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

START WITH A TREATMENT APPROVED FOR MYELOFIBROSIS WITH ANEMIA[1]

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.

VIEW THE CLINICAL DATA INSIDE ▸▸

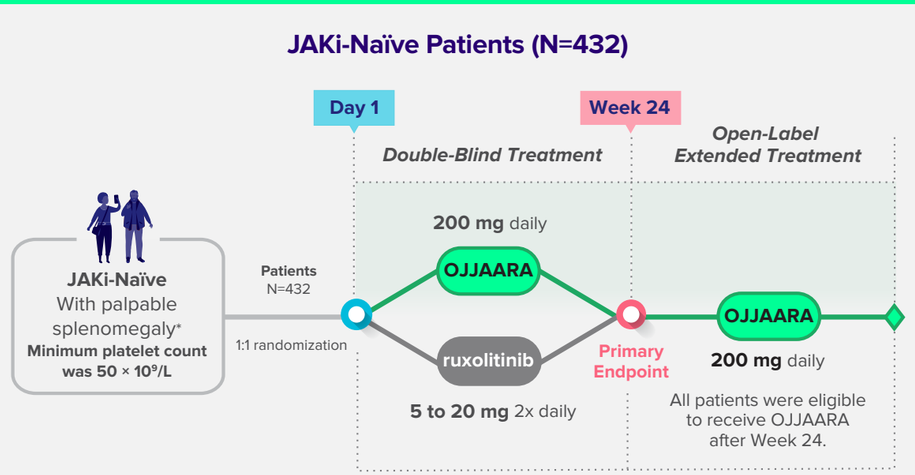
IMPORTANT SAFETY INFORMATION

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.

SIMPLIFY-1: OJJAARA was studied in a head-to-head myelofibrosis trial vs ruxolitinib[1,2]



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 myelofibrosis in SIMPLIFY-1 was based on spleen volume reduction (SVR) (≥35%)†

Additional post hoc analyses were conducted for two subsets of patients[3]:

- SVR (≥35%) response rate† (in patients with Hb 10 to <12 g/dL at baseline)
- Total symptom score (TSS) response rate‡ (≥50% reduction) and transfusion independence (TI) rate§ (in patients with Hb <10 g/dL and Hb 10 to <12 g/dL at baseline)

CT=computed tomography; Hb=hemoglobin; JAK=Janus kinase; JAKi=Janus kinase inhibitor; MRI=magnetic resonance imaging.
*Palpable splenomegaly ≥5 cm below the left costal margin.[2]
†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 defined as proportion of patients who achieved a ≥50% reduction from baseline. TSS was measured using the modified Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF) v2.0.[2]
§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.[3]

OJJAARA WAS ALSO STUDIED IN JAKi-EXPERIENCED PATIENTS. LEARN MORE AT OJJAARAHCP.COM

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.

Baseline patient characteristics[1,4]

Characteristic	Patients With Baseline Hb <10 g/dL (n=181)	Patients With Baseline Hb 10 to <12 g/dL (n=142)
Median age, years (range)	68 (25 to 86)	66 (28 to 84)
≥65 years of age	67%	56%
Male, Female	59%, 41%	50%, 50%
White, Asian, Black, Hispanic or Latino	81%, 8%, 1%, 2%	84%, 7%, 1%, 4%
Primary MF, Post-PV MF, Post-ET MF	63%, 13%, 24%	59%, 20%, 20%
Intermediate-1 risk, Intermediate-2 risk, High-risk‖	4%, 25%, 71%	25%, 39%, 35%
Transfusion independent¶	29% in the OJJAARA treatment arm, 44% in the ruxolitinib treatment arm	90% in the OJJAARA treatment arm, 83% in the ruxolitinib treatment arm
Median Hb, g/dL	8.8	10.8
Median platelet count, × 10⁹/L (range)	193 (54 to 2865)	269 (67 to 1065)
Median palpable spleen length	12 cm below the left costal margin	12 cm below the left costal margin
Median spleen volume, MRI or CT, cm^3 (range)	1843 (352 to 9022)	2018 (206 to 6288)

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 transfusions or Hb levels of <8 g/dL in the last 12 weeks before randomization.[3]

IMPORTANT SAFETY INFORMATION (cont'd)

