The day you choose JAKAVI® (ruxolitinib) is the day you could begin to change their life[1–7]

Polycythaemia vera (PV)

For your patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.[1,2,7]

References: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics. **2.** Scottish Medicines Consortium. Ruxolitinib (JAKAVI®). Available at: https://www.scottishmedicines.org.uk/medicines-advice/ruxolitinib-jakavi-full-smc2213/. Last accessed September 2025. **3.** Vannucchi AM, et al. N Engl J Med. 2015;372:426–435. **4.** Verstovsek S, et al. Haematologica. 2016;101:821–829. **5.** Griesshammer M, et al. Ann Hematol. 2018;97:1591–1600. **6.** Griesshammer M, et al. Ann Hematol. 2018;97:1591–1600. Supplementary appendix. **7.** NICE. Ruxolitinib for treating polycythaemia vera. Available at: https://www.nice.org.uk/guidance/ta921/chapter/1-Recommendations/. Last accessed September 2025.

JAKAVI® is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. JAKAVI® is also indicated for adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.[1]

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com or call 01276 698370.

Please scan or tap the QR code for JAKAVI® Prescribing Information.

NOVARTIS

JAKAVI® ruxolitinib

This material has been created and funded by Novartis.

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UK | FA-11346939 | September 2025

How do PV symptoms impair patients' QoL?

On average, patients with an MPN experience 9 symptoms at any one time*[1]

7 in 10
patients with PV felt that their symptoms reduced their QoL†[1]

81%
of patients with PV experience fatigue†[1]

45%
of patients with PV experience pruritus†[1]

"I couldn't even get my head off the pillow, let alone go up the stairs"[2]

"It's not a scratchable itch. It consumes you"[2]

Symptom reduction was reported as the primary goal of treatment by 61% of patients with PV in the MPN Landmark Survey‡[3]

* Data from patients with an MPN (N=286) surveyed in the UK MPN Landmark Survey.[1] † Data from patients with PV (n=78) surveyed in the UK MPN Landmark Survey (N=286).[1]
‡ Data from patients with PV (n=223) surveyed in the International MPN Landmark Survey (N=699).[3]

References: 1. Harrison CN, et al. BSH 2017, 27–29 March; Brighton, UK. **2.** Data on file. Novartis. Patient Quotes in PV from Advisory Board [MPN_PV_2020_001]. November 2020. **3.** Harrison CN, et al. Ann Hematol. 2017;96:1653–1665.

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JAKAVI® ruxolitinib

Don’t leave HU-resistant or HU-intolerant patients behind[1–5]

Patients with PV may become resistant to or intolerant of HU treatment*[1,6,7]

Patients with PV who are HU resistant/intolerant are at increased risk of transformation to MF and AML[8]

ELN recommends **switching patients with HU resistance or intolerance to JAKAVI®** or IFN-α based on individual clinical features‡[5]

HU resistance†[5] | HU intolerance[5]

ELN recommends switching patients to an alternative cytoreductive therapy if any one of the resistance or intolerance criteria are met[5]

- **Persistent disease-related symptoms:**
  TSS of at least 20 or an itching score of at least 10 for at least 6 months
- **Persistent thrombocytosis:**
  a platelet count >1000×10^9 cells/L, microvascular symptoms, or both, persisting for more than 3 months
- **Symptomatic or progressive splenomegaly:**
  increase in spleen size by more than 5 cm from the left costal margin in 1 year
- **Progressive and persistent leukocytosis:**
  at least 100% increase if BL count is <10×10^9 cells/L or at least 50% increase if BL count is >10×10^9 cells/L. Leukocyte count >15×10^9 cells/L confirmed at 3 months
- **Insufficient HCT control:**
  need for six or more venesections per year to keep HCT <45%

Are you monitoring your patients’ symptoms from diagnosis to help identify HU resistance or intolerance as soon as it develops?

*** HU resistance or intolerance was defined using the 2010 ELN criteria.[2,7] In a retrospective analysis of 106 patients with PV in Belgium, when using the original and modified ELN criteria, 20.7% and 39.6% of patients were resistant to or intolerant of HU, respectively.[2,4,7] † HU dosed at ≥1.5 g per day for at least 4 months and without reporting intolerance.[5] ‡ In particular, age, spleen size, symptoms, history of skin cancers and patient preferences.[5] Not all IFN-α therapies are approved for use in PV.[5]**

References: 1. Alvarez-Larrán A, et al. Blood. 2012;119:1363–1369. **2.** Barosi G, et al. Br J Haematol. 2010;148:961–963. **3.** McMullin MF, et al. Br J Haematol. 2019;184:176–191. **4.** McMullin MF, et al. Br J Haematol. 2016;172:337–349. **5.** Marchetti M, et al. Lancet Haematol. 2022;9:e301–e311. **6.** Geyer H, et al. J Clin Oncol. 2016;34:151–159. **7.** Demuynck T, et al. Ann Hematol. 2019;98:1421–1426. **8.** Alvarez-Larrán A, et al. Br J Haematol. 2016;172:786–793.

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JAKAVI® ruxolitinib

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HU resistance†[5] | **HU intolerance[5]**

ELN recommends switching patients to an alternative cytoreductive therapy if any one of the resistance or intolerance criteria are met[5]

- **Grade 3–4 or prolonged Grade 2 non-haematological toxicity:** (e.g., mucocutaneous manifestations, gastrointestinal symptoms, fever or pneumonitis) at any dose
- **Haematological toxicity:** Hb <100 g/L, platelet count <100×10^9 cells/L, or neutrophil count <1×10^9 cells/L at the lowest dose of HU to achieve a response
- **Development of non-melanoma skin cancers**
- **Development of vascular events:** clinically relevant bleeding, venous thrombosis or arterial thrombosis

Are you monitoring your patients’ symptoms from diagnosis to help identify HU resistance or intolerance as soon as it develops?

