MOMENTUM trial data for JAKi-experienced patients

OJJAARA for myelofibrosis (MF) with anemia

Multifaceted disease management starts here

Take on multiple aspects of myelofibrosis

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

In JAKi-experienced patients, OJJAARA was assessed for:

- Total Symptom Score Reduction
- Spleen Volume Reduction
- Transfusion Independence

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

Not an actual patient.

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

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

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 16-17 and accompanying full Prescribing Information.

Learn about a patient who may benefit from OJJAARA

Gloria
Age 73

Not an actual patient.

Initial treatment:
Ruxolitinib

Comorbidities: N/A

Current diagnosis:
High-risk primary MF with moderate anemia

Current treatment:
Reduced-dose ruxolitinib, ESA

BMI: 20

Anemia status:
Moderate

Spleen size:
6 cm below LCM

Transplant eligible:
Not eligible

DIPSS* score:
5 (High: >65 years; Hb <10 g/dL; WBC >25; circulating blasts ≥1%)

Gloria's anemia and thrombocytopenia prompted a reduction in her treatment dose, but her hemoglobin levels are still decreasing

About Gloria's case:

- Eighteen months ago, Gloria was diagnosed with primary myelofibrosis and was started on JAK inhibitor therapy to address her splenomegaly
- At a follow-up appointment, Gloria mentioned worsening fatigue and dyspnea on exertion. A CBC panel revealed she was moderately anemic with mild thrombocytopenia
- Her doctor decided to reduce the JAK inhibitor therapy dose and started her on ESA
- After 2 months of treatment, Gloria's splenomegaly worsened, and her anemia remained unchanged
- **Gloria's doctor is looking at alternate treatment options to help address her worsening symptomatic myelofibrosis with anemia**

About Gloria's life:

Gloria, a retired nurse in Florida, enjoys gardening and sharing birdwatching tips with her grandchildren. She once loved traveling to spot Florida's diverse birdlife but now stays closer to home due to her symptoms.

BMI=body mass index; CBC=complete blood count; DIPSS=Dynamic International Prognostic Scoring System; ESA=erythropoiesis-stimulating agents; Hb=hemoglobin; LCM=left costal margin; WBC=white blood count.

*In the DIPSS prognostic model, constitutional symptoms include weight loss, fever, and night sweats.[3]

Would you consider starting this patient on OJJAARA?

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

Hepatitis B Reactivation

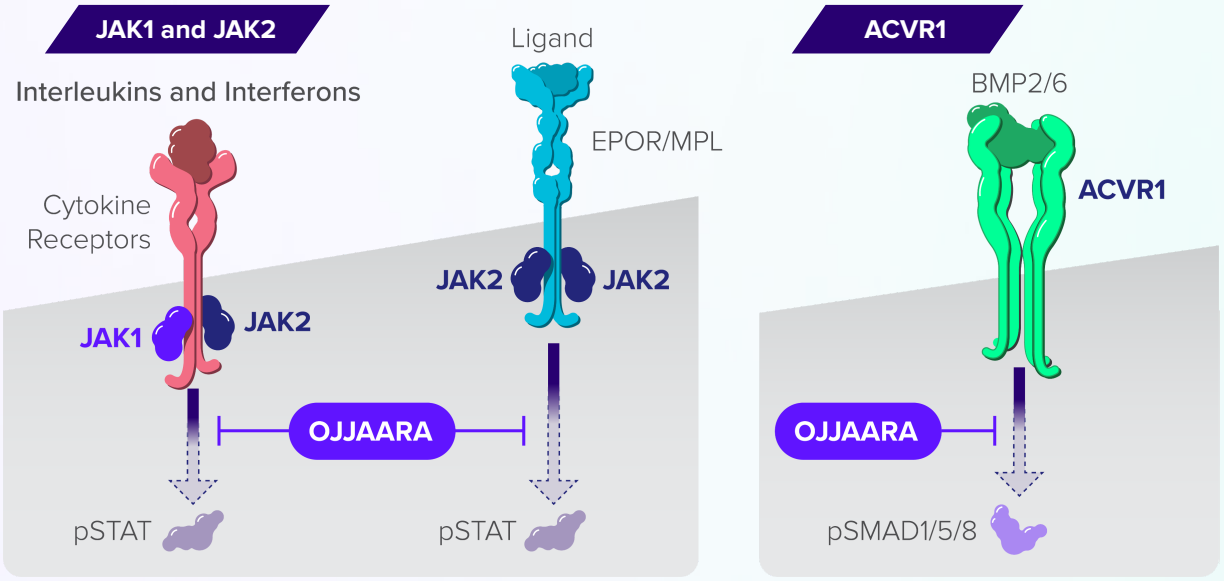
- Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine transaminase (ALT) or aspartate transaminase (AST), have been reported in patients with chronic hepatitis B virus (HBV) infection taking Janus Kinase (JAK) inhibitors, including OJJAARA. The effect of 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 16-17 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 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