Thrombocytopenia and Neutropenia

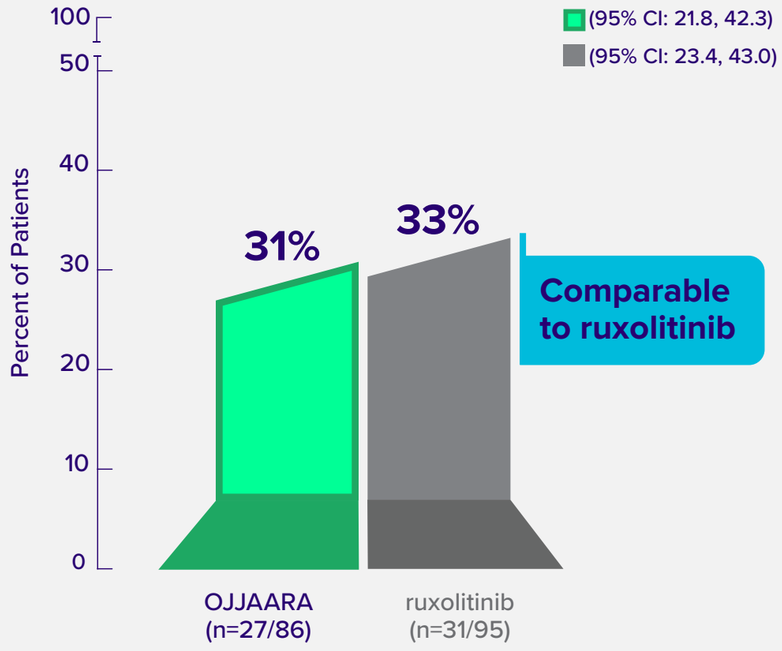
- New or worsening thrombocytopenia, with platelet count less than 50 × 10⁹/L, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than 50 × 10⁹/L.
- Severe neutropenia, absolute neutrophil count (ANC) less than 0.5 × 10⁹/L, was observed in 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.

Ojjaara (momelotinib)

31% of patients achieved SVR ≥35% with OJJAARA in patients with **Hb <10 g/dL**[1]

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



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.

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.

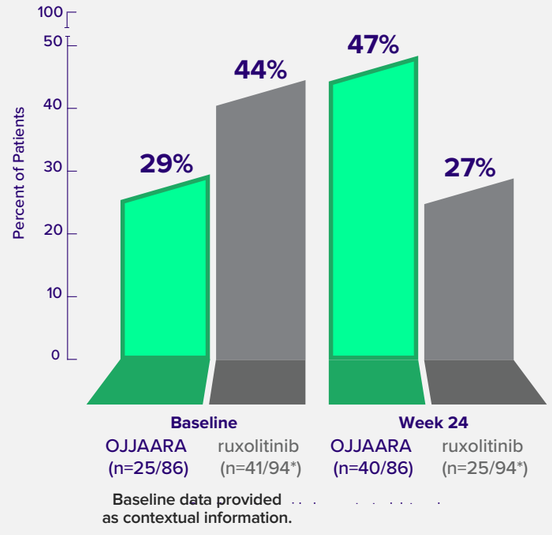
Post hoc data: Rate of TI in patients with **Hb <10 g/dL** treated with OJJAARA or ruxolitinib[3]

An additional post hoc subset analysis of TI was completed in SIMPLIFY-1 for patients who had Hb <10 g/dL at baseline (n=180). These subset data are not included in the USPI for OJJAARA.

Limitations:

- These post hoc subset data are not adjusted for multiplicity and are not powered to detect treatment differences
- Any differences in baseline characteristics of the subset are not accounted for in these data
- Results are for descriptive use only and may present chance findings

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)

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.

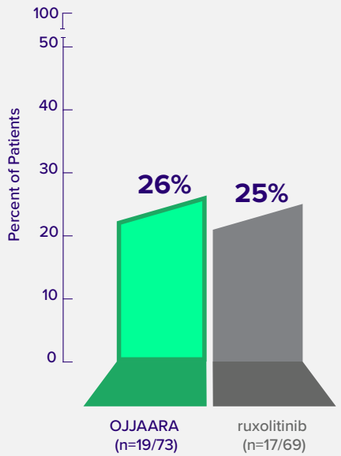
Ojjaara (momelotinib)

Post hoc data: Rate of SVR ≥35% and TSS reduction ≥50% in patients with **Hb 10 to <12 g/dL** treated with OJJAARA or ruxolitinib[3]

Additional post hoc subset analyses of SVR and TSS reduction were completed in SIMPLIFY-1 for patients who had Hb 10 to <12 g/dL at baseline (n=142). These subset data are not included in the USPI for OJJAARA.