*** HU resistance or intolerance was defined using the 2010 ELN criteria.[2,7] In a retrospective analysis of 106 patients with PV in Belgium, when using the original and modified ELN criteria, 20.7% and 39.6% of patients were resistant to or intolerant of HU, respectively.[2,4,7] † HU dosed at ≥1.5 g per day for at least 4 months and without reporting intolerance.[5] ‡ In particular, age, spleen size, symptoms, history of skin cancers and patient preferences.[5] Not all IFN-α therapies are approved for use in PV.[5]**

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Please tap below for the **JAKAVI® Prescribing Information**

JAKAVI® ruxolitinib

JAKAVI® has been assessed in Phase 3 pivotal trials in patients with PV[1–3]

RESPONSE (patients with splenomegaly) | RESPONSE-2 (patients without splenomegaly)

Phase 3, randomised, open-label, multicentre study[2]

RESPONSE

(N=222)

Eligibility criteria:

- Age ≥18
- PV with intolerance or resistance to HU
- Venesection requirement for HCT control
- Splenomegaly (MRI or CT volume ≥450 cm^3)
- Platelets >100x10^9 cells/L
- HCT 40–45%
- No prior JAK inhibitor treatment

1:1 randomisation

JAKAVI® (n=110)
PV patients: 10 mg BID

BAT† (n=112)
(n=96 crossed over to JAKAVI® at 32 weeks/ disease progression)

For 52 weeks

Primary outcomes:

- Composite of HCT control* in absence of venesection (defined as HCT of >45% and ≥3% above baseline or HCT >48%) and ≥35% reduction in spleen volume at Week 32

Key secondary outcomes:

- Complete haematological remission at Week 32
- % patients maintaining primary response at 48 weeks
- Duration of spleen volume reduction
- Symptom reduction‡
- Safety profile

Week 32 (primary endpoint) → Week 48 (primary data cut-off) → Week 80 (planned analysis) → Week 256 (final planned analysis)

Crossover of BAT to JAKAVI®

JAKAVI® extended treatment phase

Effect of baseline spleen volume on the percentage change in spleen volume at Week 32 was also assessed[2]

* HCT control defined as no venesection eligibility between Weeks 8 and 32 in RESPONSE, and between Weeks 8 and 28 in RESPONSE-2[2,3], with venesection eligibility occurring only once after randomisation and before Week 8. Venesection eligibility was defined as HCT >45% and at least 3 percentage points higher than baseline or HCT >48%.[2,3] † HU, interferon, pipobroman (not licensed for PV in the UK), anagrelide (not licensed for PV in the UK),[4] immunomodulators or observation only.[2] ‡ Symptom score was assessed using MPN-SAF and MPN-SAF TSS questionnaire.[2] § HU, interferon, immunomodulators and others.[3] ‖ Measured using MPN-SAF TSS.[3]

References: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics. **2.** Vannucchi AM, et al. N Engl J Med. 2015;372:426–435. **3.** Passamonti F, et al. Lancet Oncol. 2017;18:88–99.**4.** Mylan. Anagrelide summary of product characteristics.

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JAKAVI® ruxolitinib

JAKAVI® has been assessed in Phase 3 pivotal trials in patients with PV[1–3]

RESPONSE (patients with splenomegaly) | **RESPONSE-2 (patients without splenomegaly)**

Phase 3b, randomised, open-label, multicentre study[3]

RESPONSE-2

(N=149)

Eligibility criteria:

- Age ≥18
- Patients with intolerance or resistance to HU
- Venesection requirement for HCT control
- No requirement for splenomegaly
- No prior JAK inhibitor treatment

1:1 randomisation

JAKAVI® (n=74)
10 mg BID

BAT§ (n=75)
(n=58 crossed over to JAKAVI® after 28 weeks)

For 52 weeks

Primary outcomes:

- HCT control at Week 48 defined as no venesection eligibility (defined as HCT of >45% and ≥3% above baseline or HCT >48% [Week 8–28])

Key secondary outcomes:

- % patients achieving complete haematological remission at Week 28

Other secondary outcomes:

- Durability of HCT control and complete haematological remission at Weeks 52 and 80
- Change in venesection eligibility over time
- Change in HCT level over time
- Change in spleen length
- Change in ECOG status
- Transformation-free survival
- OS
- Safety profile
- Changes in PROs‖

Crossover of BAT to JAKAVI®

Week 28 (primary endpoint)

BAT end of treatment follow-up

Week 80

JAKAVI® end of treatment follow-up

Week 260

JAKAVI® extended treatment phase

* HCT control defined as no venesection eligibility between Weeks 8 and 32 in RESPONSE, and between Weeks 8 and 28 in RESPONSE-2[2,3], with venesection eligibility occurring only once after randomisation and before Week 8. Venesection eligibility was defined as HCT >45% and at least 3 percentage points higher than baseline or HCT >48%.[2,3] † HU, interferon, pipobroman (not licensed for PV in the UK), anagrelide (not licensed for PV in the UK),[4] immunomodulators or observation only.[2] ‡ Symptom score was assessed using MPN-SAF and MPN-SAF TSS questionnaire.[2]
§ HU, interferon, immunomodulators and others.[3] ‖ Measured using MPN-SAF TSS.[3]

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Please tap below for the **JAKAVI® Prescribing Information**

