A.O. Ordine Mauriziano di Torino

Titolo:	A phase 3, randomized, open -label study of BET inhibitor INCB057643 versus Best Available therapy in participant with myelofibrosis previously treated with Jak inhibitor (BETR-MF2)
Codice studio	KRT-232-115
Patologia:	Mielofibrosi
Tipo di Studio:	Interventistico
Tipologia	Profit
Fase:	3
Principali criteri di inclusione:	Ruxolitinib rum-in period: • Confirmed diagnosis of PMF, post-PV MF, or post- ET MF • IPSS risk category of Intermediate-1, Intermediate- 2, or High • Spleen measuring ≥ 450 cm^3 by MRI or CT scan • MF symptoms as defined by a baseline TSS of ≥ 10. Baseline TSS will be calculated as a 7-day average per MFSAF v4.0 Randomized add-on period • PMF, post-PV MF, or post-ET MF that is *TP53*WT • Treatment with ruxolitinib monotherapy for ≥ 18 weeks but < 25 weeks, and on a stable dose of ruxolitinib in the 8 consecutive weeks prior to study treatment. • Suboptimal response to standard of care ruxolitinib monotherapy
Principali criteri di esclusione	Ruxolitinib run-in period • Prior therapy with any JAK inhibitor • Prior therapy with BCL-XL, BET, MDM2,PI3K, PIM or XP01 inibitors • Prior p53-directed therapy • Prior splenectomy Randomized add-on period • Eligible for allogeneic stem cell transplantation. Patients who are eligible for stem cell transplant but refuse transplant are not excluded • Peripheral blood or bone marrow blast count ≥ 10% at any time within • 28 days prior to the first dose of study treatment
Struttura	SCDU Ematologia e Terapie Cellulari
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