

Titolo:	A global multicenter, open label, randomized, phase 3 registrational study of olverembatinib (hqp1351) in patients with chronic phase chronic myeloid leukemia
Codice studio	POLARIS-2
	Leucemia Mieloide Cronica
Tipo di Studio:	Interventistico
Tipologia	Profit
Fase:	3
Principali criteri di inclusione:	• Diagnosis of CML-CP according to CML NCCN Guidelines version 1.2024 • Evidence of typical <i>BCR::ABL1</i> transcript • Peripheral blood myeloblasts < 15% • Peripheral blood myeloblasts and promyelocytes combined < 30% • Peripheral blood basophils < 20% • Platelet $\geq 50 \times 10^9/L$ • Failure or intolerance to the most recent TKI therapy at the time of screening • Only Part A: Prior treated with at least two approved TKIs • Only Part B: Previously treated with at least one approved TKIs and have T315I mutation at screening and there are no other effective and/or tolerable therapies available
Principali criteri di esclusione:	• Known prior diagnosed CML AP or BP • Previous treatment with a hematopoietic stem-cell transplantation • Plan to undergo allogeneic hematopoietic stem cell transplantation • Only Part A: T315I or V299L mutation
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