MOMENTUM: Head-to-head trial evaluating OJJAARA vs danazol[1,4]

JAKi-Experienced Patients With Myelofibrosis Who Were Symptomatic and Anemic (N=195)*

MOMENTUM was a double-blind, 2:1 randomized, active-controlled phase 3 trial in 195 symptomatic and anemic patients with primary myelofibrosis, post-polycythemia vera (PV) myelofibrosis, or post-essential thrombocythemia (ET) myelofibrosis who had baseline splenomegaly†, minimum platelet count of 25 × 10^9/L, and were previously treated with an approved JAKi therapy. Patients receiving JAKi therapy at screening tapered therapy over more than 1 week, then completed at least 2 weeks of no treatment, starting at least 7 days before baseline assessments.

Patients were treated with OJJAARA 200 mg once daily or danazol 300 mg twice daily for 24 weeks. Upon completion of the double-blind treatment phase, all patients were eligible to receive OJJAARA during the open-label extended treatment phase.

Primary Endpoint:

- Total symptom score (TSS) response rate‡ (≥50% reduction) (superiority)

Select Key Secondary Endpoints:

- Transfusion independence (TI) rate§ (noninferiority)
- Rate of no transfusions‖ (superiority)
- Spleen volume reduction (SVR) response rate¶ (≥35%) (superiority)

Baseline Patient Characteristics

- Median age was 71 years (range 38 to 86 years)
- 79% were ≥65 years of age
- 63% were male, 37% female
- 81% were White, 9% were Asian, 2% were Black, and 6% were Hispanic or Latino
- 64% had primary MF, 19% had post-PV MF, and 17% had post-ET MF
- 5% had intermediate-1 risk, 57% had intermediate-2 risk, and 35% had high-risk disease#
- 79% of patients received RBC transfusions within 8 weeks prior to treatment
- 13% of OJJAARA patients and 15% of danazol patients were transfusion independent**
- Median Hb was 8 g/dL
- Median platelet count was 96 × 10^9/L (range 24 × 10^9/L to 733 × 10^9/L)
- Median palpable spleen length was 11 cm below the LCM
- Median central spleen volume (MRI or CT) was 2105 cm^3 (range 609 cm^3 to 9717 cm^3)
- Mean TSS (MFSAF v4.0) was 28 for patients taking OJJAARA and 26 for danazol patients

CT=computed tomography; MRI=magnetic resonance imaging; RBC=red blood cell.

*JAKi-experienced, defined as previously treated with an approved JAKi for ≥90 days or ≥28 days if therapy was complicated by ≥4 units of RBCs transfused in 8 weeks, or Grade 3 or 4 adverse events of thrombocytopenia, anemia, or hematoma. Symptomatic and anemic, defined as a Myelofibrosis Symptom Assessment Form (MFSAF) v4.0 TSS of ≥10 at screening, and Hb <10 g/dL, respectively.[4]

†Baseline splenomegaly, defined as a palpable spleen of ≥5 cm below the LCM or volume of ≥450 cm^3 on imaging.[4]

‡TSS response rate at Week 24 was defined as the proportion of patients who achieved ≥50% TSS reduction over the 28 days immediately prior compared with their own baseline score. TSS was measured using the MFSAF 4.0.[1,4]

§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.[1]

‖Rate of no transfusions at Week 24 was defined as the proportion of patients with no transfusions during the 24-week treatment period.[1]

¶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.[1,4]

#As defined by the DIPSS or International Prognostic Scoring System (IPSS) for myelofibrosis.[1]

**TI at baseline, defined as no RBC transfusions in the 12 weeks before the first dose and Hb ≥8 g/dL.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Hepatotoxicity