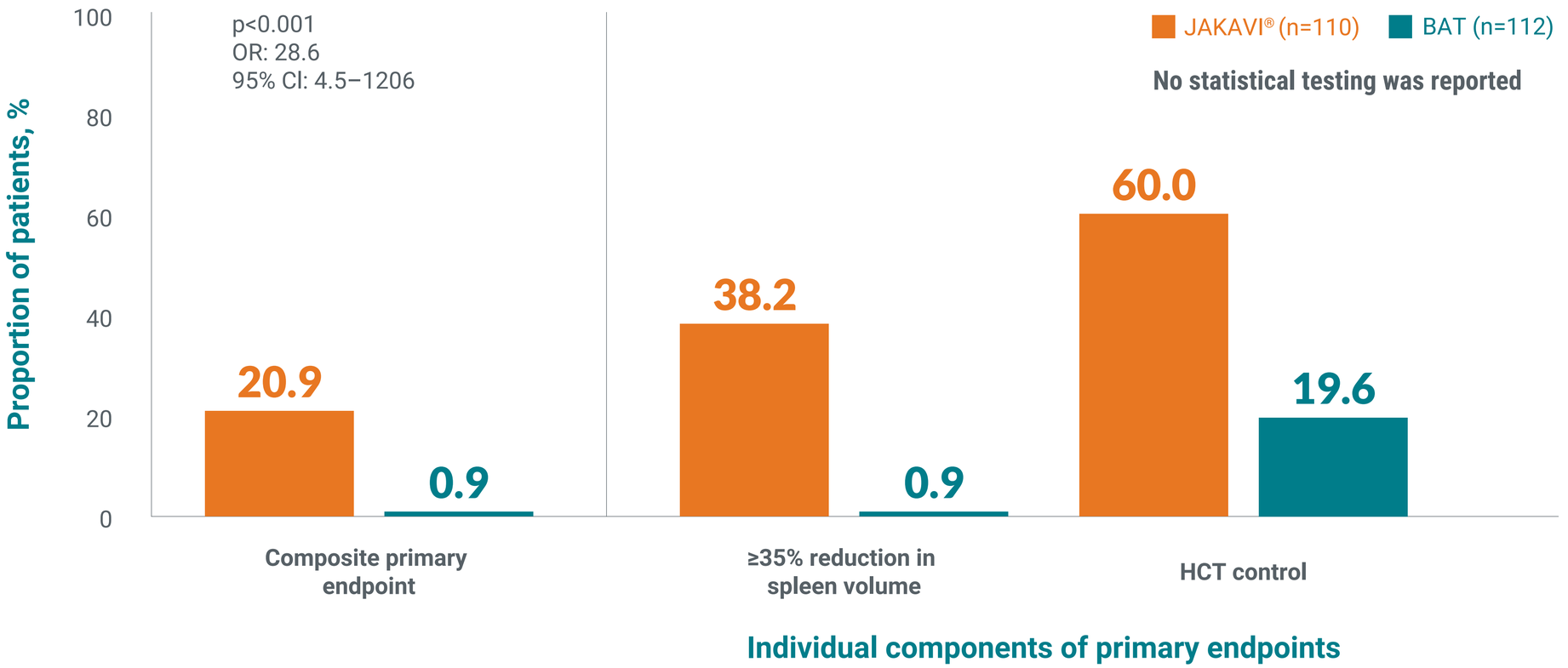
JAKAVI® ruxolitinib

JAKAVI® demonstrated improved HCT control* and spleen size reduction vs BAT in patients with splenomegaly (composite primary endpoint)[1,2]

Composite primary endpoint (Week 32) | 5-year follow-up

More patients achieved HCT control* and ≥35% reduction in spleen size at Week 32 with JAKAVI® vs BAT[2]

RESPONSE



Adapted from Vannucchi AM, et al. N Engl J Med. 2015.

RESPONSE is a Phase 3, randomised, open-label, multicentre study evaluating the efficacy and safety of JAKAVI® (n=110) vs BAT (n=112) in venesection-dependent patients with splenomegaly, who have HU-resistant or -intolerant PV.[2]

* HCT control defined as no venesection eligibility between Weeks 8 and 32, with venesection eligibility occurring only once after randomisation and before Week 8. Venesection eligibility was defined as HCT >45% and at least 3 percentage points higher than baseline or HCT >48%.[2] † There were 25 responders, six events and 19 censored.[3]

References: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics. **2.** Vannucchi AM, et al. N Engl J Med. 2015;372:426–435. **3.** Kiladjian JJ, et al. Lancet Haematol. 2020;7:e226–e237. **4.** Kiladjian JJ, et al. Lancet Haematol. 2020;7:e226–e237. Supplementary appendix.

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JAKAVI® ruxolitinib

JAKAVI® demonstrated improved HCT control* and spleen size reduction vs BAT in patients with splenomegaly (composite primary endpoint)[1,2]

Composite primary endpoint (Week 32) | **5-year follow-up**

RESPONSE

74% of patients with PV maintained primary response from Week 32 to 5 years (n=25)[†3]

No statistical testing was reported

of patients with PV were observed to have **maintained HCT control** from Week 32 to **5 years** (n=66)*[3]

of patients with PV had a probability of **maintaining ≥35% reduction in spleen volume** from Week 32 to **5 years** (n=44)[3,4]

Patients receiving BAT could cross over to JAKAVI® after Week 32.
It was therefore impossible to compare results at 5 years to BAT due to crossover.[3]

RESPONSE is a Phase 3, randomised, open-label, multicentre study evaluating the efficacy and safety of JAKAVI® (n=110) vs BAT (n=112) in venesection-dependent patients with splenomegaly, who have HU-resistant or -intolerant PV.[2]

