SIMPLIFY-1 trial data for JAKi-naïve patients

OJJAARA for myelofibrosis (MF) with anemia

Ojjaara (momelotinib)
200 mg • 150 mg • 100 mg tablets

Multifaceted disease management* starts here

Start with OJJAARA—The first & only FDA-approved JAK inhibitor indicated specifically for patients who have myelofibrosis with anemia.[1,2]

OJJAARA was also studied in JAKi-experienced patients.
Learn more at OJJAARAhcp.com

*Myelofibrosis is a heterogeneous disease.[3]

FDA=US Food and Drug Administration;
JAK=Janus kinase; JAKi=Janus kinase inhibitor.

Not an actual patient.

INDICATION

OJJAARA is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

IMPORTANT SAFETY INFORMATION

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Learn about a patient who may benefit from OJJAARA

Frank
Age 76

Not an actual patient.

Initial treatment:
Referral to specialist

Comorbidities:
Hyperlipidemia

Current diagnosis:
Intermediate-risk primary MF with anemia

Current treatment: N/A

BMI: 24.5

Anemia status:
Moderate

Spleen size:
5 cm below LCM

Transplant eligible:
Not eligible

DIPSS* score:
4 (Intermediate-2: >65 years; Hb <10 g/dL; constitutional symptoms)

Frank's myelofibrosis diagnosis is complicated by anemia

About Frank's case:

- Frank sought an examination due to a distended abdomen, where he was diagnosed with primary myelofibrosis
- His spleen did not cause discomfort or other symptoms at the time, and his healthcare provider decided to continue monitoring
- At his latest examination, Frank details new fatigue, night sweats, and bone pain. His most recent CBC panel found that he now has anemia
- **As Frank is ineligible for a transplant, his provider is now considering JAK inhibitor therapy to manage his myelofibrosis with anemia and worsening symptoms**

About Frank's life:

Frank, a proud U.S. veteran, found fulfillment after his military service as a high school teacher and coach. Now retired, he enjoys peaceful days with his spouse at their lakeside home. Once an avid walker, Frank now finds his strolls by the lake to be more challenging than before.

BMI=body mass index; CBC=complete blood count; DIPSS=Dynamic International Prognostic Scoring System; Hb=hemoglobin; LCM=left costal margin.

*In the DIPSS prognostic model, constitutional symptoms include weight loss, fever, and night sweats.[4]

Would you consider starting this patient on OJJAARA as his first JAKi?

IMPORTANT SAFETY INFORMATION (cont'd)
Risk of Infections (cont'd)

Hepatitis B Reactivation

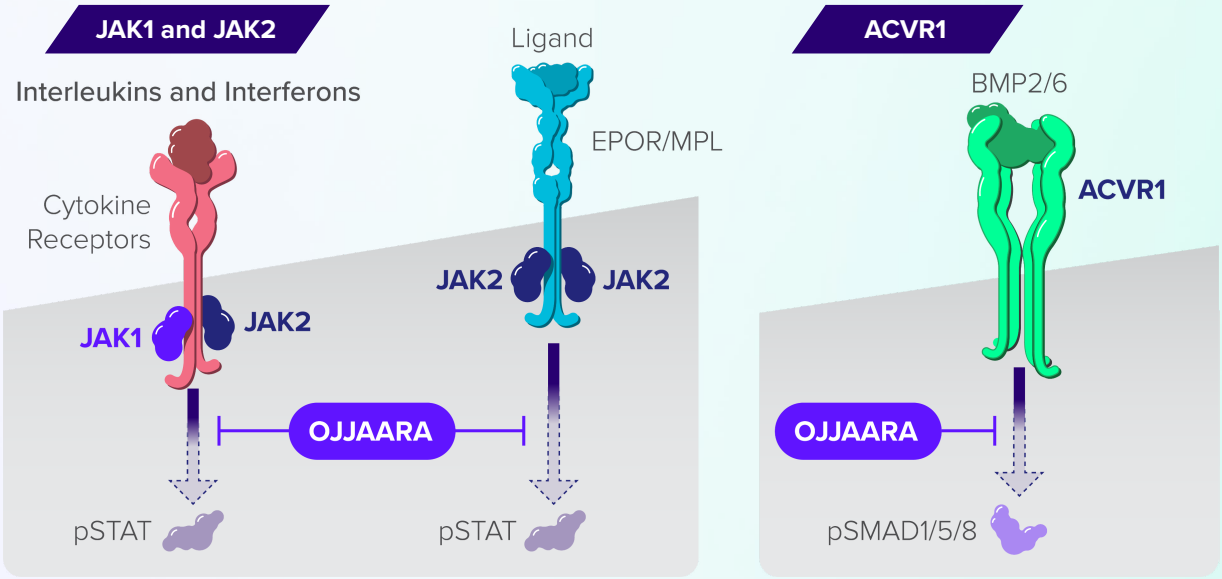
- Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine transaminase (ALT) or aspartate transaminase (AST), have been reported in patients with chronic hepatitis B virus (HBV) infection taking Janus Kinase (JAK) inhibitors, including OJJAARA. The effect of OJJAARA on viral replication in patients with chronic HBV infection is unknown. In patients with HBV infections, check hepatitis B serologies prior to starting OJJAARA. If HBsAg and/or anti-HBc antibody is positive, consider consultation with a hepatologist regarding monitoring for reactivation versus prophylactic hepatitis B therapy. Patients with chronic HBV infection who receive OJJAARA should have their chronic HBV infection treated and monitored according to clinical HBV guidelines.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Mechanism of Action: OJJAARA has a novel combination MOA that inhibits JAK1/JAK2* and ACVR1[1,2]

Myelofibrosis is an MPN associated with constitutive activation and dysregulated JAK signaling that contributes to inflammation and hyperactivation of ACVR1.



- JAK1 and JAK2 contribute to signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function
- OJJAARA and its major human circulating metabolite, M21, have higher inhibitory activity for JAK2 compared to JAK3 and tyrosine kinase 2 (TYK2)
- OJJAARA and M21 additionally inhibit ACVR1, also known as ALK2, which produces subsequent inhibition of liver hepcidin expression and increased iron availability, resulting in increased red blood cell production

*Momelotinib is an inhibitor of wild type Janus kinase 1 and 2 (JAK1/JAK2) and mutant $JAK2^{V617F}$.

ACVR1=activin A receptor type 1; ALK2=activin receptor-like kinase-2; BMP=bone morphogenetic protein; EPOR=erythropoietin receptor; MPL=myeloproliferative leukemia virus; MPN=myeloproliferative neoplasm; pSMAD=phosphorylated suppressor of mothers against decapentaplegic; pSTAT=phosphorylated signal transducer and activator of transcription.