Limitations:
- These post hoc subset data are not adjusted for multiplicity and are not powered to detect treatment differences
- Any differences in baseline characteristics of the subset are not accounted for in these data
- Results are for descriptive use only and may present chance findings

Post Hoc Subset Analysis of Patients With Hb 10 to <12 g/dL at Baseline:
Rate of SVR ≥35% From Baseline at Week 24



In the Hb 10 to <12 g/dL subset, the percentage of patients who achieved TSS reduction of ≥50% at Week 24 was 35% for OJJAARA and 45% for ruxolitinib

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.

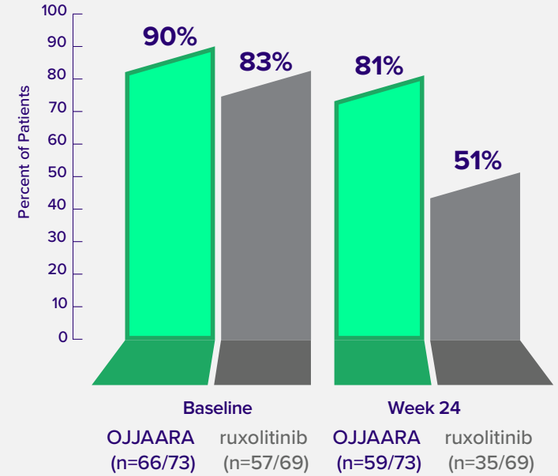
Please see additional Important Safety Information throughout and on pages 16-17 and accompanying full Prescribing Information.

Post hoc data: Rate of TI in patients with **Hb 10 to <12 g/dL** treated with OJJAARA or ruxolitinib[3]

Additional post hoc subset analysis of TI was completed in SIMPLIFY-1 for patients who had Hb 10 to <12 g/dL at baseline (n=142). These subset data are not included in the USPI for OJJAARA.

Limitations:
- These post hoc subset data are not adjusted for multiplicity and are not powered to detect treatment differences
- Any differences in baseline characteristics of the subset are not accounted for in these data
- Results are for descriptive use only and may present chance findings

Post Hoc Subset Analysis of Patients With Hb 10 to <12 g/dL at Baseline:
Rate of TI at Week 24



Baseline data provided as contextual information.

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.

Ojjaara (momelotinib)

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

Adverse Reactions Occurring in ≥10% 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
Peripheral edema	11	0	8	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%).

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

Safety profile in JAKi-naïve patients with **Hb 10 to <12 g/dL** at baseline[4]

These subset data are not included in the USPI for OJJAARA.

Adverse Reactions Occurring in ≥10% of Anemic Patients (Hb 10 to <12 g/dL) Receiving OJJAARA During Randomized Treatment in SIMPLIFY-1

	OJJAARA (n=74) Baseline Hb 10 to <12 g/dL		ruxolitinib* (n=68) Baseline Hb 10 to <12 g/dL	
Adverse Reactions	All Grades† (%)	Grade ≥3 (%)	All Grades (%)	Grade ≥3 (%)
Fatigue‡	22	1	21	3
Hemorrhage‡	22	1	16	3
Thrombocytopenia‡	22	5	31	4
Dizziness‡	19	0	13	0
Diarrhea‡	18	5	19	1
Headache‡	16	0	28	0
Bacterial infection‡,§	14	3	9	1
Arthralgia	12	0	10	0
Abdominal pain‡	11	1	21	0
Erythema	11	0	1	0
Nausea‡	11	1	7	0
Vomiting‡	11	1	4	0

Additional adverse reactions occurring in ≥5% to <10% of anemic patients (Hb 10 to <12 g/dL) receiving OJJAARA during randomized treatment in SIMPLIFY-1 included contusion (9%), renal and urinary tract infection‡,§ (9%), cough‡ (8%), dyspnea (8%), flushing (8%), paresthesia‡ (8%), constipation (7%), decreased appetite (7%), elevated liver enzymes‡ (7%), pruritus‡ (7%), asthenia (5%), hepatic injury (5%), neutropenia (5%),pyrexia‡ (5%), and rash‡ (5%).

Additional Grade ≥3 adverse reactions occurring in anemic patients (Hb 10 to <12 g/dL) receiving OJJAARA included neutropenia (4%), contusion (1%), renal and urinary tract infection (1%), pyrexia (1%), and rash (1%).

Serious adverse reactions

Occurred in 15% of the anemic patients (Hb 10 to <12 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 (4%), diarrhea (4%), and renal and urinary tract infection (3%).

Permanent discontinuation of OJJAARA due to an adverse reaction

Occurred in 4% of the anemic patients (Hb 10 to <12 g/dL) during the randomized treatment period of the SIMPLIFY-1 trial. Adverse reactions that resulted in permanent discontinuation of OJJAARA included dizziness (1%), rash (1%), and thrombocytopenia (1%).

