XPORT-MF-044: A phase 2 study to evaluate the efficacy and safety of Selinexor monotherapy in subjects with JAK inhibitor-naïve myelofibrosis and moderate thrombocytopenia

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Sindromi MIELOPROLIFERATIVE CRONICHE target: myelofibrosis and moderate thrombocytopenia

Trattamento: Selinexor 60mg vs selinexor 40 mg

Criteri inclusione:

1) A diagnosis of primary MF, post-essential thrombocythemia (ET), or postpolycythemia vera (PV) MF according to the 2016 World Health Organization (WHO) classification of MPN confirmed by the most recent local pathology report
2) Measurable splenomegaly during the screening period as demonstrated by spleen volume of ≥450 cm3 by MRI or CT scan
3) Patients with DIPSS risk category of intermediate-1, or intermediate-2, or high-risk
4) Platelet count of 50 to <100 x 109 /L without platelet transfusion within 7 days prior to the first dose of selinexor
5) Absolute neutrophil count (ANC) ≥1.0 × 109/L
6) 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.
7) Patient currently not eligible for stem cell transplantation

Criteri esclusione:

1) More than 10% blasts in peripheral blood or bone marrow
2) Previous treatment with JAK inhibitors for MF