortness of breath at rest; requiring oxygen).

BOS, bronchiolitis obliterans syndrome; FEV_1, forced expiratory volume in 1 second; HCT, hematopoietic cell transplantation; NIH, National Institutes of Health.

Phase 2 study of ruxolitinib for the treatment of SR sclerotic chronic GVHD[6]

Sclerotic chronic GVHD is a highly morbid form of chronic GVHD, often refractory to treatment and associated with significant decline in the patients' QOL

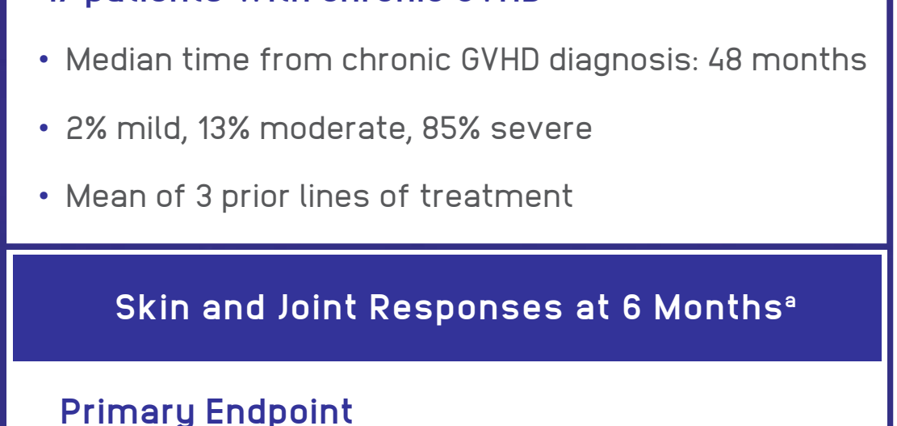
Ruxolitinib (10 mg bid for 6 months) was investigated in a single-arm phase 2 multicenter study in adult patients with sclerotic chronic GVHD

Enrolled Patients

47 patients with chronic GVHD

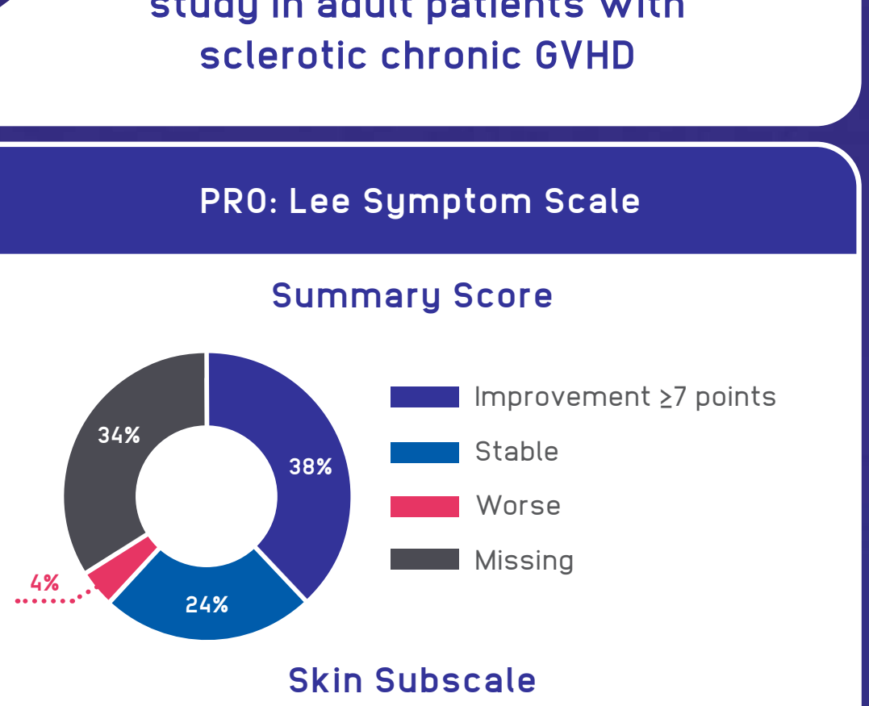
- Median time from chronic GVHD diagnosis: 48 months
- 2% mild, 13% moderate, 85% severe
- Mean of 3 prior lines of treatment

Skin and Joint Responses at 6 Months[a]



Overall chronic GVHD response at 6 months: 47%

PRO: Lee Symptom Scale



[a] Skin responses were defined as a decrease in NIH skin score by ≥1 point. Joint responses were defined as a decrease in NIH Joint and Fascia Score by ≥1 point, or increase in P-ROM score by ≥1 point. Overall chronic GVHD response was defined as improvement in ≥1 organ/site without progression in any other organ/site.