OJJAARA has a multi-modal mechanism of action that inhibits signaling pathways important in myelofibrosis[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Thrombocytopenia and Neutropenia

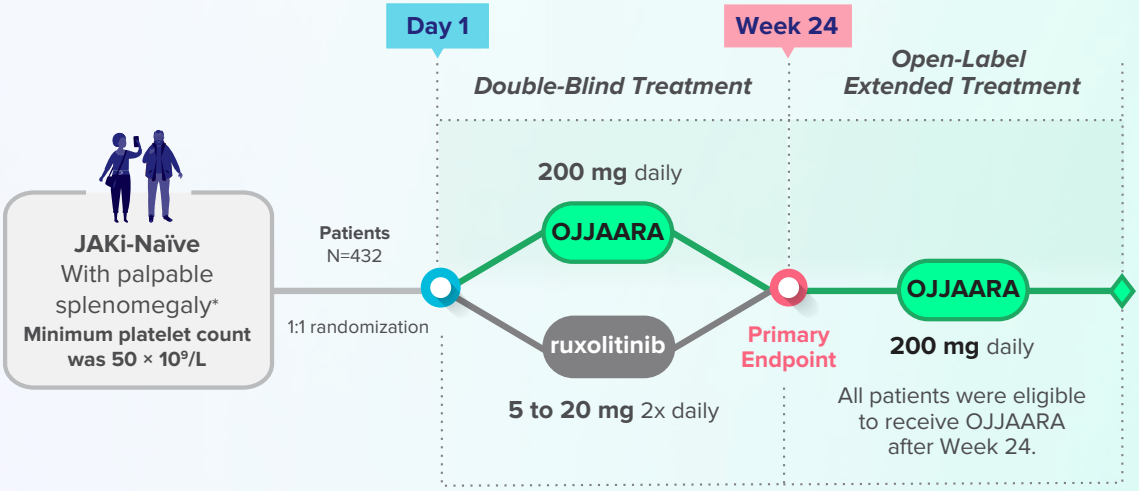
- New or worsening thrombocytopenia, with platelet count less than 50 × 10^9/L, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than 50 × 10^9/L.
- Severe neutropenia, absolute neutrophil count (ANC) less than 0.5 × 10^9/L, was observed in 2% of patients treated with OJJAARA.
- Assess complete blood counts (CBC), including platelet and neutrophil counts, before initiating treatment and periodically during treatment as clinically indicated. Interrupt dosing or reduce the dose for thrombocytopenia or neutropenia.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

SIMPLIFY-1: OJJAARA was studied in a head-to-head myelofibrosis trial vs ruxolitinib[1,5]

JAKi-Naïve Patients With Myelofibrosis (N=432)



SIMPLIFY-1 was a double-blind, randomized, active-controlled phase 3 trial in 432 patients with primary myelofibrosis, post-PV myelofibrosis, or post-ET myelofibrosis who had not previously received a JAK inhibitor.

For product approval, efficacy results were assessed in a subset of patients who had anemia (Hb <10 g/dL) at baseline (n=181)[1]

- The efficacy of OJJAARA in the treatment of patients with MF in SIMPLIFY-1 was based on spleen volume reduction (SVR) (≥35%)†

An additional post hoc analysis was conducted in a subset of patients with Hb <10 g/dL[6,7]:

- Total symptom score (TSS) response rate‡ (≥50% reduction)
- Transfusion independence (TI) rate§
- Hemoglobin response‖

CT=computed tomography; ET=essential thrombocythemia; MRI=magnetic resonance imaging; PV=polycythemia vera.
*Palpable splenomegaly ≥5 cm below the LCM.[5]
†SVR response rate at Week 24 was defined as the proportion of patients who had ≥35% reduction in spleen volume from baseline. Spleen volume was measured by MRI or CT.[1]
‡TSS response rate at Week 24 was defined as the proportion of patients who achieved a ≥50% reduction from baseline. TSS was measured using the modified Myeloproliferative Neoplasm Symptom Assessment Form v2.0.[5]
§TI rate at Week 24 was defined as the proportion of patients with no transfusion or Hb <8 g/dL between Weeks 12 and 24.[6]
‖Hemoglobin response defined as achievement of Hb >10 g/dL.[7]

IMPORTANT SAFETY INFORMATION (cont'd)

Hepatotoxicity

- Two of the 993 patients with MF who received at least one dose of OJJAARA in clinical trials experienced reversible drug-induced liver injury. Overall, new or worsening elevations of ALT and AST (all grades) occurred in 23% and 24%, respectively, of patients treated with OJJAARA; Grade 3 and 4 transaminase elevations occurred in 1% and 0.5% of patients, respectively. New or worsening elevations of total bilirubin occurred in 16% of patients treated with OJJAARA. All total bilirubin elevations were Grades 1-2. The median time to onset of any grade transaminase elevation was 2 months, with 75% of cases occurring within 4 months.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Baseline patient characteristics[1]

Subset of Patients (Hb <10 g/dL)

Characteristic	Patients With Baseline Hb <10 g/dL (n=181)
Median age, years (range)	68 (25 to 86)
≥65 years of age	67%
Male, Female	59%, 41%
White, Asian, Black, Hispanic or Latino	81%, 8%, 1%, 2%
Primary MF, Post-PV MF, Post-ET MF	63%, 13%, 24%
Intermediate-1 risk, Intermediate-2 risk, High-risk*	4%, 25%, 71%
Transfusion independent (TI)†	29% in the OJJAARA treatment arm, 44% in the ruxolitinib treatment arm
Median Hb, g/dL	8.8
Median platelet count, × 10^9/L (range)	193 (54 to 2865)
Median palpable spleen length	12 cm below the left costal margin
Median spleen volume, MRI or CT, cm^3 (range)	1843 (352 to 9022)

In clinical trials, all patients received a starting dosage of OJJAARA 200 mg once daily[1]

RBC=red blood cell.
*As defined by the International Prognostic Scoring System for myelofibrosis.[1]
†TI at baseline, defined as no RBC transfusion or Hb levels of <8 g/dL in the last 12 weeks before randomization.[6]

IMPORTANT SAFETY INFORMATION (cont'd)
Hepatotoxicity (cont'd)

- Delay starting therapy in patients presenting with uncontrolled acute and chronic liver disease until apparent causes have been investigated and treated as clinically indicated. When initiating OJJAARA, refer to dosing in patients with hepatic impairment.
- Monitor liver tests at baseline, every month for 6 months during treatment, then periodically as clinically indicated. If increases in ALT, AST or bilirubin related to treatment are suspected, modify OJJAARA dosage based upon Table 1 within the Prescribing Information.

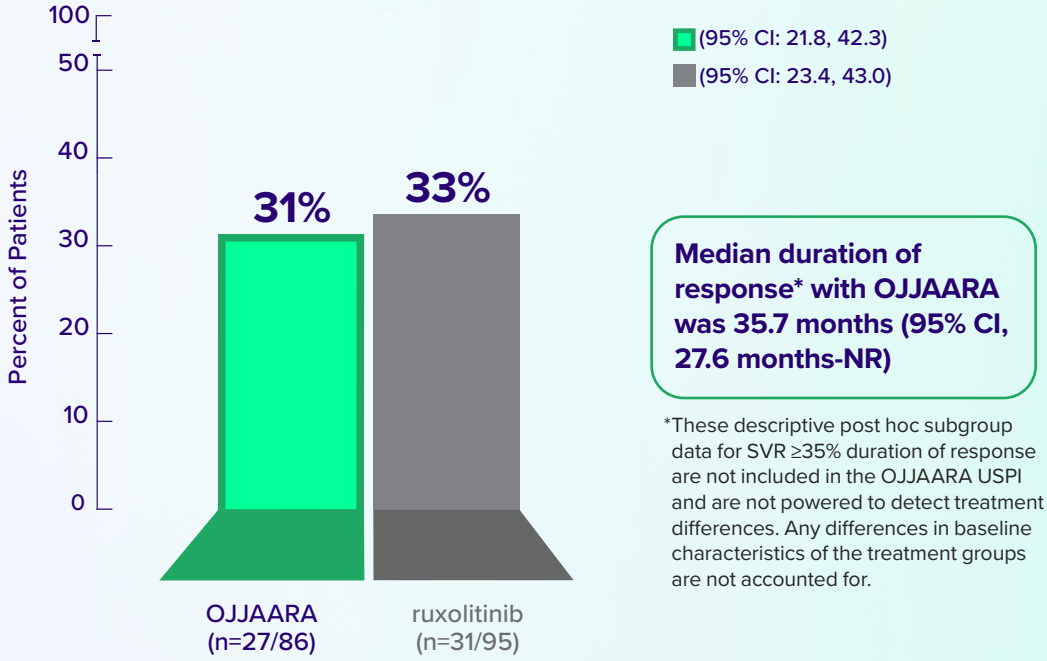
Ojjaara (momelotinib)

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Comparable rates of SVR ≥35% were observed with OJJAARA and ruxolitinib[1,8]

Efficacy results were assessed in a subset of patients who had anemia (Hb <10 g/dL) at baseline (n=181).