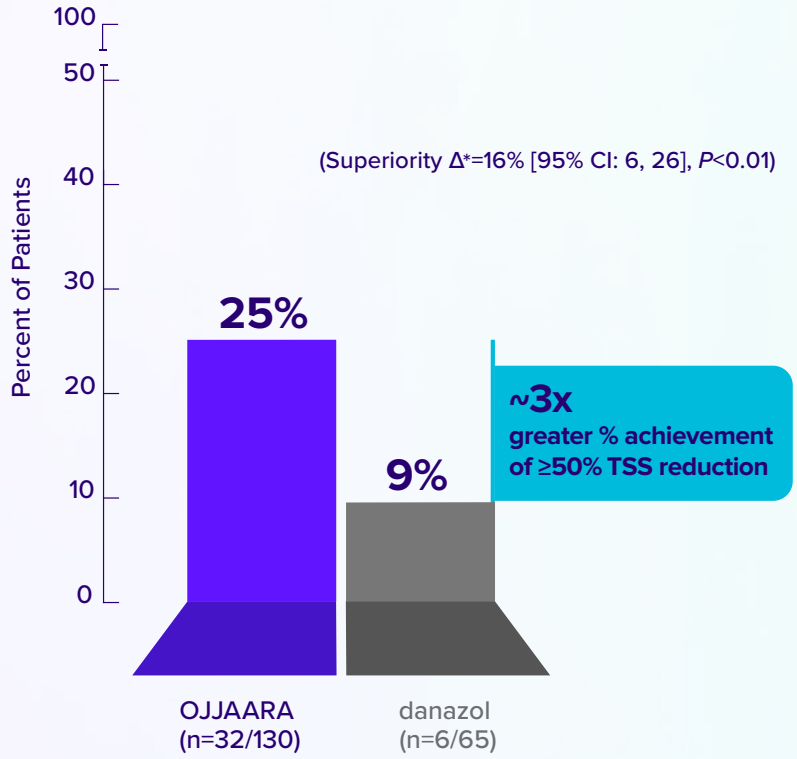
- Two of the 993 patients with MF who received at least one dose of OJJAARA in clinical trials experienced reversible drug-induced liver injury. Overall, new or worsening elevations of ALT and AST (all grades) occurred in 23% and 24%, respectively, of patients treated with OJJAARA; Grade 3 and 4 transaminase 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 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

25% of patients achieved a TSS reduction of ≥50% at Week 24 with OJJAARA[1]

Primary Endpoint: Rate of TSS Reduction of ≥50% From Baseline at Week 24



Symptoms were measured using the MFSAF v4.0 diary. The MFSAF v4.0 patient diary, completed throughout the randomized treatment period, captured the core symptoms of myelofibrosis:

- Fatigue, night sweats, itching, abdominal discomfort, pain under ribs on left side, feeling of fullness after beginning to eat, and bone pain
- For each item, symptom scores, ranging from 0 (absent) to 10 (worst imaginable), were added to create a daily TSS (maximum score of 70)

CI=confidence interval.
*Analysis stratified by baseline MFSAF v4.0 TSS (<22 vs ≥22).

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.

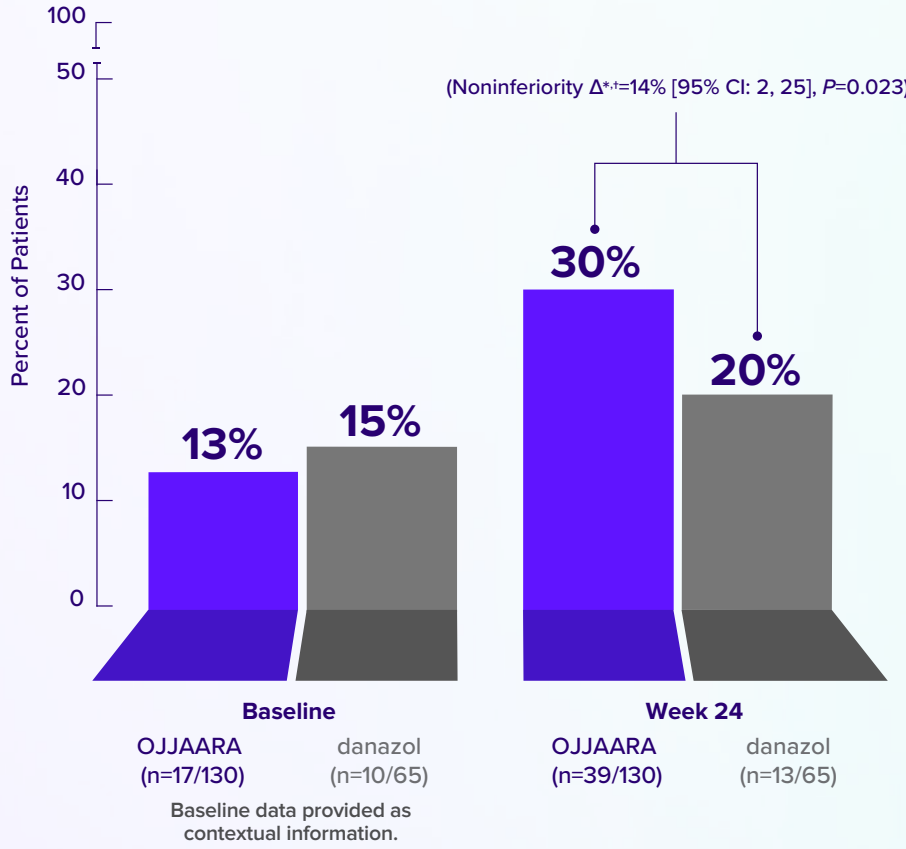
Please see additional Important Safety Information throughout and on pages 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

