VONJO®
(pacritinib) capsules

WHEN MYELOFIBROSIS PROGRESSES
AND COUNTS GO LOW,

IT'S TIME FOR VONJO[1]

VONJO is the first and only treatment specifically for adults with myelofibrosis (MF) and thrombocytopenia, indicated for patients with platelet counts <50 x 10^9/L, and studied in patients with platelet counts ≤100 x 10^9/L.*

***INDICATION:** VONJO is indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera [PPV] or post-essential thrombocythemia [PET]) MF with a platelet count below 50 × 10^9/L. This indication is approved under accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information

Contraindication

VONJO is contraindicated in patients concomitantly using strong CYP3A4 inhibitors or inducers.

Please see the Important Safety Information for VONJO throughout and the accompanying full Prescribing Information.

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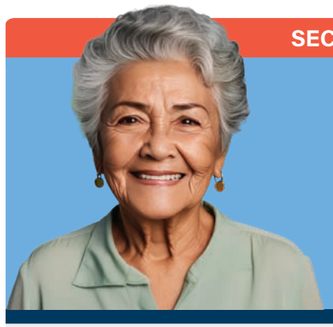
SECONDARY MF – ON RUXOLITINIB



Pam's PV has evolved to MF, and her platelet counts, symptoms, and spleen size are worsening

Pam AGE 75

Initial diagnosis:
Polycythemia vera (PV)
Baseline platelet count:
214 x 10^9/L
Initial treatment:
Cytoreductive phlebotomy and hydroxyurea 500 mg QD

Current diagnosis:
Intermediate/high-risk secondary MF (PPV)
Current treatment:
Ruxolitinib, 5 mg BID
Labs:
- Latest platelet count: 49 x 10^9/L
- Hemoglobin: 10.5 g/dL (transfusion independent)

Splenomegaly:
10 cm below LCM
Transplant eligible:
Yes but declined
DIPSS+ score*: 3

About Pam's case:

- At 68, she was diagnosed with PV and treated with weekly cytoreductive phlebotomy and hydroxyurea
- Despite successfully normalizing her hemoglobin, Pam eventually noticed new symptoms: feeling fatigued, abdominal discomfort, and complaining of unusual bruising
- Pam's doctor performed a bone marrow biopsy that showed fibrosis (Grade 2). She was informed that her PV had evolved to secondary MF (PPV) and her treatment was changed to ruxolitinib 10 mg BID
- After 2 years, there was a concerning drop in platelet counts, and her dose was reduced to 5 mg BID
- Her platelet counts continued to drop to 49 X 10^9/L on this lower dose[2]
- Despite being potentially eligible for a bone marrow transplant, as a nurse, Pam knows about the risks and comorbidities at her age, and her and her physician would prefer to manage her symptoms with a JAK inhibitor

About Pam's life:

Since diagnosis Pam has been determined not to let her MF define her and instead is focused on enjoying family life spoiling her grandchildren. She stays as physically active as possible not wanting to miss out on social events, but unfortunately growing fatigue is impacting this goal. She now depends more on her family for support, whether that's helping her get to appointments or just being there emotionally.

When there are dose reductions and platelets go low, **it's time for VONJO.**[1]

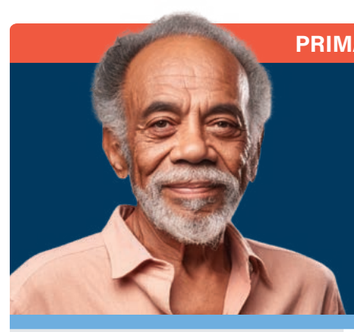
Important Safety Information (cont.)

Warnings and Precautions:

- **Hemorrhage:** Serious (11%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts <100 x 10^9/L. Serious (13%) and fatal (2%) hemorrhages have occurred in VONJO-treated patients with platelet counts <50 x 10^9/L. Grade ≥3 bleeding events (defined as requiring transfusion or invasive intervention) occurred in 15% of patients treated with VONJO compared to 7% of patients treated on the control arm. Due to hemorrhage, VONJO dose reductions, dose interruptions, or permanent discontinuations occurred in 3%, 3%, and 5% of patients, respectively.

This case study is a hypothetical patient provided for general medical education purposes only and is not to be used as a substitute for independent medical judgement for a specific patient's medical condition. The patient described represents a typical patient experience.
*DIPSS+ is used to stratify patients into 4 different risk groups: low risk (0 adverse points), intermediate-1 risk (1 adverse point), intermediate-2 risk (2-3 adverse points), and high risk (4-6 adverse points).[3]
BID=twice daily; DIPSS+=Dynamic International Prognostic Scoring System Plus; JAK=janus kinase; LCM=left costal margin; QD=once daily.