Subset Analysis of Patients With Hb <10 g/dL at Baseline:
Rate of SVR ≥35% From Baseline at Week 24



Median duration of response* with OJJAARA was 35.7 months (95% CI, 27.6 months-NR)

*These descriptive post hoc subgroup data for SVR ≥35% duration of response are not included in the OJJAARA USPI and are not powered to detect treatment differences. Any differences in baseline characteristics of the treatment groups are not accounted for.

A numerically lower percent of patients (Hb <10 g/dL) treated with OJJAARA (25%) achieved a TSS reduction of ≥50% at Week 24 compared with ruxolitinib (36%)

CI=confidence interval; NR=not reached.

IMPORTANT SAFETY INFORMATION (cont'd)

Severe Cutaneous Adverse Reactions (SCARs)

- Severe cutaneous adverse reactions (SCARs), including toxic epidermal necrolysis (TEN), have been observed in some patients treated with OJJAARA.
- If signs or symptoms of SCARs occur, interrupt OJJAARA until the etiology of the reaction has been determined. Consider early consultation with a dermatologist for evaluation and management.
- If etiology is considered to be associated with OJJAARA, permanently discontinue OJJAARA and do not reintroduce OJJAARA in patients who have experienced SCARs or other life-threatening cutaneous reactions during treatment with OJJAARA.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Post hoc data: Rates of SVR ≥35% in patients taking OJJAARA by baseline platelet counts[8]

These are post hoc subset data in patients who had Hb <10 g/dL at baseline. These data are not included in the USPI for OJJAARA.

Limitations:

- For descriptive use only; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for
- Some subgroups included a smaller sample size

Post Hoc Subset Analysis of Patients With Hb <10 g/dL at Baseline:
Rate of SVR ≥35% at Week 24

Baseline platelet subgroup	Momelotinib	ruxolitinib
>200 × 10^9/L	(n=37) **22%**	(n=47) **49%**
≥100 to <200 × 10^9/L	(n=36) **36%**	(n=34) **24%**
≥50 to <100 × 10^9/L	(n=13) **46%**	(n=13) **0**

IMPORTANT SAFETY INFORMATION (cont'd)

Major Adverse Cardiovascular Events (MACE)

- Another JAK inhibitor increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke [compared with those treated with tumor necrosis factor (TNF) blockers] in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients receiving OJJAARA of the symptoms of serious cardiovascular events and the steps to take if they occur.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

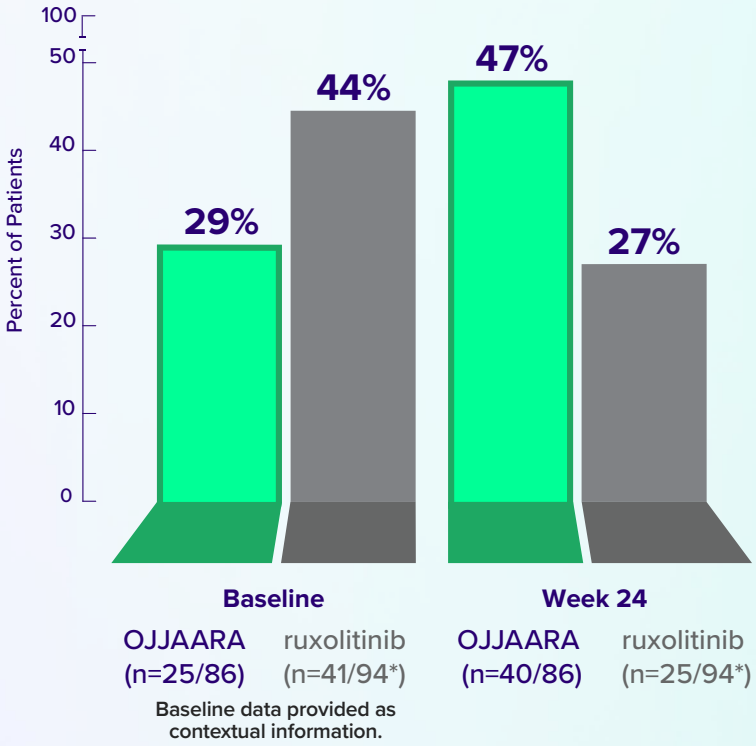
Post hoc data: Rate of TI in patients with Hb <10 g/dL treated with OJJAARA or ruxolitinib[6]

These are post hoc subset data in patients who had Hb <10 g/dL at baseline. These subset data are not included in the USPI for OJJAARA.

Limitations:

- Not adjusted for multiplicity; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for
- Results are for descriptive use only

Post Hoc Subset Analysis of Patients With Hb <10 g/dL at Baseline:
Rate of TI at Week 24



Baseline data provided as contextual information.

- 72% (18/25) of patients taking OJJAARA who were TI at baseline were also TI at Week 24
- 34% (14/41) of patients taking ruxolitinib who were TI at baseline were also TI at Week 24

*One patient who received ruxolitinib was excluded from this analysis due to a missing hemoglobin value prior to randomization.

IMPORTANT SAFETY INFORMATION (cont'd)

Thrombosis

- Another JAK inhibitor increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Evaluate patients with symptoms of thrombosis and treat appropriately.

Malignancies

- Another JAK inhibitor increased the risk of lymphoma and other malignancies excluding nonmelanoma skin cancer (NMSC) (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Current or past smokers were at increased risk.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

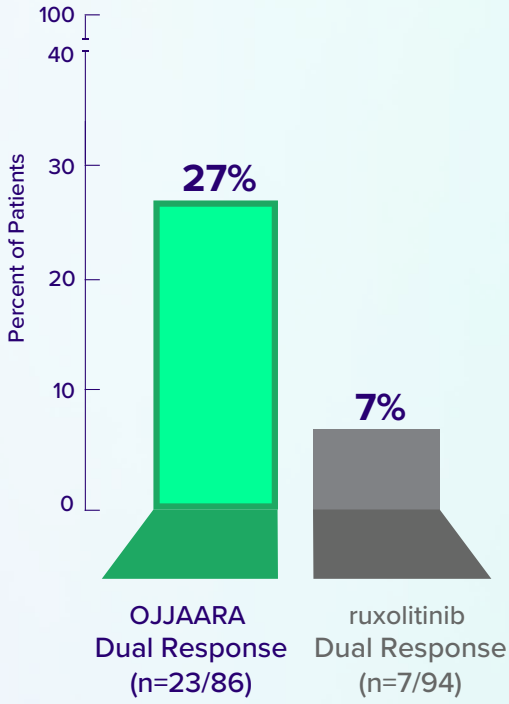
Post hoc data: Dual SVR ≥35% + TI response in patients taking OJJAARA or ruxolitinib[8]

These are post hoc subset data in patients who had Hb <10 g/dL at baseline. These subset data are not included in the USPI for OJJAARA.

