XPORT-MF-034: A Phase 1/3 study to evaluate efficacy and safety of Selinexor in combination with Ruxolitinib in treatment-naïve patients with myelofibrosis

Contatti: Daniela Cilloni daniela.cilloni@unito.it ; silvia.marini@unito.it 011 5082224

Sindromi MIELOPROLIFERATIVE CRONICHE target: Mielofibrosi

Trattamento: ruxolitinib+selinexor vs ruxolitinib+pacebo

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 ≥100 × 109/L without platelet transfusion
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