# SENTRY-2 (XPORT-MF-044): A Phase 2 Study to Evaluate the Efficacy and Safety of Selinexor Monotherapy in Patients with JAKi-naïve Myelofibrosis and Moderate Thrombocytopenia (NCT05980806)

## BACKGROUND

- Myelofibrosis (MF) is a heterogenous, progressive, and fatal disease.[1] Underlying biological hallmarks include aberrant blood and bone marrow differentiation, cytokine production and inflammation, bone marrow fibrosis, and extramedullary hematopoiesis.[1,2]
- Thrombocytopenia is common in patients with MF and associated with poor outcomes.[3]
- Selinexor, an oral exportin 1 (XPO1) inhibitor with pro-apoptotic and anti-inflammatory properties that may impact both Janus kinase (JAK) and non-JAK pathways, is undergoing investigation for treatment of MF.[4,5]

## STUDY DESIGN

- Selinexor will be evaluated in a 2-arm, sequential, multicenter, open-label, Phase 2 study with corresponding optional expansion to evaluate efficacy in up to 118 JAKi treatment-naïve patients with MF and moderate thrombocytopenia.[6]

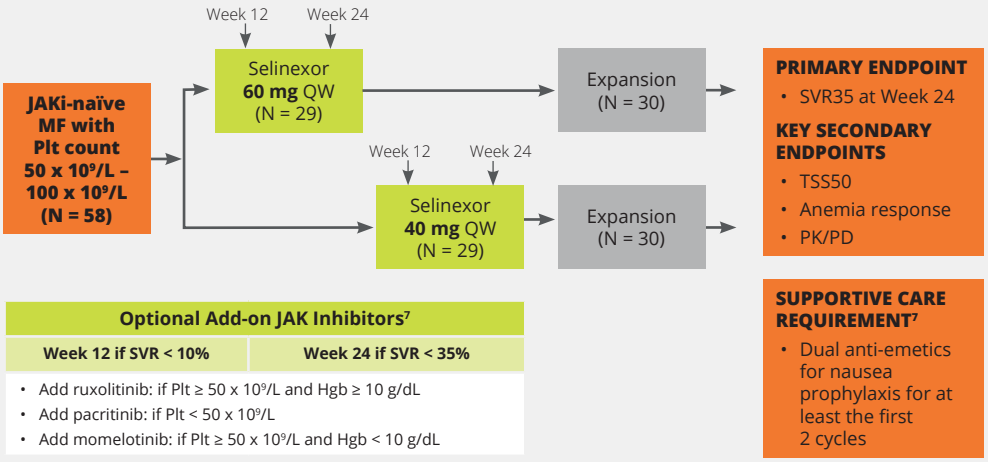
## SELECT STUDY OBJECTIVES

- To evaluate efficacy of selinexor monotherapy based on SVR[6]
- To evaluate the safety of selinexor[6]
- To evaluate the efficacy of selinexor based on TSS50[6]

## CONTACT

clinicaltrials@karyopharm.com

## TRIAL DESIGN




## SELECT INCLUSION CRITERIA[6]

- A diagnosis of primary MF or post ET or post-(PV) MF
- Measurable splenomegaly during the screening period as demonstrated by spleen volume of ≥ 450 $cm^3$ by MRI or CT scan
- DIPSS risk category of intermediate-1 with symptoms, intermediate-2, or high-risk
- ECOG PS ≤ 2
- Platelet count of 50 × $10^9$/L to 100 × $10^9$/L without platelet transfusion within 7 days prior to the first dose of the study drug
- Active symptoms of MF as determined by presence of at least 2 symptoms with a score ≥ 3 or total score of ≥ 10 at screening using the MFSAF V4.0

## SELECT EXCLUSION CRITERIA[6]

- > 10% blasts in peripheral blood or bone marrow (accelerated or blast phase)
- Previous treatment with JAKi for MF
- Previous treatment with selinexor or other XPO1 inhibitors
- Prior splenectomy or splenic radiation within 6 months prior to C1D1
- Participants unable to tolerate two forms of anti-emetics prior to each dose for the first two cycles, and the option to continue thereafter

**Scan here for more information on ClinicalTrials.gov**

C1D1, cycle 1 day 1; CT, computer topography; DIPSS, Dynamic International Prognostic Scoring System; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ET, essential thrombocytosis; Hgb, hemoglobin; JAK, Janus kinase; JAKi, Janus kinase inhibitor; MF, myelofibrosis; MFSAF, Myelofibrosis Symptom Assessment Form; MRI, magnetic resonance imaging; PD, pharmacodynamics; PK, pharmacokinetics; Plt, platelets; PV, polycythemia vera; QW, once a week; SVR35, spleen volume reduction ≥ 35%; TSS50, Proportion of patients with total symptom score reduction of ≥ 50%; XPO1, exportin-1.

**1.** Tefferi A. *Am J Hematol*. 2023;98(5):801–21. **2.** O'Sullivan JM, Harrison CN. *Clin Adv Hematol Oncol*. 2018;16(2):121–31. **3.** Sastow D, et al. *Clin Lymphoma Myeloma Leuk*. 2022;22(7):e507–20. **4.** Kashyap T, et al. *Oncotarget*. 2016;7(48):78883–95. **5.** Maloof M, et al. Poster presented at: the 15th International Congress for Myeloproliferative Neoplasms (MPN); November 2–3, 2023; Brooklyn, NY. **6.** ClinicalTrials.gov. NCT05980806. https://clinicaltrials.gov/ct2/show/NCT05980806 Accessed April 9, 2024. **7.** Karyopharm Therapeutics Inc. Clinical Study Protocol Version 2.0. XPORT-MF-044.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