Limitations:

- Not adjusted for multiplicity; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for
- Results are for descriptive use only

Post Hoc Subset Analysis of Patients With Hb <10 g/dL at Baseline:
Dual SVR ≥35% + TI Response at Week 24



IMPORTANT SAFETY INFORMATION (cont'd)

Malignancies (cont'd)

- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

Symptom Exacerbation Following Interruption or Discontinuation of Treatment

- Following discontinuation of JAK inhibitors, including OJJAARA, 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.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Post hoc data: Dual SVR ≥35% + TI response by patient subgroup[8]

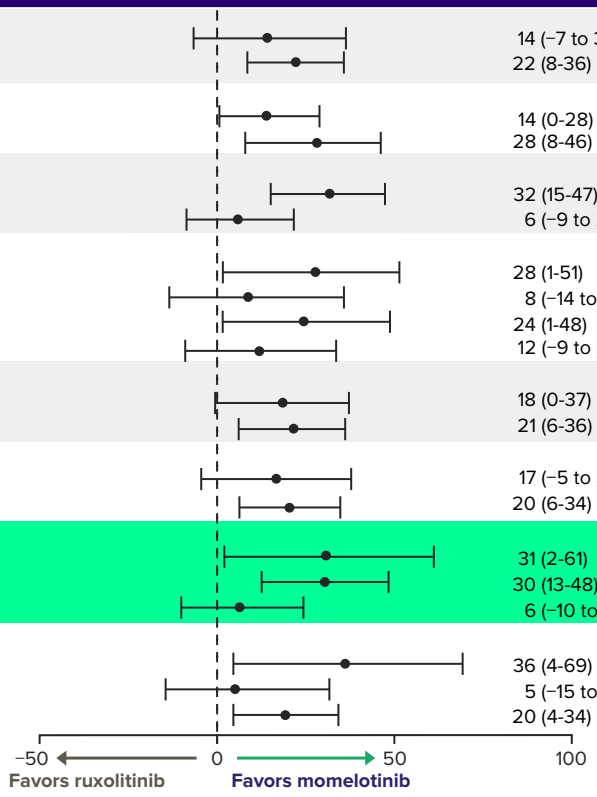
These are post hoc subset data in patients who had Hb <10 g/dL at baseline. These data are not included in the USPI for OJJAARA.

Limitations:

- For descriptive use only; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for
- Some subgroups included a smaller sample size

Post Hoc Subset Analysis of Patients With Hb <10 g/dL at Baseline: Dual SVR ≥35% + TI Response at Week 24

Baseline subgroup	No. in subgroup		Dual SVR35 + TI rate, %		Difference (95% CI)
	Momelotinib	ruxolitinib	Momelotinib	ruxolitinib	
Age, years					
<65	24	36	25	11	14 (−7 to 36)
≥65	62	58	27	5	22 (8-36)
Transfusion dependence					
Yes	49	43	18	5	14 (0-28)
No	37	51	38	10	28 (8-46)
Spleen volume					
<Median	47	43	36	5	32 (15-47)
≥Median	39	51	15	10	6 (−9 to 22)
Total Symptom Score by quartile					
<25%	24	20	38	10	28 (1-51)
≥25% to median	16	29	19	10	8 (−14 to 36)
≥Median to <75%	21	23	29	4	24 (1-48)
≥75%	24	21	17	5	12 (−9 to 33)
Hb level, g/dL					
<8	28	21	18	0	18 (0-37)
≥8	58	73	31	10	21 (6-36)
IPSS risk					
Intermediate	28	24	25	8	17 (−5 to 38)
High	58	70	28	7	20 (6-34)
Platelet count, × 10^9/L					
≥50 to <100	13	13	31	0	31 (2-61)
≥100 to 200	36	34	33	3	30 (13-48)
>200	37	47	19	13	6 (−10 to 24)
MF disease type					
Post-PV MF	11	12	36	0	36 (4-69)
Post-ET MF	16	28	13	7	5 (−15 to 31)
Primary MF	59	54	29	9	20 (4-34)



IPSS=International Prognostic Scoring System.

IMPORTANT SAFETY INFORMATION (cont'd)

Symptom Exacerbation Following Interruption or Discontinuation of Treatment (cont'd)

- If one or more of these signs and symptoms occur after discontinuation of OJJAARA, evaluate for and treat any intercurrent illness and consider restarting OJJAARA. Instruct patients not to interrupt or discontinue therapy without consulting their healthcare provider. When discontinuing or interrupting therapy for reasons other than potentially life-threatening toxicities, consider tapering the dose of OJJAARA gradually rather than discontinuing abruptly.

Adverse Reactions

- The most common adverse reactions (≥20% in either study) are thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Post hoc data: Hemoglobin response by baseline anemia status in patients taking OJJAARA[7]*

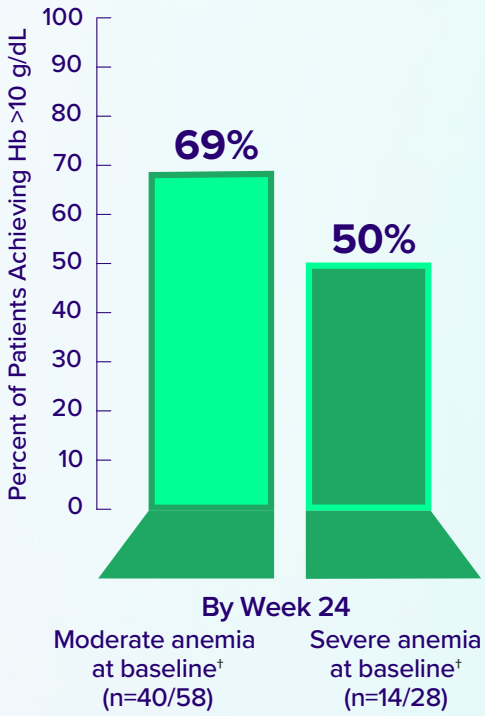
These are post hoc subset data in patients who had Hb <10 g/dL at baseline. These data are not included in the USPI for OJJAARA.

Limitations:

- For descriptive use only; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for

Post Hoc Subset Analysis of Patients With Moderate and Severe Anemia at Baseline:

Hemoglobin Response in Patients Taking OJJAARA by Week 24†



*Hemoglobin response defined as achievement of Hb >10 g/dL.
†Moderate anemia defined as Hb ≥8 g/dL to <10 g/dL. Severe anemia defined as Hb <8 g/dL.

Among patients treated with OJJAARA, the median (range) time to first Hb >10 g/dL was:

- Moderate anemia at baseline: 0.6 (0.4-5.1) months
- Severe anemia at baseline: 1.4 (0.5-4.7) months

IMPORTANT SAFETY INFORMATION (cont'd)

Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors

- Momelotinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases momelotinib maximal concentrations (C_{max}) and area under the concentration-time curve (AUC), which may increase the risk of adverse reactions with OJJAARA. Monitor patients concomitantly receiving an OATP1B1/B3 inhibitor for adverse reactions and consider OJJAARA dose modifications.