GI, gastrointestinal; PRO, patient-reported outcome.

Cytopenias in REACH3

Incidence of cytopenias in REACH3[2,3]

AE, n (%)	Ruxolitinib (n=165)		BAT (n=158)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Anemia	48 (29)	21 (13)	20 (13)	12 (8)
Thrombocytopenia[a]	35 (21)	25 (15)	23 (15)	16 (10)
Neutropenia	18 (11)	14 (9)	8 (5)	6 (4)

Despite cytopenias, patients achieved close to the maximal dose of ruxolitinib (10 mg bid) at the study endpoint (week 24)

Median dose intensity of ruxolitinib: 19.6 mg/day (4.8-20.5)

Cytopenias improved over time as patients received treatment for chronic GVHD

Clinically relevant low blood counts were defined as platelets <30x10⁹ cells/L, hemoglobin <8 g/dL, white blood cells <5x10⁹ cells/L, and absolute neutrophil count <1x10⁹ cells/L.

[a] Includes events recorded as thrombocytopenia and decreased platelet count.

Hematologic events up to cycle 7 day 1 requiring dose modification/interruption[3]

AE, n (%)	Ruxolitinib (n=165)		BAT (n=158)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Patients with ≥1 event	62 (37.6)	38 (23.0)	26 (16.5)	12 (7.6)
Blood and lymphatic system disorders	23 (13.9)	14 (8.5)	6 (3.8)	5 (3.2)
Anemia	13 (7.9)	5 (3.0)	1 (0.6)	1 (0.6)
Neutropenia	8 (4.8)	7 (4.2)	2 (1.3)	2 (1.3)
Thrombocytopenia	6 (3.6)	6 (3.6)	2 (1.3)	1 (0.6)
Febrile neutropenia	4 (2.4)	4 (2.4)	1 (0.6)	1 (0.6)
Leukopenia	3 (1.8)	3 (1.8)	0	0
Lymphopenia	1 (0.6)	1 (0.6)	1 (0.6)	1 (0.6)
Pancytopenia	0	0	2 (1.3)	2 (1.3)

Drug-Drug Interactions

Dose modification guidelines for concomitant use of ruxolitinib/ruxolitinib XR with strong CYP3A4 inhibitors or fluconazole[1,a]

Ruxolitinib/Ruxolitnib XR Dose Modifications for Patients With Chronic GVHD[1,3]

For patients receiving	
Fluconazole doses >200 mg	Avoid concomitant use of ruxolitinib/ruxolitinib XR
Fluconazole doses ≤200 mg	Use the following dosage modifications: • 5 mg ruxolitinib bid • 11 mg ruxolitinib XR qd
Other CYP3A4 inhibitors	• Monitor blood counts more frequently for toxicity • Modify the ruxolitinib/ruxolitinib XR dosage for adverse reactions, if they occur