PRIMARY MF – ON RUXOLITINIB



Alan is on a lower dose of his current treatment due to thrombocytopenia, but his platelet counts keep dropping

Alan AGE 72

Initial diagnosis:
Intermediate/high-risk primary MF
Baseline platelet count:
110 x 10^9/L
Initial treatment:
Ruxolitinib, 15 mg BID

Current diagnosis:
Intermediate/high-risk primary MF with thrombocytopenia
Current treatment:
Ruxolitinib, 10 mg BID (dose lowered after 6 months)
Labs:
- Latest platelet count: 48 x 10^9/L
- Hemoglobin: 9.4 g/dL (transfusion independent)

Splenomegaly:
8 cm below LCM
Transplant eligible: No
DIPSS+ score: 3

About Alan's case:

- Started on ruxolitinib therapy (15 mg BID) 18 months ago
- Due to worsening thrombocytopenia and anemia, his dose was reduced to 10 mg BID; his doctor is considering lowering his dose again due to continued drop in platelet counts[2]
- Alan sought help for fatigue, pain under left ribs, and always feeling full; blood tests showed that his platelet counts continued to drop
- On his monthly lab work, his platelet counts were 90, 65, 74, 35, and most recently 48 (x 10^9/L)
- Alan worries he's not getting the most out of his current treatment

About Alan's life:

Alan spends most of his free time keeping his house and several acres in good shape but also enjoys taking the occasional fishing trip with friends to relax. After his wife Patty passed away a few years ago, he now depends on his 3 daughters to help him with doctor visits and medical needs. Despite several challenges and setbacks with his MF treatment, he's determined to stay in control of his health.

When signs of thrombocytopenia in a patient's MF start to show, **it's time for VONJO.**[1]

Important Safety Information (cont.)

Warnings and Precautions (cont.):

- **Hemorrhage (cont.):** Avoid use of VONJO in patients with active bleeding and hold VONJO 7 days prior to any planned surgical or invasive procedures. Assess platelet counts periodically, as clinically indicated. Manage hemorrhage using treatment interruption and medical intervention.

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RBC=red blood cell.

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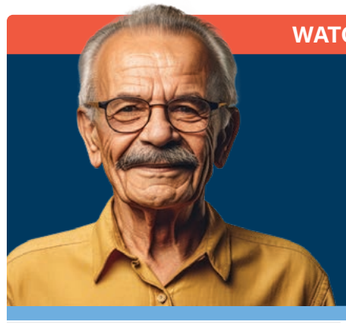
WATCH AND WAIT



After months of watchful waiting, Norman is seeing changes in his MF as his platelet counts and symptoms get worse

Norman AGE 77

Initial diagnosis:
Intermediate/high-risk primary MF
Baseline platelet count:
123 x 10^9/L
Initial treatment:
Watch and wait

Current diagnosis:
Thrombocytopenic MF
Current treatment:
N/A - watch and wait
Labs:
- Latest platelet count: 45 x 10^9/L
- Hemoglobin: 12 g/dL (transfusion independent)

Splenomegaly: No
Transplant eligible:
Yes but declined
DIPSS+ score: 2

About Norman's case:

- Norman was being monitored with watchful waiting since his MF was first diagnosed 12 months ago
- He was stable for the first 6 months, but recently, his platelet counts have declined significantly. Recent platelet counts were 75, 58, and most recently 45 (x 10^9/L)
- Norman presented with new symptoms of shortness of breath and small spots on the skin (petechiae) at most recent visit, resulting in a diagnosis of thrombocytopenic MF
- Norman was eligible to receive a bone marrow transplant; however, he declined due to the potential risks and complications of the procedure

About Norman's life:

Norman and his wife of 40 years enjoy the quiet life in the suburbs where they foster dogs for a local rescue organization. He has settled down with age, going to tai chi classes with his friends to stay flexible, but fatigue is limiting some of the activities he enjoys, such as walking the dogs or going on vacation with his wife.

If you see platelet counts continue to get low, **it's time for VONJO.**[1]

Important Safety Information (cont.)

Warnings and Precautions (cont.):

- **Diarrhea:** VONJO causes diarrhea in approximately 48% of patients compared to 15% of patients treated on the control arm. The median time to resolution in VONJO-treated patients was 2 weeks. The incidence of reported diarrhea decreased over time with 41% of patients reporting diarrhea in the first 8 weeks of treatment, 15% in Weeks 8 through 16, and 8% in Weeks 16 through 24. Diarrhea resulted in treatment interruption in 3% of VONJO-treated patients. None of the VONJO-treated patients reported diarrhea that resulted in treatment discontinuation. Serious diarrhea adverse reactions occurred in 2% of patients treated with VONJO compared to no such adverse reactions in patients in the control arm.