Breast Cancer Resistance Protein (BCRP) Substrates

- Momelotinib is a BCRP inhibitor. OJJAARA may increase exposure of BCRP substrates, which may increase the risk of BCRP substrate adverse reactions. When administered concomitantly with OJJAARA, initiate rosuvastatin (BCRP substrate) at 5 mg and do not increase to more than 10 mg once daily. Dose adjustment of other BCRP substrates may also be needed. Follow approved product information recommendations for other BCRP substrates.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

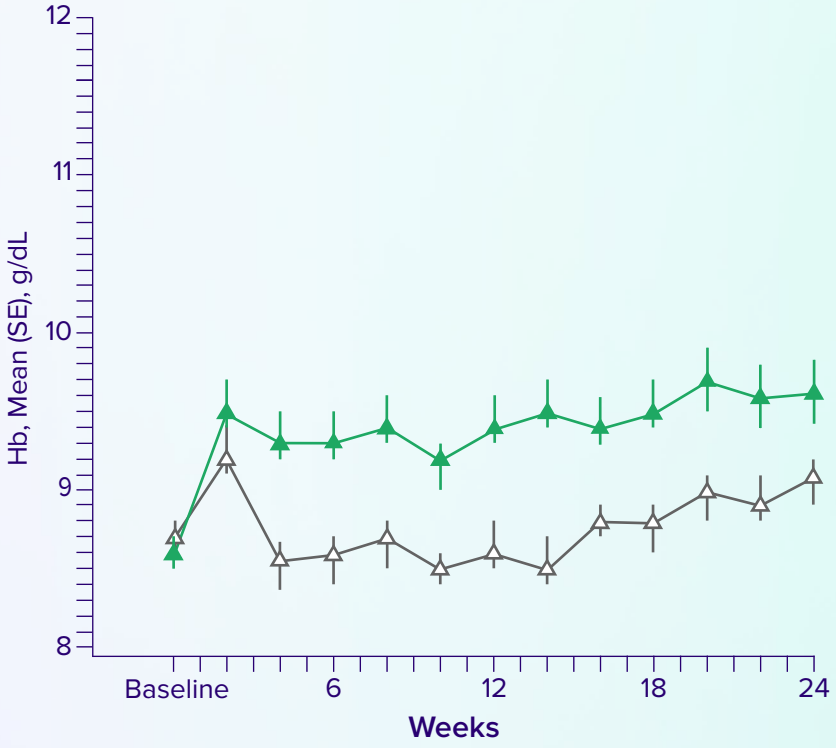
Post hoc data: Mean hemoglobin levels over 24 weeks[6]

These are post hoc subset data in patients who had Hb <10 g/dL at baseline. Data reflect mean hemoglobin levels over time, collected from patients with available laboratory data who remained in the study at each time point during the randomized treatment period. These data are not included in the USPI for OJJAARA.

Limitations:

- For descriptive use only; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for

Post Hoc Subset Analysis of Patients With Hb <10 g/dL at Baseline:
Mean Hemoglobin Levels Through Week 24



▲ OJJAARA (n)	86	75	68
△ ruxolitinib (n)	94	89	84

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy

- Available data in pregnant women are insufficient. OJJAARA should only be used during pregnancy if the expected benefits to the mother outweigh the potential risks to the fetus.

Lactation

- It is not known whether OJJAARA is excreted in human milk. Because of the potential for serious adverse reactions in a breastfed child, patients should not breastfeed during treatment with OJJAARA, and for at least 1 week after the last dose of OJJAARA.

Ojjaara (momelotinib)

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

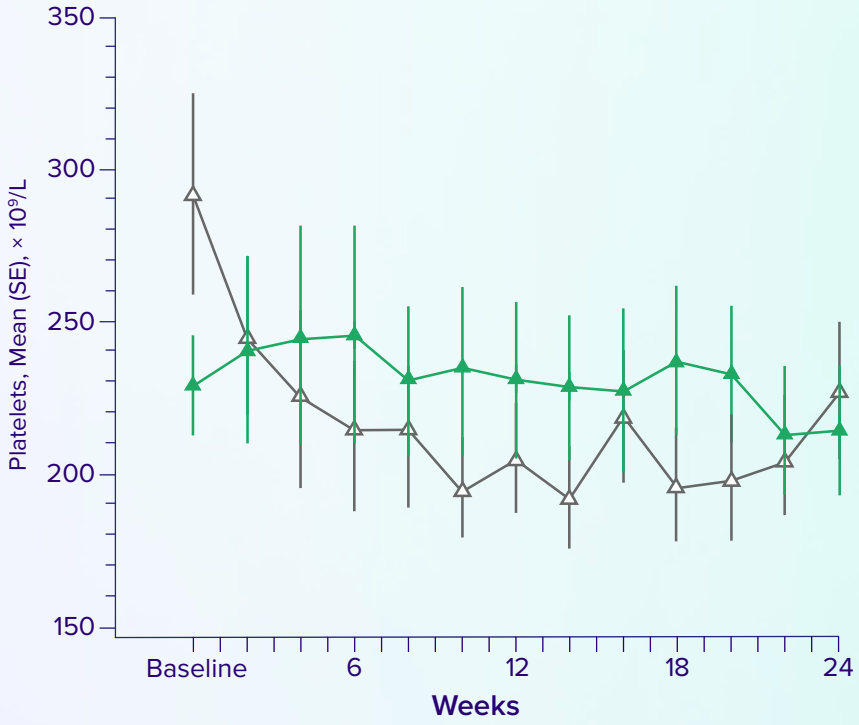
Post hoc data: Mean platelet levels over 24 weeks[9]

These are post hoc subset data in patients who had Hb <10 g/dL at baseline. Data reflect mean platelet levels over time, collected from patients with available laboratory data who remained in the study at each time point during the randomized treatment period. These data are not included in the USPI for OJJAARA.

Limitations:

- For descriptive use only; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for

Post Hoc Subset Analysis of Patients With Hb <10 g/dL at Baseline:
Mean Platelet Levels Through Week 24



	Baseline	Week 6	Week 12	Week 18	Week 24
▲ OJJAARA (n)	86		70		65
△ ruxolitinib (n)	94		85		79

IMPORTANT SAFETY INFORMATION (cont'd)

Thrombocytopenia and Neutropenia

- New or worsening thrombocytopenia, with platelet count less than 50 × 10^9/L, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than 50 × 10^9/L.
- Severe neutropenia, absolute neutrophil count (ANC) less than 0.5 × 10^9/L, was observed in 2% of patients treated with OJJAARA.
- Assess complete blood counts (CBC), including platelet and neutrophil counts, before initiating treatment and periodically during treatment as clinically indicated. Interrupt dosing or reduce the dose for thrombocytopenia or neutropenia.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Well-characterized safety profile in JAKi-naïve patients with Hb <10 g/dL at baseline[1]

Adverse Reactions Occurring in ≥5% of Anemic Patients (Hb <10 g/dL) Receiving OJJAARA During Randomized Treatment in SIMPLIFY-1