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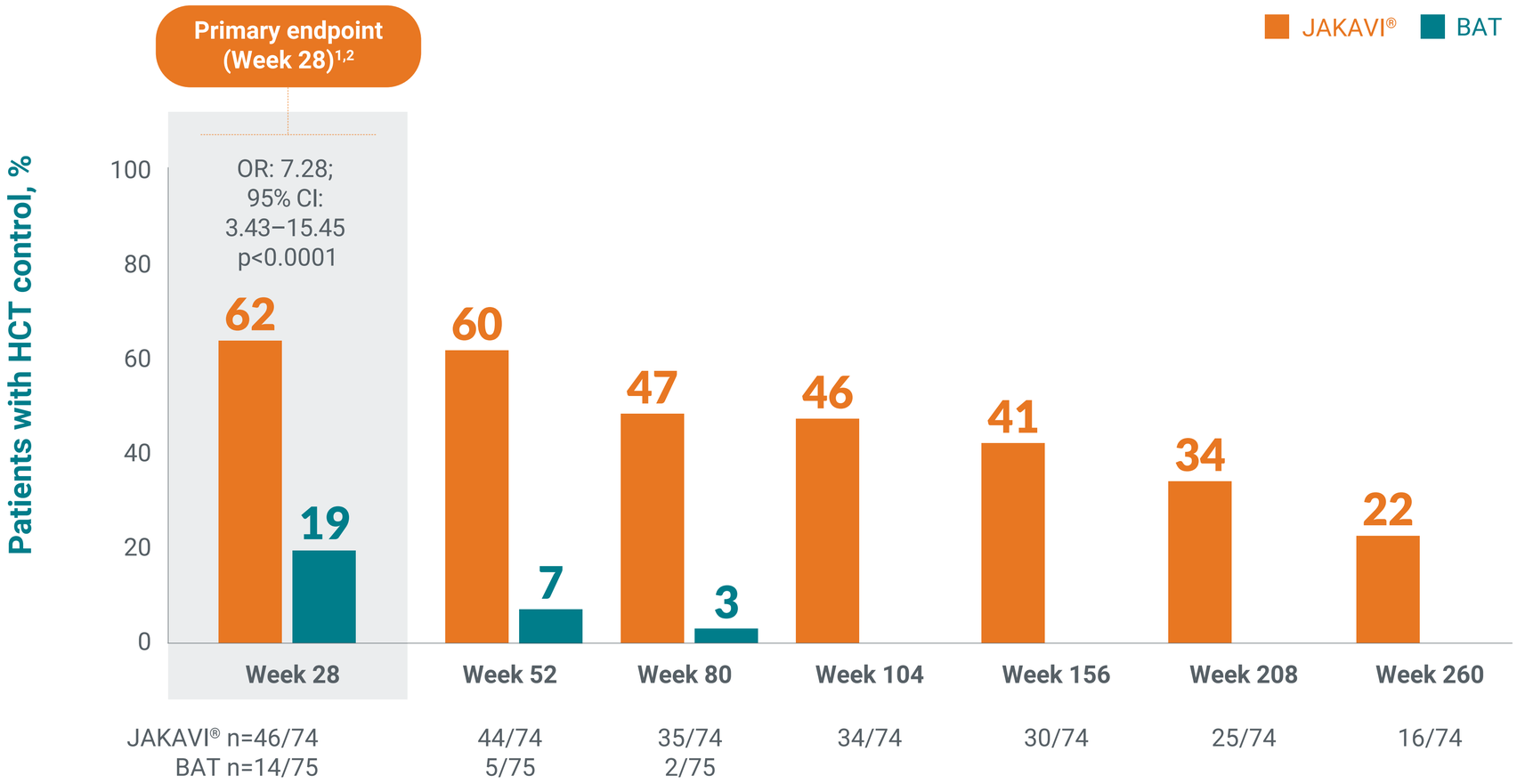
JAKAVI® ruxolitinib

JAKAVI® demonstrated improved HCT control* vs BAT in patients without splenomegaly[1]

Primary endpoint (Week 28)

Durability of HCT control* with JAKAVI® up to 5 years[2]

RESPONSE-2



22%

of patients receiving JAKAVI® achieved and sustained HCT control* through **5 years** (n=16/74)[2]

Adapted from Passamonti F, et al. Lancet Haematol. 2022.

Patients receiving BAT could cross over to JAKAVI® after Week 28.
It was therefore impossible to compare results at 5 years to BAT due to crossover.[1,2]

RESPONSE-2 is a Phase 3b, prospective, randomised, open-label, multicentre study assessing the efficacy and safety of JAKAVI® (n=74) vs BAT (n=75) in venesection-dependent patients with PV without splenomegaly who are resistant to or intolerant of HU.[1]

* HCT control defined as no venesection eligibility between Weeks 8 and 28, with venesection eligibility occurring only once after randomisation and before Week 8. Venesection eligibility was defined as HCT >45% and at least 3 percentage points higher than baseline or HCT >48%.[1]

References: 1. Passamonti F, et al. Lancet Oncol. 2017;18:88–99. **2.** Passamonti F, et al. Lancet Haematol. 2022;9:e480–e492.