No empiric dose adjustments needed with voriconazole or posaconazole

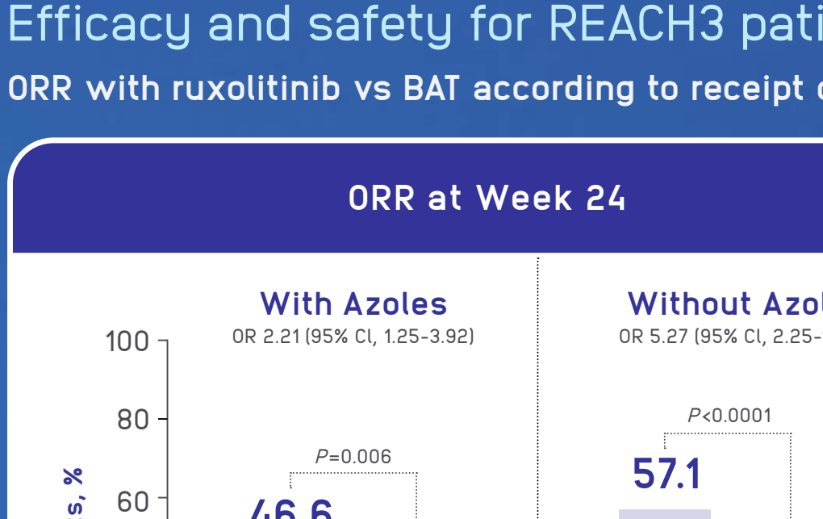
[a] Fluconazole 100-400 mg qd (a moderate CYP3A4 and CYP2C9 inhibitor) increases steady-state ruxolitinib AUC by approximately 100-300%.

AUC, area under the curve.

REACH3 post hoc analysis: Effects of concomitant azoles on ruxolitinib treatment in patients with chronic GVHD[7,8]

Full Analysis Set (N=329)

More than two-thirds of patients in REACH3 received concomitant azoles[4]



Safety Analysis Set (N=323)

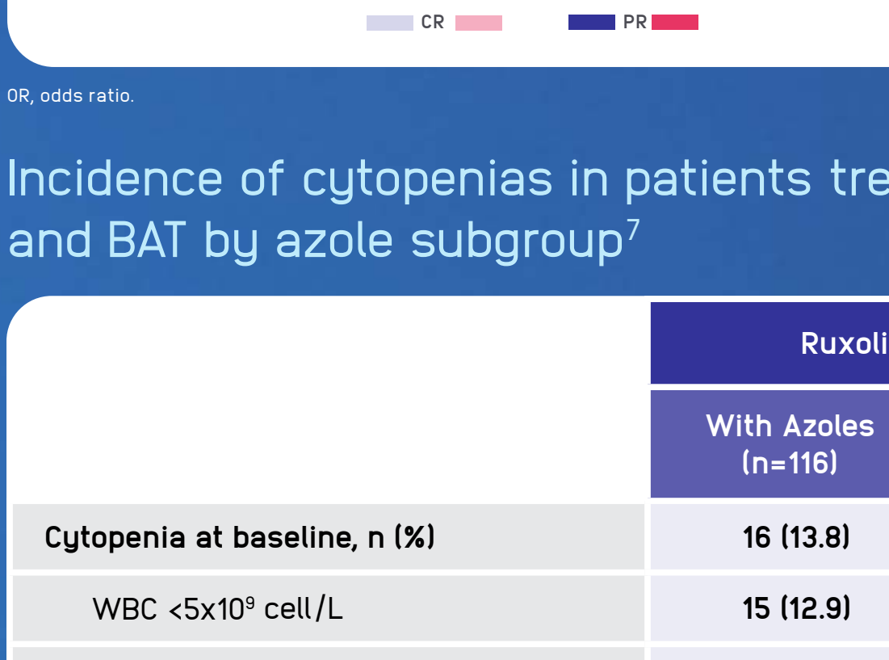
Azole Received[a], %	Ruxolitinib (n=165)	BAT (n=158)
Posaconazole	29.1	34.2
Fluconazole[b]	24.8	24.7
Voriconazole	23.0	12.7
Isavuconazole[c]	3.6	4.4

[a] Patients may have been exposed to more than one azole during the follow-up period. [b] Includes fluconazole and fosfluconazole. [c] Includes isavuconazole and isavuconazonium sulfate.

Efficacy and safety for REACH3 patients receiving concomitant azoles[7]

ORR with ruxolitinib vs BAT according to receipt of concomitant azoles

ORR at Week 24



Week 24 ORR was significantly higher with ruxolitinib vs BAT in patients who received azoles as well as those who did not

OR, odds ratio.