	OJJAARA (n=85) Baseline Hb <10 g/dL		ruxolitinib* (n=95) Baseline Hb <10 g/dL	
Adverse Reactions	All Grades† (%)	Grade ≥3 (%)	All Grades (%)	Grade ≥3 (%)
Dizziness‡	24	1	15	2
Fatigue‡	22	0	25	1
Bacterial infection‡,§	21	8	12	2
Hemorrhage‡	21	1	18	2
Thrombocytopenia‡	21	11	34	6
Diarrhea‡	20	1	20	1
Nausea‡	20	0	3	1
Abdominal pain‡	18	1	14	1
Cough‡	14	0	11	0
Hypotension‡	14	2	0	0
Pain in extremity	12	0	5	0
Pyrexia‡	12	1	11	0
Rash‡	12	0	3	0
Renal and urinary tract infection‡,§	12	1	4	0
Elevated liver enzymes‡	11	4	9	0
Headache‡	11	0	16	0

*Study was not designed to evaluate meaningful comparisons of the incidence of adverse reactions across treatment groups.
†Adverse reactions graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) v.4.03.
‡Grouped term includes other related terms.
§Excludes opportunistic infections.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Well-characterized safety profile in JAKi-naïve patients with Hb <10 g/dL at baseline[1] (cont'd)

Adverse Reactions Occurring in ≥5% of Anemic Patients (Hb <10 g/dL) Receiving OJJAARA During Randomized Treatment in SIMPLIFY-1 (cont'd)

	OJJAARA (n=85) Baseline Hb <10 g/dL		ruxolitinib* (n=95) Baseline Hb <10 g/dL	
Adverse Reactions	All Grades† (%)	Grade ≥3 (%)	All Grades (%)	Grade ≥3 (%)
Peripheral edema	11	0	8	0
Arrhythmia‡	8	2	2	1
Paresthesia‡	8	0	3	0
Pneumonia‡	8	8	5	3
Vomiting‡	8	0	5	0
Back pain	7	1	2	0
Viral infection‡,§	6	0	13	2
Vitamin B1 deficiency	6	0	7	0

*Study was not designed to evaluate meaningful comparisons of the incidence of adverse reactions across treatment groups.
†Adverse reactions graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) v.4.03.
‡Grouped term includes other related terms.
§Excludes opportunistic infections.

Serious adverse reactions

Occurred in 28% of the anemic patients (Hb <10 g/dL) who received OJJAARA during the randomized treatment period of the SIMPLIFY-1 trial; the most common serious adverse reactions (≥2%) included bacterial infection (7%), pneumonia (6%), heart failure (4%), arrhythmia (2%), and respiratory failure (2%). A fatal adverse reaction (bacterial infection) occurred in 1 patient who received OJJAARA.

Permanent discontinuation of OJJAARA due to an adverse reaction

Occurred in 19% of the anemic patients (Hb <10 g/dL) during the randomized treatment period of the SIMPLIFY-1 trial. Adverse reactions that resulted in permanent discontinuation of OJJAARA (≥2%) included bacterial infection (2%), dizziness (2%), fatigue (2%), hypotension (2%), and thrombocytopenia (2%).

Dosage reductions or treatment interruptions of OJJAARA due to an adverse reaction

Occurred in 21% of patients. Adverse reactions requiring dosage reduction and/or treatment interruption (≥2%) were thrombocytopenia (8%), pneumonia (4%), bacterial infection (2%), abdominal pain (2%), elevated liver enzymes (2%), and hypotension (2%).

To report SUSPECTED ADVERSE REACTIONS, contact GSK at gsk.public.reportum.com or 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

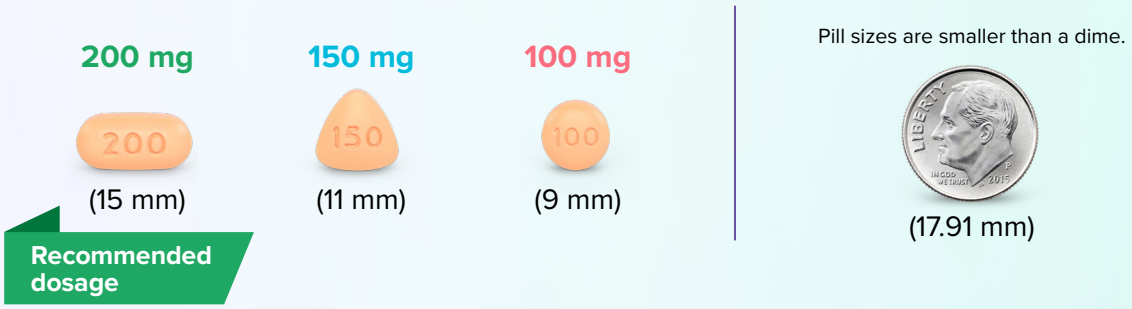
Dosage and Administration: One pill, once daily for patients who have MF with anemia[1]

- The recommended dosage of OJJAARA is **200 mg orally once daily**
- OJJAARA may be **taken with or without food**
- Swallow OJJAARA tablets whole. Do not cut, crush, or chew tablets
- If a dose of OJJAARA is missed, the next scheduled dose should be taken the following day

Laboratory monitoring for safety[1]

- Obtain the following blood tests prior to starting treatment with OJJAARA, periodically during treatment, and as clinically indicated:
  - Complete blood count (CBC) with platelets
  - Hepatic panel

OJJAARA is available in 3 dosage strengths[1,10]:



Drug interactions[1]

- **Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors:** Momelotinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases momelotinib maximal concentrations (C_{max}) and area under the concentration-time curve (AUC), which may increase the risk of adverse reactions with OJJAARA. Monitor patients concomitantly receiving an OATP1B1/B3 inhibitor for adverse reactions and consider OJJAARA dose modifications
- **Breast Cancer Resistance Protein (BCRP) Substrates:** Momelotinib is a BCRP inhibitor. OJJAARA may increase exposure of BCRP substrates, which may increase the risk of BCRP substrate adverse reactions. When administered concomitantly with OJJAARA, initiate rosuvastatin (BCRP substrate) at 5 mg and do not increase to more than 10 mg once daily. Dose adjustment of other BCRP substrates may also be needed. Follow approved product information recommendations for other BCRP substrates

IMPORTANT SAFETY INFORMATION (cont'd)

Hepatic Impairment

- Momelotinib exposure increased with severe hepatic impairment (Child-Pugh C). The recommended starting dose of OJJAARA in patients with severe hepatic impairment (Child-Pugh C) is 150 mg orally once daily. No dose modification is recommended for patients with mild hepatic impairment (Child-Pugh A) or moderate hepatic impairment (Child-Pugh B).

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Dosage and Administration: Dosage modifications[1]

For hepatic impairment

The recommended starting dosage in patients with severe hepatic impairment (Child-Pugh Class C) is 150 mg orally once daily. No dose adjustment is recommended for patients with mild or moderate hepatic impairment.

For adverse reactions

Manage hematologic and non-hematologic adverse reactions as described in the following table.