Please tap below for the **JAKAVI® Prescribing Information**

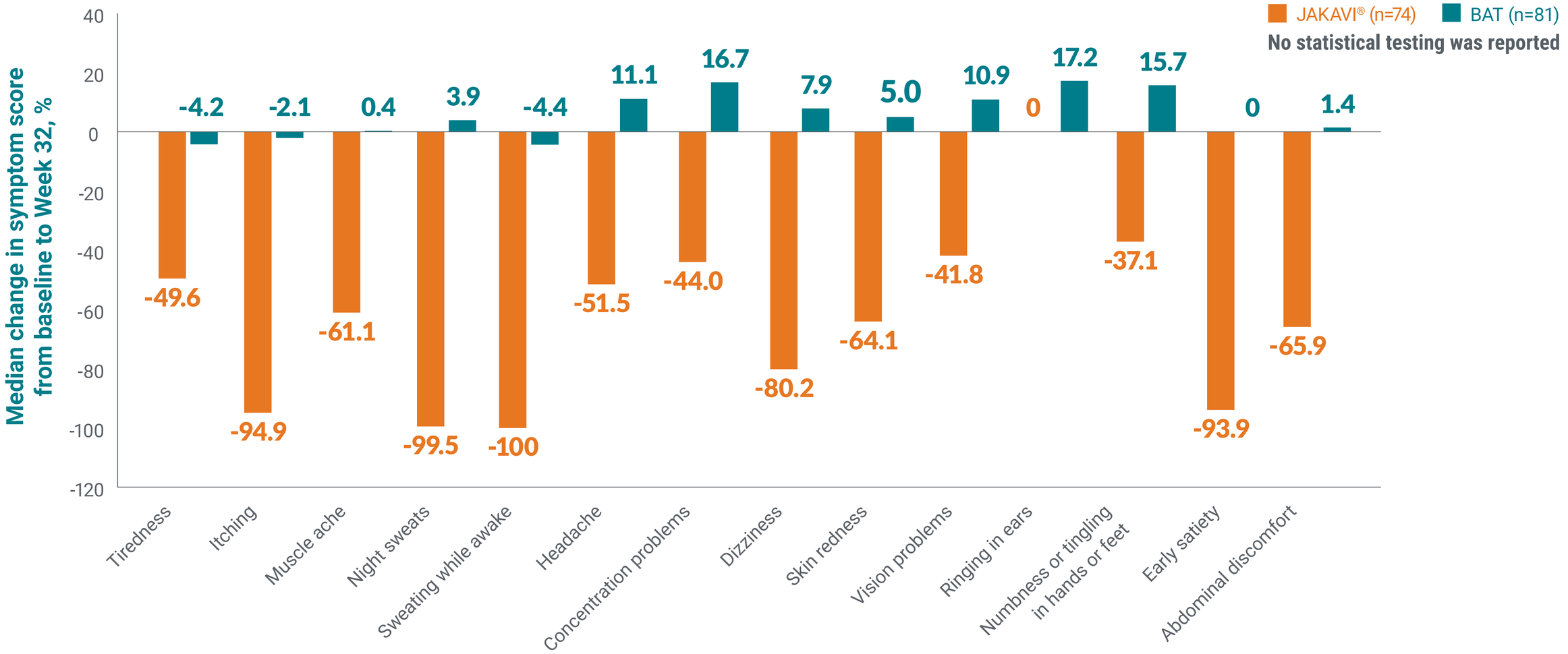
JAKAVI® ruxolitinib

Patients with splenomegaly receiving JAKAVI® reported a decrease in symptom burden while patients on BAT experienced increased symptoms (no p-value reported)*[1,2]

Week 32 | 5-year follow-up

Median change in PV symptom score at Week 32 with JAKAVI® vs BAT†[2]

RESPONSE



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* Symptom score was assessed using MPN-SAF and MPN-SAF TSS questionnaire.[2] QoL was assessed using the EORTC QLQ-C30 questionnaire.[2] † Patients with data at both baseline (value >0) and Week 32 were included in the analysis.[2]

References: 1. Kiladjian JJ, et al. Lancet Haematol. 2020;7:e226–e237. **2.** Vannucchi AM, et al. N Engl J Med. 2015;372:426–435. **3.** Kiladjian JJ, et al. Lancet Haematol. 2020;7:e226–e237. Supplementary appendix.

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JAKAVI® ruxolitinib

Patients with splenomegaly receiving JAKAVI® reported a decrease in symptom burden while patients on BAT experienced increased symptoms (no p-value reported)*[1,2]

Week 32 | **5-year follow-up**

RESPONSE

Mean change in global health status–QoL scale in patients originally randomised to JAKAVI® (Week 32 and 256) and BAT (Week 32)[1–3]

Patients receiving BAT could cross over to JAKAVI® after Week 32.
It was therefore impossible to compare results at 5 years to BAT due to crossover.[1]

RESPONSE is a Phase 3, randomised, open-label, multicentre study evaluating the efficacy and safety of JAKAVI® (n=110) vs BAT (n=112) in venesection-dependent patients with splenomegaly, who have HU-resistant or -intolerant PV.[2]

* Symptom score was assessed using MPN-SAF and MPN-SAF TSS questionnaire.[2] QoL was assessed using the EORTC QLQ-C30 questionnaire.[2] † Patients with data at both baseline (value >0) and Week 32 were included in the analysis.[2]

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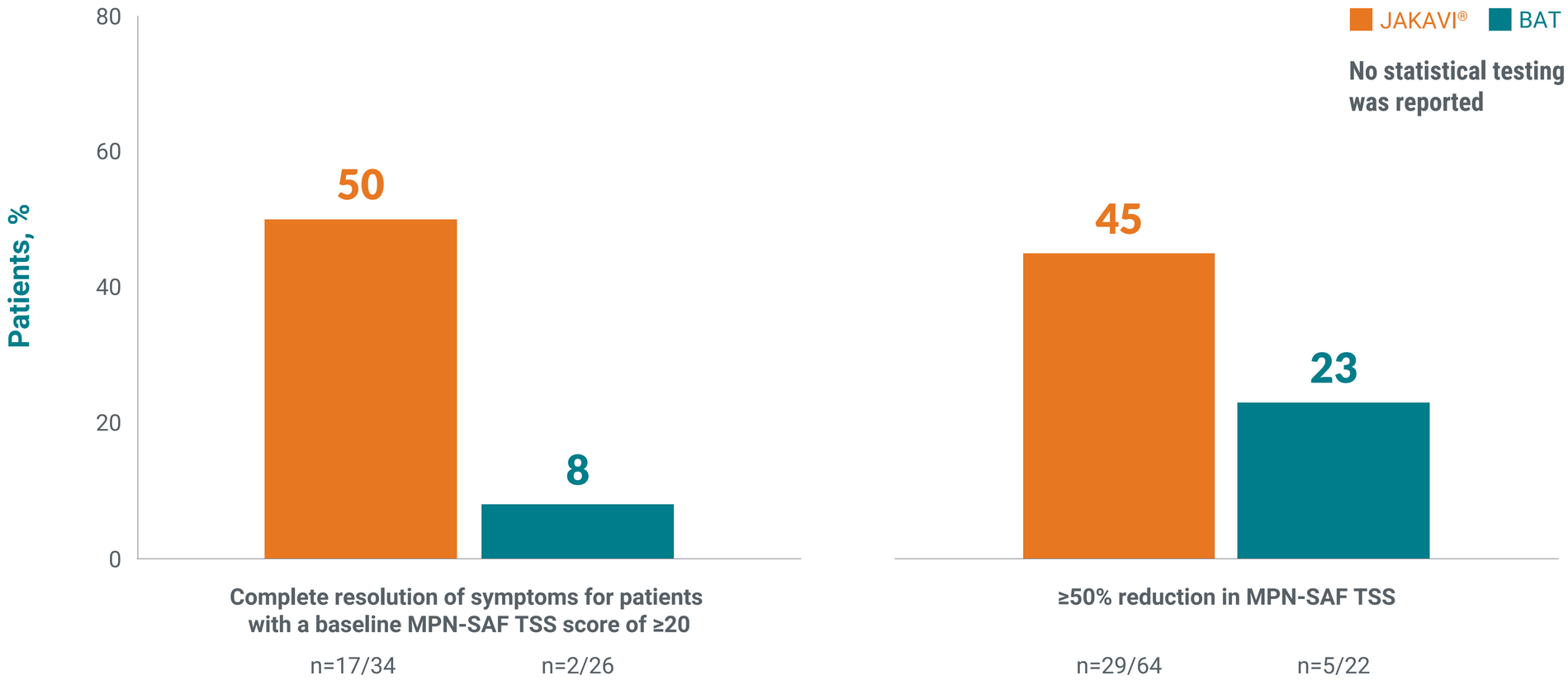
JAKAVI® ruxolitinib