Incidence of cytopenias in patients treated with ruxolitinib and BAT by azole subgroup[7]

	Ruxolitinib (n=165)		BAT (n=158)	
	With Azoles (n=116)	Without Azoles (n=49)	With Azoles (n=102)	Without Azoles (n=56)
Cytopenia at baseline, n (%)	16 (13.8)	8 (16.3)	23 (22.5)	10 (17.9)
WBC <5x10⁹ cell/L	15 (12.9)	6 (12.2)	19 (18.6)	10 (17.9)
Platelets <30x10⁹ cells/L	2 (1.7)	1 (2.0)	5 (4.9)	0
Hemoglobin <8 g/dL	1 (0.9)	0	0	0
ANC <1x10⁹ cells/L	2 (1.7)	3 (6.1)	2 (2.0)	0
Cytopenia up to week 24, n (%)	74 (63.8)	31 (63.3)	56 (54.9)	25 (44.6)
WBC <5x10⁹ cell/L	70 (60.3)	28 (57.1)	51 (50.0)	23 (41.1)
Platelets <30x10⁹ cells/L	14 (12.1)	3 (6.1)	11 (10.8)	3 (5.4)
Hemoglobin <8 g/dL	17 (14.7)	5 (10.2)	9 (8.8)	4 (7.1)
ANC <1x10⁹ cells/L	15 (12.9)	8 (16.3)	14 (13.7)	3 (5.4)

Development of cytopenias at week 24 was similar for patients who received ruxolitinib with azoles vs without azoles

Mean and median ruxolitinib dose intensity up to week 24 were similar in patients with vs without concomitant administration of azoles

The mean dose of ruxolitinib (10 mg orally twice daily) was generally well tolerated when administered with concomitant azoles

ANC, absolute neutrophil count; WBC, white blood cell.

More Information

For more information about ruxolitinib in chronic GVHD, please see the links below:

Ruxolitinib for Glucocorticoid-Refractory Chronic Graft-versus-Host Disease
Zeiser R, et al. *N Engl J Med.* 2021;385:228-238.
LEARN MORE

A Phase 2 Multicenter Trial of Ruxolitinib to Treat Bronchiolitis Obliterans Syndrome After Allogeneic HCT.
DeFilipp Z, et al. *Blood Adv.* 2025;9(2):244-253.
LEARN MORE

Ruxolitinib for Treatment of Steroid Refractory Sclerotic Chronic Graft-Versus-Host Disease (cGVHD): Results of a Multicenter Phase II Trial
Bhatt VR, et al. *Blood.* 2022. 140 (Supplement 1): 1379–1380.
LEARN MORE

Impact of Concomitant Azoles on Ruxolitinib Treatment in Patients With GVHD: Post Hoc Analyses of REACH2 and REACH3
Mahmoudjafari Z, et al. *Blood Adv.* 2025 Aug 26;9:4206-4216.
LEARN MORE

Impact of Cytopenias and Early Versus Late Treatment With Ruxolitinib in Patients With Steroid-Refractory Acute or Chronic Graft-Versus-Host Disease
Mahmoudjafari Z, et al. *Bone Marrow Transplant.* 2025 Jan;60:69-78.
LEARN MORE

For more information, please see the Full Prescribing Information, and Patient Information.

1. Jakafi/Jakafi XR (ruxolitinib). Prescribing information. Incyte Corporation. May 2026. 2. Zeiser R, et al. *N Engl J Med.* 2021;385:228-238. 3. Data on File. Incyte Corporation. 4. Mahmoudjafari Z, et al. *Bone Marrow Transplant.* 2025 Jan;60:69-78. 5. DeFilipp Z, et al. *Blood Adv.* 2025;9(2):244-253.. 6. Bhatt VR, et al. *Blood.* 2022. 140 (Supplement 1): 1379–1380. 7. Mahmoudjafari Z, et al. *Blood Adv.* 2025 Aug 26;9:4206-4216 8. Kintsch E, et al. Hematology/Oncology Pharmacy Association Annual Conference 2024. Poster 65.

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Warnings, Precautions, and Specific Populations

Thrombocytopenia, Anemia and Neutropenia

- Treatment with Jakafi/Jakafi XR can cause thrombocytopenia, anemia and neutropenia
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi/Jakafi XR. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi/Jakafi XR
- Severe neutropenia (ANC less than 0.5×10^9/L) was generally reversible by withholding Jakafi/Jakafi XR until recovery
- Perform a pre-treatment CBC and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated

CBC, complete blood count.