Thrombocytopenia – Baseline Platelet Count ≥100 × 10^9/L[1]*			
	Dose at Time of Platelet Decline		
	200 mg	150 mg	100 mg
Current Platelet Count (× 10^9/L)	**New recommended dose***		
20 × 10^9/L to <50 × 10^9/L	150 mg	100 mg	Discontinue
<20 × 10^9/L	• Interrupt treatment until platelets recover to 50 × 10^9/L • Restart OJJAARA at a daily dose of 50 mg below the last given dose†		
Thrombocytopenia – Baseline Platelet Count ≥50 × 10^9/L to <100 × 10^9/L*			
<20 × 10^9/L	• Interrupt treatment until platelets recover to 50 × 10^9/L • Restart OJJAARA at a daily dose of 50 mg below the last given dose†		
Thrombocytopenia – Baseline Platelet Count <50 × 10^9/L*			
<20 × 10^9/L	• Interrupt treatment until platelets recover to baseline • Restart OJJAARA at a daily dose of 50 mg below the last given dose†		
Neutropenia*			
Absolute neutrophil count (ANC) <0.5 × 10^9/L	• Interrupt treatment until ANC ≥0.75 × 10^9/L • Restart OJJAARA at a daily dose of 50 mg below the last given dose†		
Hepatotoxicity (unless other apparent causes)			
	Dose Modification*		
ALT and/or AST >5 × ULN (or >5 × baseline, if baseline is abnormal) and/or total bilirubin >2 × ULN (or >2 × baseline, if baseline is abnormal)	• Interrupt treatment until AST and ALT ≤2 × ULN or baseline‡ and total bilirubin ≤1.5 × ULN or baseline§ • Restart OJJAARA at a daily dose of 50 mg below the last given dose† • If reoccurrence of ALT or AST elevations >5 × ULN, permanently discontinue OJJAARA		
Other Non-Hematologic			
	Dose Modification*		
Grade 3 or higher‖	• Interrupt treatment until the toxicity resolves to Grade 1 or lower (or baseline) • Restart OJJAARA at a daily dose of 50 mg below the last given dose†		

ALT=alanine transaminase; AST=aspartate transaminase; ULN=upper limit of normal.
*Reinitiate or escalate treatment up to starting dosage as clinically appropriate.[1]
†May reinitiate treatment at 100 mg if previously dosed at 100 mg.[1]
‡If baseline >2 × ULN.[1]
§If baseline >1.5 × ULN.[1]
‖Graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE).[1]

Discontinue OJJAARA in patients unable to tolerate 100 mg once daily[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Females and Males of Reproductive Potential

- Advise females of reproductive potential who are not pregnant to use highly effective contraception during therapy and for at least 1 week after the last dose of OJJAARA.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

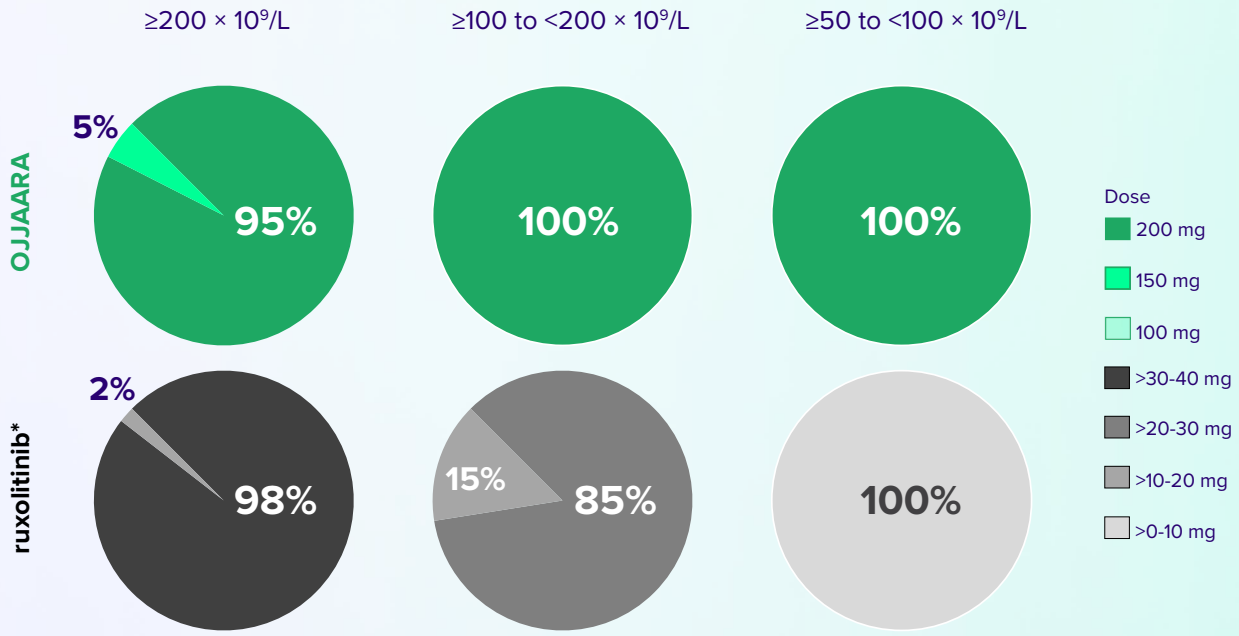
Post hoc data: Mean daily doses during Week 1 by baseline platelet counts[8]

These are post hoc subset data in patients who had Hb <10 g/dL at baseline. These data are not included in the USPI for OJJAARA.

Limitations:

- For descriptive use only; not powered to detect treatment differences
- Differences in baseline characteristics not accounted for

Post Hoc Subset Analysis in Patients With Hb <10 g/dL at Baseline:
Mean Daily Doses During Study Week 1 by Baseline Platelet Counts



*Per protocol, ruxolitinib dosing was aligned with prescribing information.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

INDICATION

OJJAARA is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

IMPORTANT SAFETY INFORMATION

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Hepatitis B Reactivation

- Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine transaminase (ALT) or aspartate transaminase (AST), have been reported in patients with chronic hepatitis B virus (HBV) infection taking Janus Kinase (JAK) inhibitors, including OJJAARA. The effect of OJJAARA on viral replication in patients with chronic HBV infection is unknown. In patients with HBV infections, check hepatitis B serologies prior to starting OJJAARA. If HBsAg and/or anti-HBc antibody is positive, consider consultation with a hepatologist regarding monitoring for reactivation versus prophylactic hepatitis B therapy. Patients with chronic HBV infection who receive OJJAARA should have their chronic HBV infection treated and monitored according to clinical HBV guidelines.

Thrombocytopenia and Neutropenia

- New or worsening thrombocytopenia, with platelet count less than 50×10^9/L, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than 50×10^9/L.
- Severe neutropenia, absolute neutrophil count (ANC) less than 0.5×10^9/L, was observed in 2% of patients treated with OJJAARA.
- Assess complete blood counts (CBC), including platelet and neutrophil counts, before initiating treatment and periodically during treatment as clinically indicated. Interrupt dosing or reduce the dose for thrombocytopenia or neutropenia.

Hepatotoxicity

- Two of the 993 patients with MF who received at least one dose of OJJAARA in clinical trials experienced reversible drug-induced liver injury. Overall, new or worsening elevations of ALT and AST (all grades) occurred in 23% and 24%, respectively, of patients treated with OJJAARA; Grade 3 and 4 transaminase elevations occurred in 1% and 0.5% of patients, respectively. New or worsening elevations of total bilirubin occurred in 16% of patients treated with OJJAARA. All total bilirubin elevations were Grades 1-2. The median time to onset of any grade transaminase elevation was 2 months, with 75% of cases occurring within 4 months.
- Delay starting therapy in patients presenting with uncontrolled acute and chronic liver disease until apparent causes have been investigated and treated as clinically indicated. When initiating OJJAARA, refer to dosing in patients with hepatic impairment.
- Monitor liver tests at baseline, every month for 6 months during treatment, then periodically as clinically indicated. If increases in ALT, AST or bilirubin related to treatment are suspected, modify OJJAARA dosage based upon Table 1 within the Prescribing Information.

