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JAKAVI - in myelofibrosis - HCP

Prescribing information

Image

Image

JAKAVI® (ruxolitinib) in myelofibrosis

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]

For your eligible myelofibrosis patients with disease-related splenomegaly or symptoms[1–6]

Image

Treatment with **JAKAVI® can help reduce**:

- **spleen size** vs BAT: 28% of patients treated with JAKAVI® (n=41/144) achieved at least a 35% reduction in spleen volume at Week 48 compared to 0% of patients treated with BAT (n=0/72) (p<0.001, primary endpoint)*[7]

- **symptom burden** vs placebo: 45.9% of patients treated with JAKAVI® (n=68/149) achieved an improvement of 50% or more in the total symptom score from baseline to Week 24 compared to 5.3% of patients treated with placebo (n=8/152) (OR=15.3; 95% CI: 6.9–33.7; p<0.001) (prespecified secondary endpoint)†[6]

Image

Recommended by the **BSH guidelines** as a treatment option and reimbursed across the UK in eligible patients[2,8,9]

Image

In an exploratory analysis, **long-term treatment** with JAKAVI® was associated with **prolonged survival vs control**[10]

In an analysis of 5-year pooled data from the COMFORT studies, the risk of death **(exploratory endpoint)** was reduced by 30% in patients randomised to JAKAVI® (n=301) vs control (n=227, placebo in COMFORT-I, BAT in COMFORT-II); median OS (JAKAVI® vs control), 5.3 vs 3.8 years (HR, 0.70; 95% CI, 0.54–0.91; p=0.0065)[10]

Image

Well-characterised safety profile.[1] For more information about the safety profile of

JAKAVI® in MF, please click **here**

Footnotes & references

*Spleen volume was assessed by MRI, or by CT for patients in whom MRI was contraindicated or in facilities where MRI was not readily available. Spleen length was assessed by manual palpation at every study visit using a soft centimetre ruler from the costal margin to the point of greatest splenic protrusion.[6,7]
†COMFORT-I: randomised, double-blind, Phase III trial comparing efficacy and safety of JAKAVI® (n=155) with placebo (n=154) in patients with intermediate-2 or high-risk MF. 41.9% of patients in the JAKAVI® group achieved a reduction in spleen volume of 35% or more at Week 24 (primary endpoint) vs with 0.7% in the placebo group (OR=134.4; 95% CI: 18.0–1004.9, p<0.001).[6] COMFORT-II: randomised Phase III trial comparing JAKAVI®

(n=146) with BAT (n=73, any commercially available agents as monotherapy or in combination, or no therapy at all) in patients with primary MF, post-PV MF or post-ET MF. In prespecified exploratory analyses of patient reported outcomes (as assessed by means of the EORTC QLQ-C30 and FACT-Lym subscales), improvements in quality-of-life and role functioning scores were observed in patients who received JAKAVI®, compared to patients who received BAT; no statistical analyses were conducted. At Week 48, patients receiving JAKAVI® had marked reductions in myelofibrosis-associated symptoms, including appetite loss, dyspnoea, fatigue, insomnia and pain, whereas patients receiving the best available therapy had worsening symptoms.[7]

BAT, best available therapy; BSH, British Society for Haematology; CI, confidence interval; COMFORT, Controlled Myelofibrosis Study with Oral JAK Inhibitor Treatment; CT, computed tomography; EORTC QLQ-C30, European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire; ET, essential thrombocythaemia; FACT-Lym, The Functional Assessment of Cancer Therapy-Lymphoma; HR, hazard ratio; JAK, janus kinase; MF, myelofibrosis; MRI, magnetic resonance imaging; OR, odds ratio; OS, overall survival.

References

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10. Verstovsek S, et al. *J Hematol Oncol* 2017;10:156.

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Learn more about the JAKAVI safety profile in MF

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