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NEWLY DIAGNOSED

Dan was just diagnosed with MF, and he's thrombocytopenic

Dan AGE 64

Initial diagnosis:
High-risk (de novo) thrombocytopenic primary MF
Labs:
- Latest platelet count: 42 x 10^9/L
- Hemoglobin: 9 g/dL (transfusion independent)

Splenomegaly:
8 cm below LCM
Transplant eligible:
Yes but not optimal due to splenomegaly
DIPSS+ score: 4

About Dan's case:

- Dan is a physically active, otherwise healthy man who came to his doctor because of painful pressure under his left ribs and unexplained weight loss
- Initial physical exam revealed splenomegaly (8 cm below LCM), and blood tests confirmed that Dan's platelet counts were extremely low (plt 42 x 10^9/L) and he was anemic (Hgb 9 g/dL)
- Dan was referred to a hematologist, who confirmed his diagnosis as de novo thrombocytopenic MF

About Dan's life:

Dan lives alone after a divorce 15 years ago and spends most of his time running his accounting business, tailgating at football games with friends, and restoring classic cars. Recent abdominal pain and fatigue have started to limit how much he can stay active. His health has never been something that worried him or garnered a lot of his attention, but his recent MF diagnosis is making him more concerned about the life he's worked so hard to build.

When a patient is diagnosed with MF and their counts are already low, **it's time for VONJO.**[1]

Important Safety Information (cont.)

Warnings and Precautions (cont.):

- **Diarrhea (cont.):** Control preexisting diarrhea before starting VONJO treatment. Manage diarrhea with antidiarrheal medications, fluid replacement, and dose modification. Treat diarrhea with antidiarrheal medications promptly at the first onset of symptoms. Interrupt or reduce VONJO dose in patients with significant diarrhea despite optimal supportive care.

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Hgb=hemoglobin; plt=platelet counts.

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If these patients remind you of someone you know, **it's time for VONJO.**[1]

SECONDARY MF – ON RUXOLITINIB

Pam

Her PV evolved to MF, and now **it is progressing again.**

Age: 75
Initial diagnosis: Polycythemia vera
Baseline platelet count: 214 x 10^9/L
Initial treatment: Cytoreductive phlebotomy and hydroxyurea 500 mg QD

Current diagnosis: Intermediate/high-risk secondary MF (PPV)
Current treatment: Ruxolitinib, 5 mg BID
Labs:
- Latest platelet count: 49 x 10^9/L
- Hemoglobin: 10.5 g/dL (transfusion independent)

Splenomegaly: 10 cm below LCM
Transplant eligible: Yes but declined
DIPSS+ score: 3

PRIMARY MF – ON RUXOLITINIB

Alan

His MF was already complicated by anemia, **but now he's also thrombocytopenic.**

Age: 72
Initial diagnosis: Intermediate/high-risk primary MF
Baseline platelet count: 110 x 10^9/L
Initial treatment: Ruxolitinib, 15 mg BID

Current diagnosis: Intermediate/high-risk primary MF with thrombocytopenia
Current treatment: Ruxolitinib, 10 mg BID (dose lowered after 6 months)
Labs:
- Latest platelet count: 48 x 10^9/L
- Hemoglobin: 9.4 g/dL (transfusion independent)

Splenomegaly: 8 cm below LCM
Transplant eligible: No
DIPSS+ score: 3

WATCH AND WAIT

Norman

After a few months of watchful waiting, **he's seeing changes in his MF.**

Age: 77
Initial diagnosis: Intermediate/high-risk primary MF
Baseline platelet count: 123 x 10^9/L
Initial treatment: Watch and wait

Current diagnosis: Thrombocytopenic MF
Current treatment: N/A - watch and wait
Labs:
- Latest platelet count: 45 x 10^9/L
- Hemoglobin: 12 g/dL (transfusion independent)

Splenomegaly: No
Transplant eligible: Yes but declined
DIPSS+ score: 2

NEWLY DIAGNOSED

Dan

He was just diagnosed with MF, **and he's thrombocytopenic.**

Age: 64
Initial diagnosis: High-risk (de novo) thrombocytopenic primary MF
Labs:
- Latest platelet count: 42 x 10^9/L
- Hemoglobin: 9 g/dL (transfusion independent)

Splenomegaly: 8 cm below LCM
Transplant eligible: Yes but not optimal due to splenomegaly
DIPSS+ score: 4

These case studies are hypothetical patients provided for general medical education purposes only and are not to be used as a substitute for independent medical judgement for a specific patient's medical condition.

References

1. VONJO. Prescribing information. Sobi, Inc.; 2024. **2.** Palandri F, et al. *Cancer.* 2023;129:1704-1713 **3.** Gangat N, et al. *J Clin Oncol.* 2011;29(4):392-397. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myeloproliferative Neoplasms V.2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 8, 2024. To view the most recent and complete versions of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

Important Safety Information (cont.)