30% of patients achieved TI with OJJAARA at Week 24[1,4]

TI rate with OJJAARA was statistically noninferior to danazol.

Secondary Endpoint: Rate of TI at Week 24 (No Transfusion or Hb <8 g/dL Between Weeks 12 and 24)



*Analysis stratified by baseline red blood cell or whole blood units transfused in the 8-week period before randomization (0, 1-4, ≥5 units).
†Noninferiority difference between OJJAARA response rate and 80% of danazol response rate.

IMPORTANT SAFETY INFORMATION (cont'd)

Severe Cutaneous Adverse Reactions (SCARs)

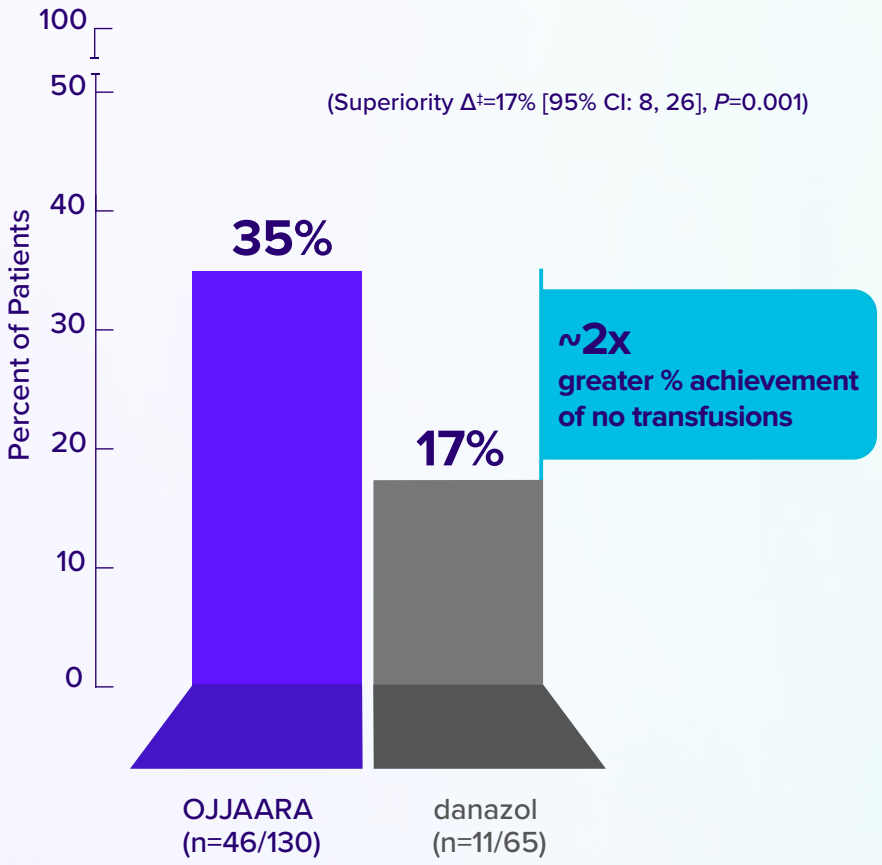
- Severe cutaneous adverse reactions (SCARs), including toxic epidermal necrolysis (TEN), have been observed in some patients treated with OJJAARA.
- If signs or symptoms of SCARs occur, interrupt OJJAARA until the etiology of the reaction has been determined. Consider early consultation with a dermatologist 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 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