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

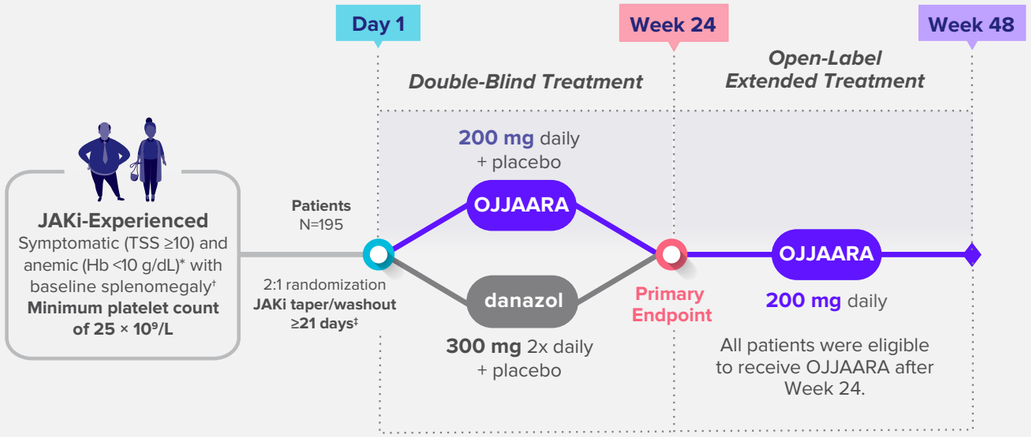
Occurred in 11% of patients. Adverse reactions requiring dosage reduction and/or treatment interruption (≥2%) were thrombocytopenia (5%), elevated liver enzymes (4%), diarrhea (3%), and hepatic injury (3%).

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

Ojjaara (momelotinib)

MOMENTUM: Head-to-head trial evaluating OJJAARA vs danazol[1,5]

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



MOMENTUM was a double-blind, randomized, active-controlled Phase 3 trial in 195 symptomatic and anemic patients with primary myelofibrosis, post-PV myelofibrosis, or post-ET myelofibrosis who had been previously treated with an approved JAK inhibitor therapy.

Primary Endpoint:	Select Key Secondary Endpoints:
TSS response rate[§] (≥50% reduction) (superiority)	TI rate[‖] (noninferiority) Rate of no transfusions[¶] (superiority) SVR response rate[#] (≥35%) (superiority)

*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.[5]

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

‡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.[5]

§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 v4.0.[1,5]

‖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.[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.[1,5]

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.

MOMENTUM: Baseline patient characteristics[1]

Characteristic	Overall Population (N=195)
Median age, years (range)	71 (38 to 86)
≥65 years of age	79%
Male, Female	63%, 37%
White, Asian, Black, Hispanic or Latino	81%, 9%, 2%, 6%
Primary MF, Post-PV MF, Post-ET MF	64%, 19%, 17%
Intermediate-1 risk, Intermediate-2 risk, High-risk**	5%, 57%, 35%
Received RBC transfusions within 8 weeks prior to treatment	79% (Median of 4 RBC units; IQR: 1-6)
Transfusion independent††	13% in OJJAARA treatment arm, 15% in danazol treatment arm
Median Hb, g/dL	8
Median platelet count, × 10^9/L (range)	96 (24 to 733)
Median palpable spleen length	11 cm below the left costal margin
Median central spleen volume, MRI or CT, cm^3 (range)	2105 (609 to 9717)
Mean TSS, MFSAF v4.0	28 in OJJAARA treatment arm, 26 in danazol treatment arm

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

IQR=interquartile range.

**As defined by the Dynamic International Prognostic Scoring System for Myelofibrosis.

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

IMPORTANT SAFETY INFORMATION (cont'd)

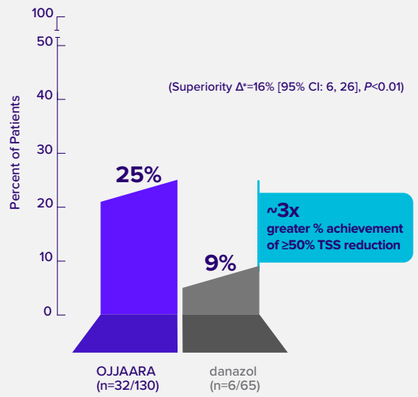
Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors

- 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.