Severe Cutaneous Adverse Reactions (SCARs)

- Severe cutaneous adverse reactions (SCARs), including toxic epidermal necrolysis (TEN), have been observed in some patients treated with OJJAARA.
- If signs or symptoms of SCARs occur, interrupt OJJAARA until the etiology of the reaction has been determined. Consider early consultation with a dermatologist for evaluation and management.
- If etiology is considered to be associated with OJJAARA, permanently discontinue OJJAARA and do not reintroduce OJJAARA in patients who have experienced SCARs or other life-threatening cutaneous reactions during treatment with OJJAARA.

Major Adverse Cardiovascular Events (MACE)

- Another JAK inhibitor increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke [compared with those treated with tumor necrosis factor (TNF) blockers] in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients receiving OJJAARA of the symptoms of serious cardiovascular events and the steps to take if they occur.

Thrombosis

- Another JAK inhibitor increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Evaluate patients with symptoms of thrombosis and treat appropriately.

Continue to see additional Important Safety Information.

Ojjaara (momelotinib)

IMPORTANT SAFETY INFORMATION (cont'd)

Malignancies

- Another JAK inhibitor increased the risk of lymphoma and other malignancies excluding nonmelanoma skin cancer (NMSC) (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Current or past smokers were at increased risk.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

Symptom Exacerbation Following Interruption or Discontinuation of Treatment

- Following discontinuation of JAK inhibitors, including OJJAARA, 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 OJJAARA, evaluate for and treat any intercurrent illness and consider restarting OJJAARA. Instruct patients not to interrupt or discontinue therapy without consulting their healthcare provider. When discontinuing or interrupting therapy for reasons other than potentially life-threatening toxicities, consider tapering the dose of OJJAARA gradually rather than discontinuing abruptly.

Adverse Reactions

- The most common adverse reactions (≥20% in either study) are thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors

- Momelotinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases momelotinib maximal concentrations (C_{max}) and area under the concentration-time curve (AUC), which may increase the risk of adverse reactions with OJJAARA. Monitor patients concomitantly receiving an OATP1B1/B3 inhibitor for adverse reactions and consider OJJAARA dose modifications.

Breast Cancer Resistance Protein (BCRP) Substrates

- Momelotinib is a BCRP inhibitor. OJJAARA may increase exposure of BCRP substrates, which may increase the risk of BCRP substrate adverse reactions. When administered concomitantly with OJJAARA, initiate rosuvastatin (BCRP substrate) at 5 mg and do not increase to more than 10 mg once daily. Dose adjustment of other BCRP substrates may also be needed. Follow approved product information recommendations for other BCRP substrates.

Pregnancy

- Available data in pregnant women are insufficient. OJJAARA should only be used during pregnancy if the expected benefits to the mother outweigh the potential risks to the fetus.

Lactation

- It is not known whether OJJAARA is excreted in human milk. Because of the potential for serious adverse reactions in a breastfed child, patients should not breastfeed during treatment with OJJAARA, and for at least 1 week after the last dose of OJJAARA.

Females and Males of Reproductive Potential

- Advise females of reproductive potential who are not pregnant to use highly effective contraception during therapy and for at least 1 week after the last dose of OJJAARA.

Hepatic Impairment

- Momelotinib exposure increased with severe hepatic impairment (Child-Pugh C). The recommended starting dose of OJJAARA in patients with severe hepatic impairment (Child-Pugh C) is 150 mg orally once daily. No dose modification is recommended for patients with mild hepatic impairment (Child-Pugh A) or moderate hepatic impairment (Child-Pugh B).

Please see full Prescribing Information, including Patient Information, for OJJAARA.

References: 1. OJJAARA (momelotinib). Prescribing Information. GSK; 2026. **2.** Chifotides HT, Bose P, Verstovsek S. Momelotinib: an emerging treatment for myelofibrosis patients with anemia. *J Hematol Oncol*. 2021;15(1):7. doi:10.1186/s13045-021-01157-4 **3.** Verstovsek S, Yu J, Kish JK, et al. Real-world risk assessment and treatment initiation among patients with myelofibrosis at community oncology practices in the United States. *Ann Hematol*. 2020;99(11):2555-2564. **4.** Passamonti F, Cervantes F, Vannucchi AM, et al. A dynamic prognostic model to predict survival in primary myelofibrosis: a study by the IWG-MRT (International Working Group for Myeloproliferative Neoplasms Research and Treatment). *Blood*. 2010;115(9):1703-1708. doi:10.1182/blood-2009-09-245837 **5.** Mesa RA, Kiladjian JJ, Catalano JV, et al. SIMPLIFY-1: a phase III randomized trial of momelotinib versus ruxolitinib in Janus kinase inhibitor-naïve patients with myelofibrosis. *J Clin Oncol*. 2017;35(34):3844-3850. doi:10.1200/JCO.2017.73.4418 **6.** Gupta V, Oh S, Devos T, et al. Momelotinib vs. ruxolitinib in myelofibrosis patient subgroups by baseline hemoglobin levels in the SIMPLIFY-1 trial. *Leuk Lymphoma*. 2024;65(7):965-977. doi:10.1080/10428194.2024.2328800 **7.** Palandri F, O'Connell C, Vachhani P, et al. Survival impact and kinetics of hemoglobin improvement with momelotinib in patients with myelofibrosis and moderate to severe anemia: post hoc analyses of SIMPLIFY-1 and MOMENTUM. Poster presented at the European Hematology Association 2025 Congress, Milan, Italy, June 12-15, 2025. Poster PF828. **8.** Palandri F, Schaap NPM, Rey J, et al. Impact of dual spleen response and transfusion independence on survival in JAK inhibitor-naive patients with myelofibrosis and anemia treated with momelotinib: a subgroup analysis of SIMPLIFY-1. Poster presented at the European Hematology Association 2025 Congress, Milan, Italy, June 12-15, 2025. Poster PS1829. **9.** Gupta V, Oh S, Devos T, et al. Momelotinib vs. ruxolitinib in myelofibrosis patient subgroups by baseline hemoglobin levels in the SIMPLIFY-1 trial. Supplement. *Leuk Lymphoma*. 2024;65(7):965-977. doi:10.1080/10428194.2024.2328800 **10.** Data on file, GSK.

Ojjaara (momelotinib)

Start your appropriate patients on a treatment approved for myelofibrosis with anemia[1]

Explore efficacy data for OJJAARA, studied in JAKi-naïve & JAKi-experienced patients at OJJAARAhcp.com

Spleen Volume Reduction[1]
See the data ▸

Total Symptom Score[1]
See the data ▸

Transfusion Independence[6]
Post hoc analysis.
Results are descriptive.
See the data ▸

Safety
See the data ▸

Not an actual patient.

INDICATION

OJJAARA is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

IMPORTANT SAFETY INFORMATION

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Please see additional Important Safety Information throughout and on pages 19-20 and accompanying full Prescribing Information.

PMUS-MMLLBND260025 April 2026
Produced in USA.
Digital File: SIMPLIFY-1 Core Summary Brochure

Ojjaara (momelotinib) | GSK