Patients with splenomegaly receiving JAKAVI® reported a decrease in symptom burden while patients on BAT experienced increased symptoms (no p-value reported)*[1,2]

Week 28 | 5-year follow-up

RESPONSE-2

More patients with PV reported complete resolution of symptoms with JAKAVI® vs BAT (secondary endpoint)†[1]



Adapted from Passamonti F, et al. Lancet Oncol. 2017.

RESPONSE-2 is a Phase 3b, prospective, randomised, open-label, multicentre study assessing the efficacy and safety of JAKAVI® (n=74) vs BAT (n=75) in venesection-dependent patients with PV without splenomegaly who are resistant to or intolerant of HU.[1,2]

* Symptom score was assessed using MPN-SAF TSS questionnaire.[1] † Complete resolution of symptoms is defined as MPN-SAF TSS reduction of ≥10 points from baseline at Week 16 and maintained until Week 28 (for patients with a baseline score of ≥20).[1] ‡ Median follow-up was 67 months.[2]

References: 1. Passamonti F, et al. Lancet Oncol. 2017;18:88–99. **2.** Passamonti F, et al. Lancet Haematol. 2022;9:e480–e492.

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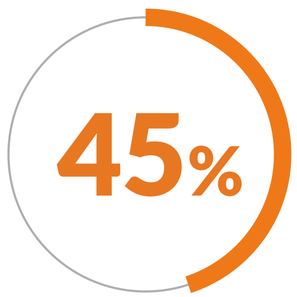
JAKAVI® ruxolitinib

Patients with splenomegaly receiving JAKAVI® reported a decrease in symptom burden while patients on BAT experienced increased symptoms (no p-value reported)*[1,2]

Week 28 | **5-year follow-up**

RESPONSE-2

More patients on JAKAVI® reported ≥50% reduction from baseline in MPN-SAF TSS vs BAT at the end-of-treatment visit (secondary endpoint)‡[2]



JAKAVI® (n=28/62)

BAT (n=10/63)

(OR: 4.36; 95% CI: 1.88–10.12)[2]

No p-value reported

Patients receiving JAKAVI® at Week 80, including patients who had crossed over, could enter an extended treatment period up to Week 260. At Week 80, patients receiving BAT who did not cross over to JAKAVI® were not eligible for the extended treatment period but had an end-of-treatment visit at Week 80, or at the time of discontinuation.[2]

RESPONSE-2 is a Phase 3b, prospective, randomised, open-label, multicentre study assessing the efficacy and safety of JAKAVI® (n=74) vs BAT (n=75) in venesection-dependent patients with PV without splenomegaly who are resistant to or intolerant of HU.[1,2]

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Please tap below for the **JAKAVI® Prescribing Information**

JAKAVI® ruxolitinib

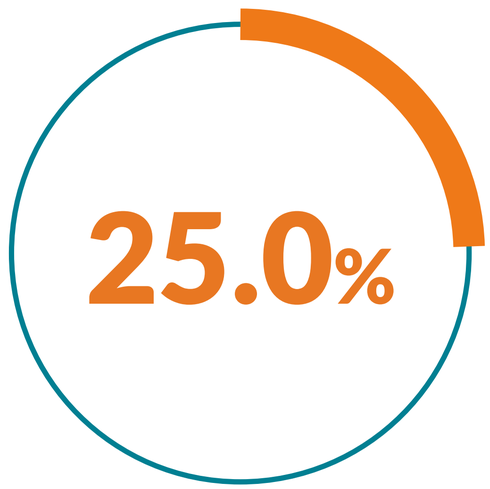
JAKAVI® has a generally well-characterised safety profile[1]

Haematological AEs | Non-Haematological AEs

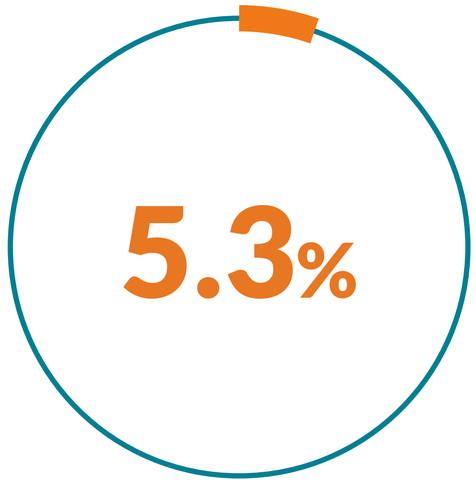
RESPONSE
RESPONSE-2

Most commonly reported All-Grade AEs in patients with PV who received JAKAVI®

Anaemia



Thrombocytopenia



Neutropenia

Discontinuation due to adverse events, regardless of causality, was observed in **19.4%** of patients.[1]

Please refer to the SmPC for full safety profile.