Ojjaara (momelotinib)

Efficacy of OJJAARA vs danazol

Primary Endpoint: Rate of TSS Reduction of ≥50% From Baseline at Week 24[1]

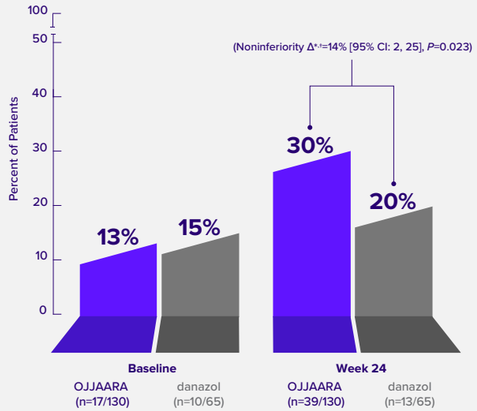


- **Achievement of ≥50% TSS reduction was almost 3x greater with OJJAARA vs danazol**

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)

Secondary Endpoint: Rate of TI at Week 24 (No Transfusion or Hb <8 g/dL Between Weeks 12 and 24)[1,5]



Baseline data provided as contextual information.

- **30% of patients achieved TI with OJJAARA at Week 24**
- **TI rate with OJJAARA was statistically noninferior to danazol**

Additional secondary endpoint data[1]

Achievement of no transfusions was about 2x greater with OJJAARA vs danazol

- **Secondary Endpoint: 35%** (n=46/130) of patients treated with OJJAARA received no transfusions[‡,§] during the 24-week treatment period vs **17%** (n=11/65) with danazol (superiority Δ*=17% [95% CI: 8, 26], *P*=0.001)

Achievement of ≥35% SVR was about 7x greater with OJJAARA vs danazol

- **Secondary Endpoint: 22%** (n=29/130) of patients treated with OJJAARA achieved ≥35% SVR vs **3%** (2/65) with danazol from baseline at Week 24 (superiority Δ*=18% [95% CI: 10, 27], *P*=0.001)

*Analyses stratified by baseline MFSAF v4.0 TSS (<22 vs ≥22), baseline palpable spleen length below the left costal margin (<12 vs ≥12 cm), and baseline RBC or whole blood units transfused in the 8-week period before randomization (0, 1-4, ≥5 units).[1]
†Noninferiority difference between OJJAARA response rate and 80% of danazol response rate.[1]
‡Least squares means and difference are reported.[1]
§Eight patients treated with OJJAARA and 3 patients treated with danazol had no transfusion, but discontinued treatment prior to Week 24.[1]

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.

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

Adverse Reactions Occurring in ≥10% 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

‖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 CTCAE v5.
#Grouped term includes other related terms.
**Excludes opportunistic infections.

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 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Ojjaara (momelotinib)

One pill, once daily for patients who have myelofibrosis with anemia[1]

In clinical trials, all patients started treatment with OJJAARA at the recommended dosage

ONE PILL, ONCE DAILY

- 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

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

See next page for information on dosage modifications due to hepatic impairment and adverse reactions.

Additional information on dosing from clinical trials with OJJAARA

In SIMPLIFY-1, patients were eligible to switch to open-label OJJAARA after 24 weeks (without tapering of the JAK inhibitor received during the randomization period).

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.
- 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.

Dosage modifications[1]

Dosage modification 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.

Dosage modification for adverse reactions

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

Thrombocytopenia

Baseline Platelet Count	Platelet Count	Dose Modification*
≥100 × 10^9/L	20 × 10^9/L to <50 × 10^9/L	• Reduce daily dose by 50 mg from the last given dose
	<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†
≥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†
<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)	Dose Modification*
<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 CTCAE.

Discontinue OJJAARA in patients unable to tolerate 100 mg once daily.

See Prescribing Information for information on drug interactions with Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors and Breast Cancer Resistance Protein (BCRP) Substrates.

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.

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.

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 accompanying full Prescribing Information.

References: 1. OJJAARA (momelotinib). Prescribing Information. GSK; 2023. **2.** 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 **3.** 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 **4.** Data on file, GSK. **5.** 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 **6.** Chifotides HT, Bose P, Verstovsek S. Momelotinib: an emerging treatment for myelofibrosis patients with anemia. *J Hematol Oncol.* 2022;15(1):7. doi:10.1186/s13045-021-01157-4

Ojjaara (momelotinib)

THE FIRST & ONLY FDA-APPROVED JAKi INDICATED SPECIFICALLY

FOR PATIENTS WHO HAVE MYELOFIBROSIS WITH ANEMIA[1,6]

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PMUS-MMLLBND240012 October 2024
Produced in USA.

File Name: GSK Leave Behind 1