35% of patients achieved no transfusions with OJJAARA[1]

Secondary Endpoint: Rate of No Transfusions*,† (During the 24-Week Treatment Period)



*Least squares means and difference are reported.
†Eight patients treated with OJJAARA and 3 patients treated with danazol had no transfusion, but discontinued treatment prior to Week 24.
‡Analysis stratified by baseline red blood cell or whole blood units transfused in the 8-week period before randomization (0, 1-4, ≥5 units).

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 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Post hoc data: Hemoglobin response by baseline anemia status in patients taking OJJAARA[1,5]*

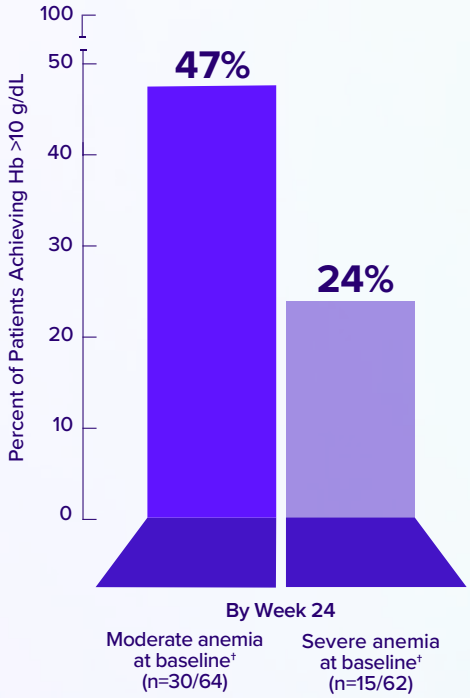
These are post hoc subset data in patients who had Hb <10 g/dL at baseline. These data are not included in the USPI for OJJAARA.

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



*Treatment 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) times to first Hb >10 g/dL were:

- Moderate anemia at baseline: 0.5 (0.3-4.6) months
- Severe anemia at baseline: 0.5 (0.5-5.6) months

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

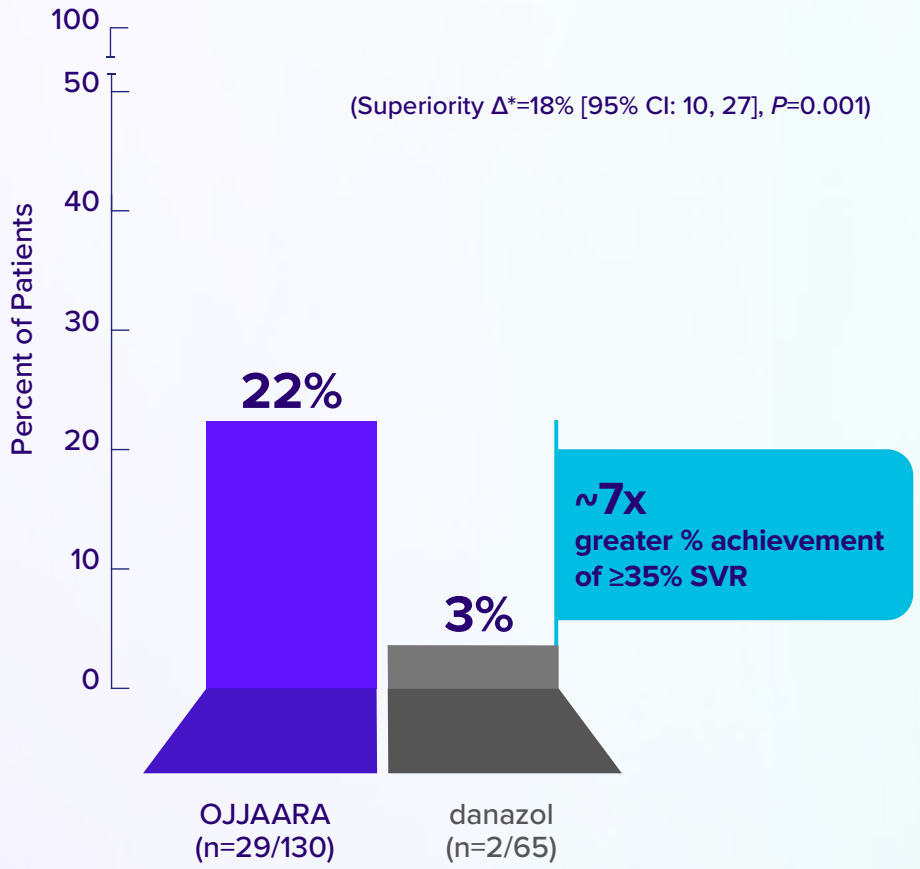
- Another JAK inhibitor increased the risk of lymphoma and other malignancies excluding nonmelanoma skin cancer (NMSC) (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Current or past smokers were at increased risk.