Risk of Infection

- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting therapy with Jakafi/Jakafi XR until active serious infections have resolved. Observe patients receiving Jakafi/Jakafi XR 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/Jakafi XR for signs and symptoms of active tuberculosis and manage promptly
- Prior to initiating Jakafi/Jakafi XR, 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/Jakafi XR. The decision to continue Jakafi/Jakafi XR during treatment of active tuberculosis should be based on the overall risk-benefit determination

PML

- PML has occurred with Jakafi treatment. If PML is suspected, stop Jakafi/Jakafi XR and evaluate

Herpes Zoster and Herpes Simplex

- Herpes zoster infection has been reported in patients receiving Jakafi
- 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. Monitor patients for the development of herpes simplex infections. If a patient develops evidence of dissemination of herpes simplex, consider interrupting treatment with Jakafi/Jakafi XR; 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/Jakafi XR 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

HBV, hepatitis B virus; PML, progressive multifocal leukoencephalopathy.

Symptom Exacerbation Following Interruption or Discontinuation of Treatment

- Following discontinuation of JAK-inhibitors, including Jakafi/Jakafi XR, signs and symptoms from myeloproliferative neoplasms may flare. Some patients with MF have experienced one or more of the following after discontinuing JAK-inhibitors: fever, respiratory distress, hypotension, disseminated intravascular coagulation, or multi-organ failure
- If one or more of these signs and symptoms occur after discontinuation of Jakafi/Jakafi XR, or while tapering the dose, evaluate for and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi/Jakafi XR. Instruct patients not to interrupt or discontinue therapy without consulting their healthcare provider. When discontinuing or interrupting therapy with Jakafi/Jakafi XR for reasons other than life-threatening toxicities, consider tapering the dose of Jakafi/Jakafi XR gradually rather than discontinuing abruptly

MF, myelofibrosis.

NMSC

- NMSCs including basal cell, squamous cell, and Merkel cell carcinoma have occurred in patients treated with Jakafi/Jakafi XR. Perform periodic skin examinations

NMSC, non-melanoma skin cancer.

Lipid Elevations

- Treatment with Jakafi has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein cholesterol, and triglycerides. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined in patients treated with Jakafi/Jakafi XR. Assess lipid parameters approximately 8-12 weeks following initiation of Jakafi/Jakafi XR therapy. Monitor and treat according to clinical guidelines for the management of hyperlipidemia

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/Jakafi XR is not indicated
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi/Jakafi XR 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

MACE, major adverse cardiovascular event.

Thrombosis

- Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi/Jakafi XR 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

TNF, tumor necrosis factor.

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/Jakafi XR 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/Jakafi XR, 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

Pregnancy and Lactation

- There are no studies with the use of Jakafi/Jakafi XR in pregnant women to inform drug-associated risks
- Use of Jakafi/Jakafi XR during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus
- Advise women not to breastfeed during treatment with Jakafi/Jakafi XR and for 2 weeks after the final dose

Pediatric Use

- The safety and effectiveness of Jakafi/Jakafi XR for treatment of chronic GVHD or steroid-refractory acute GVHD has not been established in pediatric patients younger than 12 years old

Renal Impairment

- Total exposure of ruxolitinib and its active metabolites increased with moderate and severe renal impairment, and end stage renal disease on dialysis
- Modify Jakafi/Jakafi XR dosage as recommended

Hepatic Impairment

- Exposure of ruxolitinib increased with mild (Child-Pugh A), moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment
- Reduce Jakafi/Jakafi XR dosage as recommended for patients with Stage 4 liver acute GVHD
- Monitor blood counts more frequently for toxicity and modify the Jakafi/Jakafi XR dosage for adverse reactions if they occur for patients with Score 3 liver chronic GVHD

Geriatric Use

- Clinical studies of Jakafi in patients with acute GVHD 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 chronic GVHD 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

Jakafi/Jakafi XR (ruxolitinib). Prescribing information. Incyte Corporation. May 2026.

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