Please tap below for the **JAKAVI® Prescribing Information**

JAKAVI® ruxolitinib

Reference: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics.

JAKAVI® has a generally well-characterised safety profile[1]

Haematological AEs | **Non-Haematological AEs**

RESPONSE
RESPONSE-2

Most commonly reported All-Grade AEs in patients with PV who received JAKAVI®

20.3%
Weight gain

19.4%
Dizziness

17.9%
Headache

45.3% increased alanine aminotransferase
42.6% increased aspartate aminotransferase
34.7% hypercholesterolaemia

Discontinuation due to adverse events, regardless of causality, was observed in **19.4%** of patients.[1]

Please refer to the SmPC for full safety profile.

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Reference: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics.

JAKAVI® has a generally well-characterised safety profile[1]

	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1000 to <1/100)	Not known
Infections and infestations	• Urinary tract infections • Herpes zoster	• Pneumonia	• Sepsis • HBV reactivation	• Tuberculosis*
Blood and lymphatic system disorders†	• Anaemia† of any CTCAE‡ Grade • Thrombocytopenia† of any CTCAE‡ Grade • Bleeding (any bleeding including intracranial, gastrointestinal, bruising and other bleeding) • Bruising • Other bleeding (including epistaxis, post-procedural haemorrhage and haematuria)	• Anaemia† CTCAE‡ Grade 3 (<8.0–6.5 g/dL) • Thrombocytopenia† CTCAE‡ Grade 3 (50,000–25,000/mm^3) • Neutropenia† of any CTCAE‡ Grade • Pancytopenia†§ • Gastrointestinal bleeding	• Anaemia† CTCAE‡ Grade 4 (<6.5 g/dL) • Thrombocytopenia† CTCAE‡ Grade 4 (<25,000/mm^3) • Neutropenia† – CTCAE‡ Grade 4 (<500/mm^3) – CTCAE‡ Grade 3 (<1000–500/mm^3) • Intracranial bleeding	
Metabolism and nutrition disorders	• Weight gain • Hypercholesterolaemia† of any CTCAE‡ Grade • Hypertriglyceridaemia† of any CTCAE‡ Grade			
Nervous system disorders	• Dizziness • Headache			
Gastrointestinal disorders	• Elevated lipase of any CTCAE‡ Grade • Constipation	• Flatulence		
Hepatobiliary disorders	• Raised alanine aminotransferase† of any CTCAE‡ Grade • Raised aspartate aminotransferase† of any CTCAE‡ Grade	• Raised alanine aminotransferase† CTCAE‡ Grade 3 (>5x–20x ULN)		
Vascular disorders	• Hypertension			

Selected special warnings and precautions for JAKAVI® include myelosuppression, infections, progressive multifocal leukoencephalopathy, lipid abnormalities/elevations, herpes zoster, MACE, thrombosis, second primary malignancies such as lymphoma and non-melanoma skin cancers.[1] Please refer to the SmPC for full information.

* ADR derived from post-marketing experience.[1] † Frequency is based on new or worsened laboratory abnormalities compared to baseline.[1] ‡ Common Terminology Criteria for Adverse Events (CTCAE) version 3.0; Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe, Grade 4 = life-threatening.[1] § Pancytopenia is defined as haemoglobin level <100 g/L, platelet count <100x10^9/L, and neutrophil count <1.5x10^9/L (or low white blood cell count of Grade 2 if neutrophil count is missing), simultaneously in the same lab assessment.[1]

Reference: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics.

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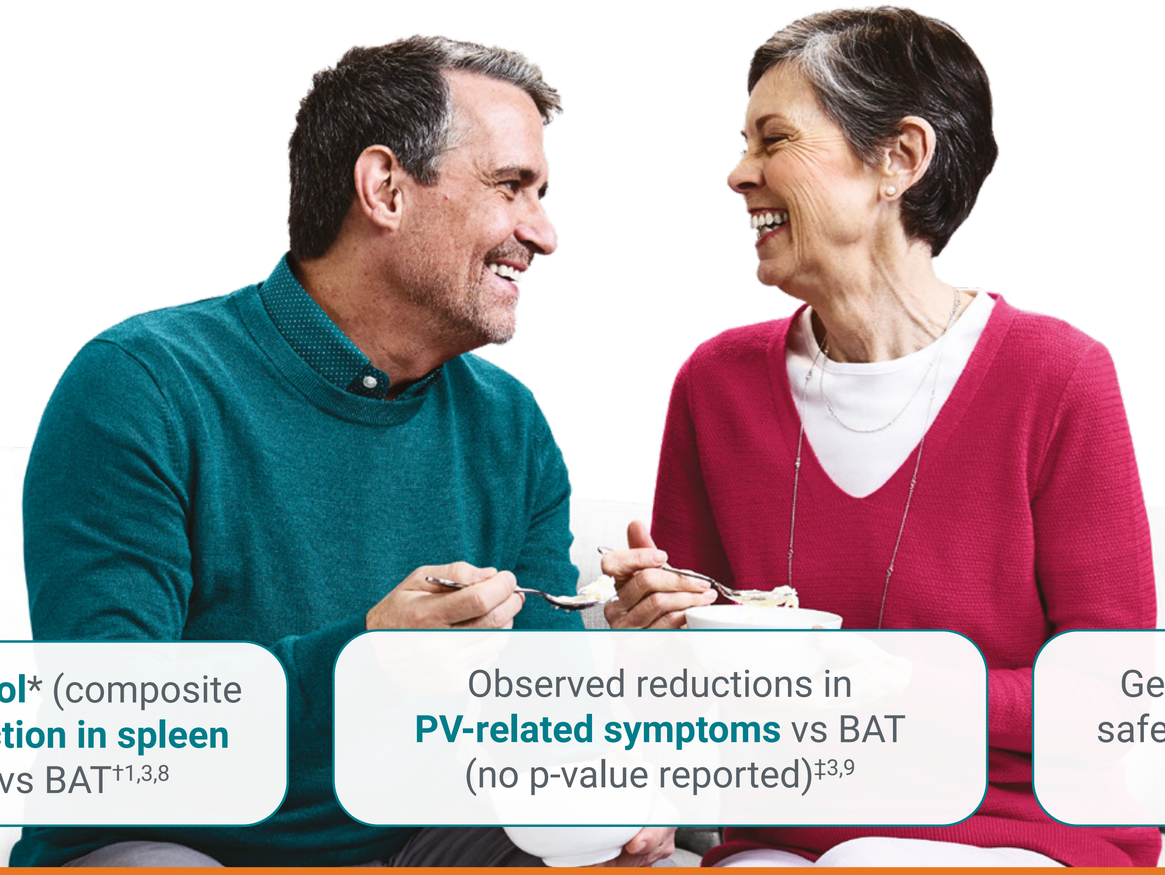
JAKAVI® ruxolitinib