Please see additional Important Safety Information throughout and on pages 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

22% of patients achieved a spleen volume reduction of ≥35% with OJJAARA[1]

Secondary Endpoint: Rate of SVR ≥35% From Baseline at Week 24



*Analysis stratified by baseline palpable spleen length below the left costal margin (<12 vs ≥12 cm).

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.

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 16-17 and accompanying full Prescribing Information.

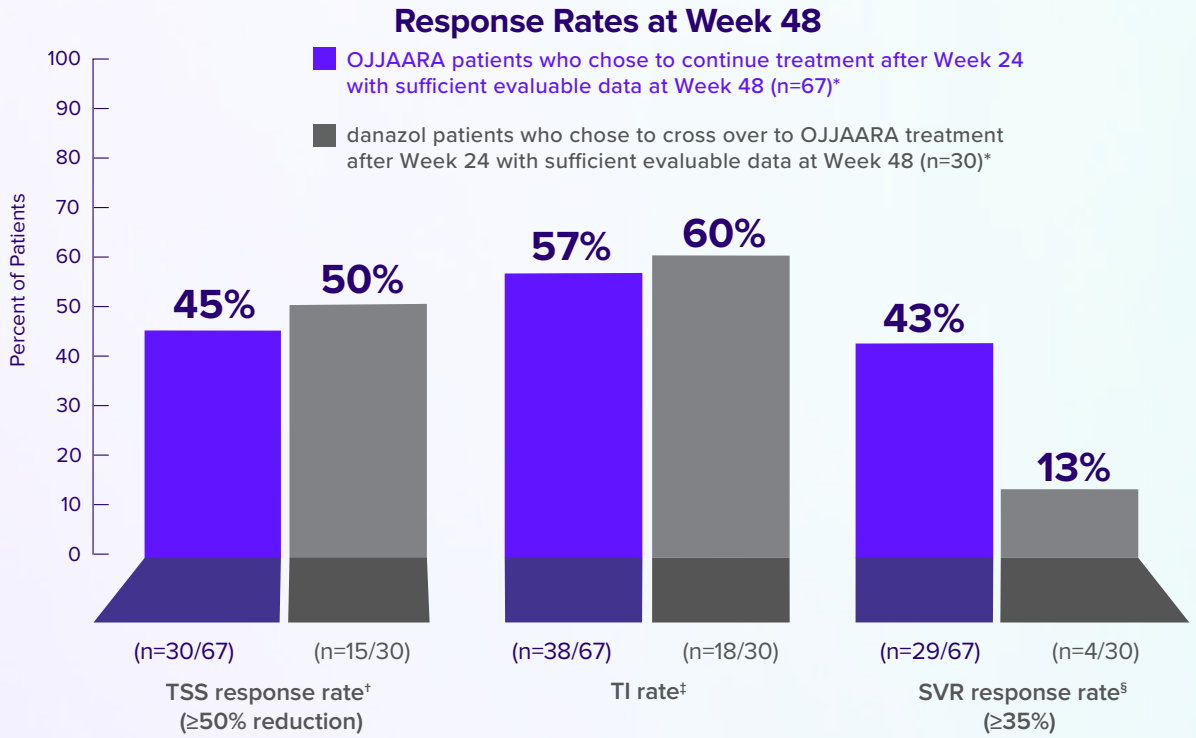
Ojjaara (momelotinib)

Post hoc data: TSS reduction, TI, and SVR at Week 48 in patients who received open-label OJJAARA[6]

These analyses were based upon data from the open-label extension (OLE) period (Week 24 to Week 48). These data are not included in the USPI for OJJAARA.