Warnings and Precautions (cont.):

- **Thrombocytopenia:** VONJO can cause worsening thrombocytopenia. VONJO dosing was reduced due to worsening thrombocytopenia in 2% of patients with preexisting moderate to severe thrombocytopenia (platelet count <100 x 10^9/L). VONJO dosing was reduced due to worsening thrombocytopenia in 2% of patients with preexisting severe thrombocytopenia (platelet count <50 x 10^9/L).

  Monitor platelet count prior to VONJO treatment and as clinically indicated during treatment. Interrupt VONJO in patients with clinically significant worsening of thrombocytopenia that lasts for more than 7 days. Restart VONJO at 50% of the last given dose once the toxicity has resolved. If toxicity recurs, hold VONJO. Restart VONJO at 50% of the last given dose once the toxicity has resolved.
- **Prolonged QT Interval:** VONJO can cause prolongation of the QTc interval. QTc prolongation of >500 msec was higher in VONJO-treated patients than in patients in the control arm (1.4% vs 1%). QTc increase from baseline by 60 msec or higher was greater in VONJO-treated patients than in control arm patients (1.9% vs 1%). Adverse reactions of QTc prolongation were reported for 3.8% of VONJO-treated patients and 2% of control arm patients. No cases of torsades de pointes were reported.

  Avoid use of VONJO in patients with a baseline QTc of >480 msec. Avoid use of drugs with significant potential for QTc prolongation in combination with VONJO. Correct hypokalemia prior to and during VONJO treatment. Manage QTc prolongation using VONJO interruption and electrolyte management.
- **Major Adverse Cardiac Events (MACE):** Another Janus associated kinase (JAK)-inhibitor has increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated.

  Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with VONJO particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur.
- **Thrombosis:** Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated.

  Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately.
- **Secondary Malignancies:** Another JAK-inhibitor has increased the risk of lymphoma and other malignancies excluding non-melanoma skin cancer (NMSC) (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which VONJO is not indicated. Patients who are current or past smokers are at additional increased risk.

  Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with VONJO, 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.
- **Risk of Infection:** Another JAK-inhibitor increased the risk of serious infections (compared to best available therapy) in patients with myeloproliferative neoplasms. Serious bacterial, mycobacterial, fungal, and viral infections may occur in patients treated with VONJO. Delay starting therapy with VONJO until active serious infections have resolved.

  Observe patients receiving VONJO for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines.
- **Interactions With CYP3A4 Inhibitors or Inducers:** Coadministration of VONJO with strong CYP3A4 inhibitors or inducers is contraindicated. Monitor for increased adverse reactions of VONJO when administered with moderate CYP3A4 inhibitors.

Adverse Reactions

The most frequent serious adverse reactions occurring in ≥3% patients receiving VONJO 200 mg twice daily were anemia (8%), thrombocytopenia (6%), pneumonia (6%), cardiac failure (4%), disease progression (3%), pyrexia (3%), and squamous cell carcinoma of skin (3%).

Fatal adverse reactions among patients treated with VONJO 200 mg twice daily included events of disease progression (3%), and multiorgan failure, cerebral hemorrhage, meningorrhagia, and acute myeloid leukemia in <1% of patients, respectively.

The most common adverse reactions (reported in ≥20% of patients) include diarrhea, thrombocytopenia, nausea, anemia, and peripheral edema.

Please see the accompanying full Prescribing Information for VONJO.

VONJO®
(pacritinib) capsules

VONJO®
(pacritinib) capsules

WHEN YOUR PATIENTS WITH MF
BECOME THROMBOCYTOPENIC,
THAT'S THE MOMENT YOU KNOW
IT'S TIME FOR VONJO[1]

- **Evaluated against best available therapy in PERSIST-2, a study of patients with platelet counts ≤100 x 10^9/L with or without anemia[1]**
- **First and only JAK1-sparing inhibitor of JAK2, ACVR1, and IRAK1[1]**
- **Recommendations for pacritinib (VONJO) are included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[4]***

*See the NCCN Guidelines® for detailed recommendations, including other options.
ACVR1=activin A receptor, type 1; IRAK1=interleukin-1 receptor-associated kinase 1; NCCN=National Comprehensive Cancer Network® (NCCN®).

INDICATION: VONJO is indicated for the treatment of adults with intermediate or high-risk primary or secondary (PPV or PET) MF with a platelet count below 50 × 10^9/L. This indication is approved under accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information

Adverse Reactions

The most common adverse reactions (reported in ≥20% of patients) include diarrhea, thrombocytopenia, nausea, anemia, and peripheral edema.

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