

Titolo:	Phase 3 Randomized, Double-Blind, Placebo-controlled Studies Assessing Ziftomenib in Combination with Either Standard of Care Nonintensive (Venetoclax+Azacitidine) or Intensive (7+3) Therapy in Patients with Untreated NPM1 Mutated or KMT2A Rearranged Acute Myeloid Leukemia
Codice studio	KO-MEN-17
Patologia:	Leucemia mieloide acuta
Tipo di Studio:	Interventistico
Tipologia	Profit
Fase:	3
Principali criteri di inclusione:	• Diagnosis of AML per the 2022 WHO Classification. • Creatinine clearance ≥ 30 mL/min • If the patient is a candidate for non-intensive therapy (VEN+AZA): Documented NPM1-m • If the patient is a candidate for intensive therapy (7+3): Documented NPM1-m or KMT2A-r (patient with a partial tandem duplication [PTD] are not eligible); Documented FLT3 wild-type or ITD ratio <0.05 OR ineligible to receive FLT3-targeted therapy
Principali criteri di esclusione:	• Diagnosis of either acute promyelocytic leukemia (APL), blast phase chronic myeloid leukemia, or isolated myeloid sarcoma • Known history of BCR-ABL mutation • Patient who has been previously treated (including chemotherapy, targeted drugs, monoclonal antibodies and investigational drugs, excluding supportive treatments and hydroxycarbamide) for hematologic disorders, such as AML or MDS
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