Limitations:

- There is potential for enrichment of data in this population due to inherent biases of the open-label crossover design, since patients who did not tolerate the drug or did not respond may not have enrolled in the open-label phase
- Data were missing for patients who discontinued or did not complete the Week 48 visit, excluding them from the denominator in these observational analyses. The impact of patients with missing Week 48 data is unknown, but there is potential for enrichment of the data
- Due to the open-label crossover design, there was no randomization, no blinding, and no comparator arm from Week 24 to Week 48
- These descriptive data are not adjusted for multiplicity and not powered to show statistical significance



*Percentages were based on number of patients who entered the open-label period and provided sufficient data for evaluation for all endpoints at Week 48; this was 67/93 patients in the OJJAARA group who chose to continue treatment and 30/41 patients in the danazol group who chose to cross over to OJJAARA.

†TSS response at Week 48, defined as reaching ≥50% mean reduction compared with baseline over the last 28 days before the end of Week 48 (the MFSAF was administered daily for 1 week every month during the open-label period).

‡TI rate at Week 48, defined as the proportion of patients with no transfusions or Hb <8 g/dL in the last 12 weeks of treatment.

§SVR response rate at Week 48, defined as the proportion of patients who had ≥35% reduction in spleen volume from baseline on imaging at Week 48.

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.

Please see additional Important Safety Information throughout and on pages 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Post hoc data: In patients taking OJJAARA who did not respond at Week 24, and continued open-label OJJAARA, there were some newly reported responders for TSS reduction, TI, and SVR at Week 48[6,7]

These analyses were based upon data from the open-label extension (OLE) period (Week 24 to Week 48). These data are not included in the USPI for OJJAARA.

Limitations:

- There is potential for enrichment of data in this population due to inherent biases of the open-label crossover design, since patients who did not tolerate the drug or did not respond may not have enrolled in the open-label phase
- Data were missing for patients who discontinued or did not complete the Week 48 visit, excluding them from the denominator in these observational analyses. The impact of patients with missing Week 48 data is unknown, but there is potential for enrichment of the data
- Due to the open-label crossover design, there was no randomization, no blinding, and no comparator arm from Week 24 to Week 48
- These descriptive data are not adjusted for multiplicity and not powered to show statistical significance

Percentage of Week 24 nonresponders in the OJJAARA group who achieved response at Week 48

TSS Reduction*	TI†	SVR‡
29% (n=12/42)	24% (n=8/33)	23% (n=10/43)

*TSS response at Week 48, defined as reaching ≥50% mean reduction compared with baseline over the last 28 days before the end of Week 48 (the MFSAF was administered daily for 1 week every month during the open-label period).
†TI rate at Week 48, defined as the proportion of patients with no transfusions or Hb <8 g/dL in the last 12 weeks of treatment.
‡SVR response rate at Week 48, defined as the proportion of patients who had ≥35% reduction in spleen volume from baseline on imaging at Week 48.

IMPORTANT SAFETY INFORMATION (cont'd)

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 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Well-characterized safety profile in JAKi-experienced patients[1]

Adverse Reactions Occurring in ≥5% of Patients Receiving OJJAARA During Randomized Treatment in MOMENTUM

	OJJAARA (n=130)		danazol* (n=65)	
Adverse Reactions	All Grades† (%)	Grade ≥3 (%)	All Grades (%)	Grade ≥3 (%)
Thrombocytopenia‡	28	22	17	12
Diarrhea‡	22	0	9	2
Hemorrhage‡	22	2	18	8
Fatigue‡	21	2	20	5
Nausea‡	16	2	9	3
Bacterial infection‡,§	15	8	18	8
Abdominal pain‡	13	1	18	3
Viral infection‡,§	12	5	3	0
Pruritus‡	11	2	11	0
Elevated liver enzymes‡	10	2	9	3
Pyrexia‡	10	2	8	0
Cough‡	8	0	5	0
Paresthesia‡	8	1	2	0
Dizziness‡	8	2	2	0
Vomiting‡	8	1	0	0
Rash‡	6	0	11	0
Renal and urinary tract infection‡,§	6	2	11	5
Arrhythmia‡	5	1	6	2
Neutropenia	5	5	3	3

*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.5.
‡Grouped term includes other related terms.
§Excludes opportunistic infections.

Please see additional Important Safety Information throughout and on pages 16-17 and accompanying full Prescribing Information.

