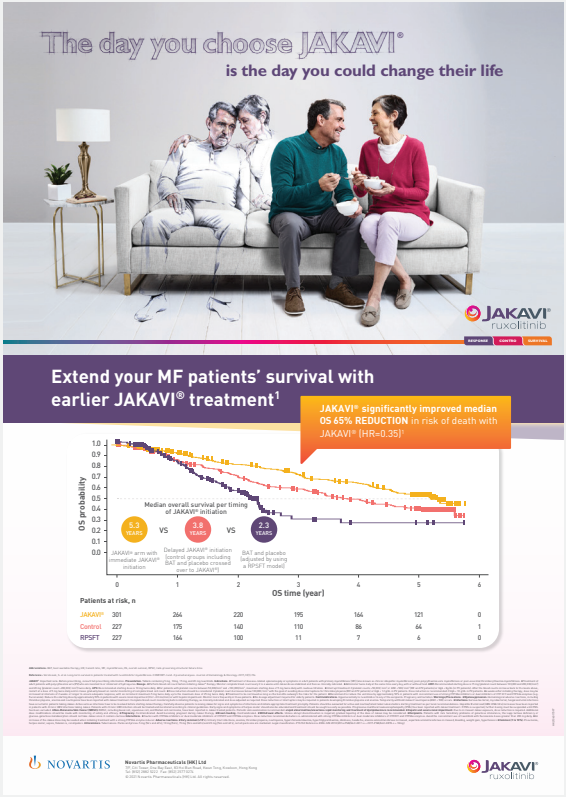

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JAKAVI® ruxolitinib

HK-NOV-210078P Virtual booth ad development and resize - Jakavi medical ad
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The day you choose JAKAVI®

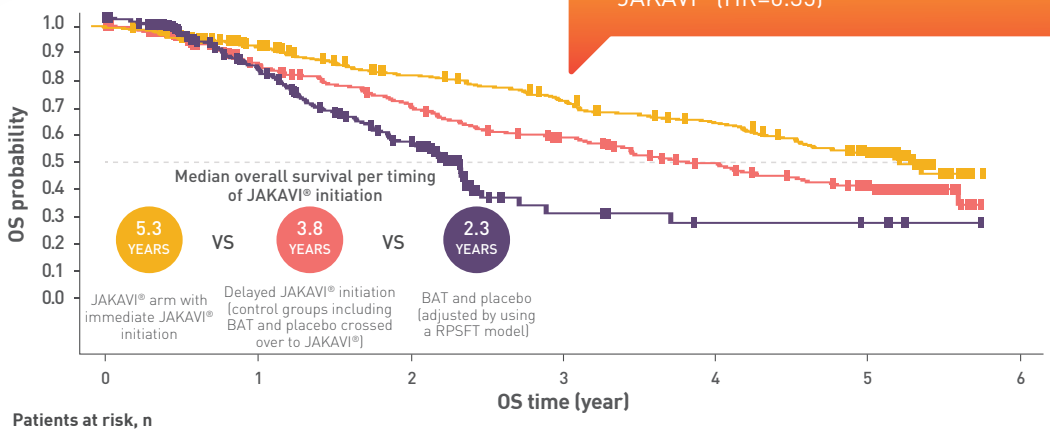
is the day you could change their life

JAKAVI® ruxolitinib

RESPONSE | CONTRO | SURVIVAL

Extend your MF patients' survival with earlier JAKAVI® treatment[1]

JAKAVI® significantly improved median OS 65% REDUCTION in risk of death with JAKAVI® (HR=0.35)[1]



Patients at risk, n

JAKAVI®	301	264	220	195	164	121	0
Control	227	175	140	110	86	64	1
RPSFT	227	164	100	11	7	6	0

Abbreviations: BAT, best available therapy; HR, hazard ratio; MF, myelofibrosis; OS, overall survival; RPSF, rank-preserving structural failure time

Reference : Verstovsek, S. et al. Long-term survival in patients treated with ruxolitinib for myelofibrosis: COMFORT-I and -II pooled analyses. Journal of Hematology & Oncology. 2017;10(1):156