The day you choose JAKAVI® (ruxolitinib)

is the day you could begin to change their life[1–7]

RECOMMENDED BY NICE[7]



Increased HCT control* (composite endpoint) and **reduction in spleen size** at Week 32 vs BAT†[1,3,8]

Observed reductions in **PV-related symptoms** vs BAT (no p-value reported)‡[3,9]

Generally **well-characterised** safety profile with up to **5 years** of safety data[1,8,10]

JAKAVI® (ruxolitinib) is recommended by NICE for treating polycythaemia vera in eligible adult patients who are resistant to or intolerant of hydroxyurea (please refer to the guidance for the full criteria). It is only recommended if the company provides it according to the commercial arrangement.[7]

* HCT control was defined as no venesection eligibility (venesection eligibility defined as HCT of >45% and ≥3% above baseline or HCT >48%).[3,8] † In RESPONSE at Week 32, JAKAVI® (n=110) demonstrated significantly higher rates of HCT control* and ≥35% reductions in spleen volume vs BAT (n=112; p<0.001),[1,3] which was maintained by 74% of patients on JAKAVI® (n=25) at Week 256.[10] In RESPONSE-2 at Week 28, JAKAVI® (n=74) demonstrated higher rates of HCT control* vs BAT (n=75; p<0.0001).[9] At Week 260, 22% of patients on JAKAVI® had maintained or achieved HCT control (n=74).[8] RESPONSE-2 was conducted in patients without splenomegaly.[8,9] In RESPONSE and RESPONSE-2, patients receiving BAT could cross over to JAKAVI® after Week 32 and 28, respectively. It was therefore impossible to compare results at 5 years to BAT due to crossover.[8,10] ‡ In RESPONSE at Week 32, 49% vs 5% of patients achieved ≥50% reduction in MPN-SAF TSS for JAKAVI® (n=74) vs BAT (n=81).[3] In RESPONSE-2 at Week 28, 45% vs 23% of patients achieved ≥50% reduction in MPN-SAF TSS for JAKAVI® (n=64) vs BAT (n=22).[9]

References: 1. Novartis Pharmaceuticals UK Ltd. JAKAVI® summary of product characteristics. **2.** Scottish Medicines Consortium. Ruxolitinib (JAKAVI®). Available at: https://www.scottishmedicines.org.uk/medicines-advice/ruxolitinib-jakavi-full-smc2213/. Last accessed September 2025. **3.** Vannucchi AM, et al. N Engl J Med. 2015;372:426–435. **4.** Verstovsek S, et al. Haematologica. 2016;101:821–829. **5.** Griesshammer M, et al. Ann Hematol. 2018;97:1591–1600. **6.** Griesshammer M, et al. Ann Hematol. 2018;97:1591–1600. Supplementary appendix. **7.** NICE. Ruxolitinib for treating polycythaemia vera. TA921, 2023. Available at: https://www.nice.org.uk/guidance/ta921. Last accessed September 2025. **8.** Passamonti F, et al. Lancet Haematol. 2022;9:e480–e492. **9.** Passamonti F, et al. Lancet Oncol. 2017;18:88–99. **10.** Kiladjian JJ, et al. Lancet Haematol. 2020;7:e226–e237.

Abbreviations: ADR, adverse drug reaction; AE, adverse event; AMR, acute myeloid leukaemia; BAT, best available therapy; BID, twice daily; BL, baseline; CI, confidence interval; CT, computed tomography; CTCAE, common terminology criteria for adverse events; ECOG, Eastern Cooperative Oncology Group; ELN, European LeukemiaNet; EORTC QLQ-C30, European Organisation for the Research and Treatment of Cancer core quality of life questionnaire; Hb, haemoglobin; HBV, hepatitis B virus; HCT, haematocrit; HU, hydroxyurea; IFN, interferon; JAK, janus kinase; MACE, major adverse cardiac event; MF, myelofibrosis; MPN-SAF TSS, Myeloproliferative Neoplasms Symptom Assessment Form Total Symptom Score; MRI, magnetic resonance imaging; NICE, National Institute for Health and Care Excellence; OR, odds ratio; OS, overall survival; PRO, patient-reported outcome; PV, polycythaemia vera; QoL, quality of life; SmPC, summary of product characteristics; TSS, total symptom score; ULN, upper limit of normal.

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