Ojjaara (momelotinib)

Well-characterized safety profile in JAKi-experienced patients[1] (cont'd)

Serious adverse reactions

Occurred in 35% of patients who received OJJAARA during the randomized treatment period of the MOMENTUM trial; the most common serious adverse reactions (≥2%) included bacterial infection (8%), viral infection (5%), hemorrhage (4%), acute kidney injury (3%), pneumonia (3%), pyrexia (3%), thrombosis (3%), syncope (2%), thrombocytopenia (2%), and renal and urinary tract infection (2%). Fatal adverse reactions occurred in 12% of patients who received OJJAARA; the most common (≥2%) fatal adverse reaction was viral infection (5%).

Permanent discontinuation of OJJAARA due to an adverse reaction

Occurred in 18% of patients during the randomized treatment period of the MOMENTUM trial. Adverse reactions that resulted in permanent discontinuation (≥2%) included viral infection (2%) and thrombocytopenia (2%).

Dosage reduction or treatment interruption of OJJAARA due to an adverse reaction

Occurred in 34% of patients. Adverse reactions requiring dosage reduction and/or treatment interruption (≥2%) included thrombocytopenia (13%), bacterial infection (2%), diarrhea (2%), and neutropenia (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.

The safety profile for OJJAARA during the open-label extension period (Weeks 24 to 48) was consistent with what was observed during the randomized treatment[6]

These open-label extension data are not included in the USPI for OJJAARA

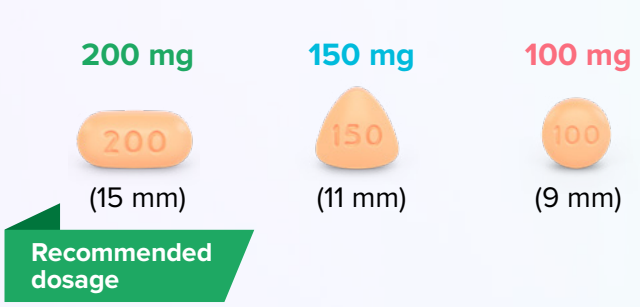
Dosage and Administration: One pill, once daily for patients who have MF with anemia[1]

- 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:
  - CBC with platelets
  - Hepatic panel

OJJAARA is available in 3 dosage strengths[1,8]:



Pill sizes are smaller than a dime.

(17.91 mm)

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)

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.

Please see additional Important Safety Information throughout and on pages 16-17 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.
†May reinitiate treatment at 100 mg if previously dosed at 100 mg.
‡If baseline >2 × ULN.
§If baseline >1.5 × ULN.
‖Graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE).

Discontinue OJJAARA in patients unable to tolerate 100 mg once daily

Please see additional Important Safety Information throughout and on pages 16-17 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.

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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.

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 for OJJAARA.

References: 1. OJJAARA (momelotinib). Prescribing Information. GSK; 2025. **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.** 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 **4.** Verstovsek S, Gerds AT, Vannucchi AM, et al; MOMENTUM Study Investigators. Momelotinib versus danazol in symptomatic patients with anaemia and myelofibrosis (MOMENTUM): results from an international, double-blind, randomised, controlled, phase 3 study. *Lancet*. 2023;401(10373):269-280. doi:10.1016/S0140-6736(22)02036-0 **5.** 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: European Hematology Association 2025 Congress; June 12-15, 2025; Milan, Italy. Poster PF828. **6.** Gerds AT, Verstovsek S, Vannucchi AM, et al. Momelotinib versus danazol in symptomatic patients with anaemia and myelofibrosis previously treated with a JAK inhibitor (MOMENTUM): an updated analysis of an international, double-blind, randomised phase 3 study. *Lancet Haematol*. 2023;10(9):e735-e746. doi:10.1016/S2352-3026(23)00174-6 **7.** Gerds AT, Verstovsek S, Vannucchi AM, et al. Momelotinib versus danazol in symptomatic patients with anaemia and myelofibrosis previously treated with a JAK inhibitor (MOMENTUM): an updated analysis of an international, double-blind, randomised phase 3 study. Supplement. *Lancet Haematol*. 2023;10(9):e735-e746. doi:10.1016/S2352-3026(23)00174-6 **8.** 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-experienced & JAKi-naïve patients at OJJAARAhcp.com

Total Symptom Score[1]
See the data ▸

Transfusion Independence[1]
See the data ▸

Spleen Volume Reduction[1]
See the data ▸

Safety
See the data ▸

Not an actual patient.

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