JAKAVI® Important note: Before prescribing, consult full prescribing information. **Presentation**: Tablets containing 5 mg, 10mg, 15 mg, and 20 mg ruxolitinib. **Indications**: ♦Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (MF) (also known as chronic idiopathic myelofibrosis), post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis. ♦Treatment of adult patients with polycythaemia vera (PV) who are resistant to or intolerant of hydroxyurea. **Dosage**: ♦Perform blood cell count before initiating Jakavi® therapy. Monitor complete blood count every 2 to 4 weeks until Jakavi doses stabilized and then as clinically indicated. ♦Administer twice daily at the same time every day, with or without food. ♦**MF:** Recommended starting dose is 15 mg (platelet count between 100,000 and 200,000/mm³) and 20 mg (platelet count >200,000/ mm³) twice daily. ♦**PV:** Recommended starting dose is 10 mg twice daily. ♦For patients with platelet counts between 50,000/mm³ and <100,000/mm³, maximum starting dose of 5 mg twice daily with cautious titration. ♦Interrupt treatment if platelet counts <50,000/ mm³ or ANC <500/ mm³ (MF and PV patients) or Hgb < 8g/dL (in PV patients). After the blood counts increase back to the levels above, restart at a dose of 5 mg twice daily and increase gradually based on careful monitoring of complete blood cell count. ♦Dose reduction should be considered if platelet count decreases below 100,000/ mm³ with the goal of avoiding dose interruptions for thrombocytopenia (MF and PV patients) or Hgb < 10 g/dL in PV patients. Dose reduction is recommended if Hgb < 10 g/dL in PV patients. ♦4 weeks after initiating therapy, dose may be increased at intervals of 2 weeks or longer to ensure adequate response, with an increment maximum 5 mg twice daily up to the maximum dose of 25 mg twice daily. ♦Treatment to be continued as long as the benefits outweigh the risks for the patient. ♦Recommend to reduce the unit dose by approximately 50% in patients with concomitant use of strong CYP3A4 inhibitors or dual inhibitors of CYP 2C9 and CYP3A4 enzymes (e.g. fluconazole). Reduce the starting dose by approximately 50% in patients with severe renal impairment (Clcr <30 mL/min) or with hepatic impairment. Monitor more frequently in these patients. ♦No dosage adjustment required for elderly patients. **Contraindications**: Hypersensitivity to ruxolitinib or to any of the excipients. Pregnancy and lactation. **Warnings/Precautions**: ♦**Myelosuppression:** Hematological adverse reactions, including thrombocytopenia, anemia and neutropenia have been reported with Jakavi treatment. Complete blood count monitoring before initiating therapy, as clinically indicated and dose adjusted as required. Dose reduction or interruption may be required in patients developing thrombocytopenia and anemia. Temporarily withhold Jakavi if neutropenia (ANC < 500) occurs. ♦**Infections:** Serious bacterial, mycobacterial, fungal and viral infections have occurred in patients taking Jakavi. Active serious infections have to be resolved before starting Jakavi therapy. Carefully observe patients receiving Jakavi for signs and symptoms of infections and initiate appropriate treatment promptly. Patients should be evaluated for active and inactive/latent tuberculosis before starting treatment as per local recommendations. Hepatitis B viral load (HBV-DNA titre) increases have been reported in patients with chronic HBV infections taking Jakavi. Patients with chronic HBV infection should be treated and monitored according to clinical guidelines. Early signs and symptoms of herpes zoster should also be educated and treatment should be sought as early as possible. Progressive multifocal leukoencephalopathy (PML) has been reported with Jakavi treatment. If PML is suspected, further dosing must be suspended until PML has been excluded. ♦**Non-Melanoma Skin Cancer (NMSC):** NMSC, including basal cell, squamous cell, and Merkel cell carcinoma, have been reported in Jakavi treated patients. Periodic skin examination recommended. ♦**Lipid abnormalities/elevations: Lipid monitoring and treatment of dyslipidaemia is recommended.** ♦**Hepatic and severe renal impairment:** Due to increased Jakavi exposure, dose reduction is required. Additional dose modifications should be made with monitoring of safety and efficacy. ♦**Pregnancy**: Contraindicated. Avoid becoming pregnant during Jakavi therapy. ♦**Breast-feeding**: Contraindicated. ♦**Withdrawal effects**: Unless abrupt discontinuation is required, gradual tapering of the dose of Jakavi may be considered. ♦**Excipients**: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Jakavi since it contains lactose **Interactions:** ♦Caution with CYP3A4 inhibitors or dual moderate inhibitors of CYP2C9 and CYP3A4 enzymes. Dose reduction recommended when co-administered with strong CYP3A4 inhibitors or dual moderate inhibitors of CYP2C9 and CYP3A4 enzymes. Avoid the concomitant use of ruxolitinib with fluconazole doses greater than 200 mg daily. ♦An increase of the Jakavi dose may be needed when initiating treatment with a strong CYP3A4 enzyme inducer. **Adverse reactions: ♦Very common (>10%):** Urinary tract infections, anemia, thrombocytopenia, neutropenia, hypercholesterolaemia, hypertriglyceridaemia, dizziness, headache, alanine aminotransferase increased, aspartate aminotransferase increased, bleeding, weight gain, hypertension ♦**Common (1 to 10%):** Pneumonia, herpes zoster, sepsis, flatulence, constipation. ♦**Uncommon:** Tuberculosis. Packs and prices: 5 mg (56's and 60's), 10 mg (56's), 15 mg (56's and 60's) and 20 mg (56's and 60's), not all pack size are marketed. Legal classification: P151153 Reference: EMA JUN 2018 (2014-PSB/DLC-0811-s + 2017-PSB/DLC-0878-s + 10mg)

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JAKAVI® ruxolitinib