AOU Città della Salute e della Scienza di Torino – PO Molinette

Titolo:	A Phase 2, Open-label, Multicentre Study investigating tolerability and efficacy of gilteritinib in combination with fludarabine, cytarabine and idarubicin (FLAI) as induction therapy of Newly Diagnosed Non-M3 FLT3-positive Acute Myeloid Leukemia
Patologia:	AML
Tipo di Studio:	Open-label, multicentre
Fase:	2
Principali criteri di inclusione:	The patient is ≥ 18 and ≤65 years old The patient has an Eastern Cooperative Oncology Group (ECOG) performance score (PS) of 0 to 2 The patient has adequate baseline organ function, including cardiac, renal, and hepatic function: -Left ventricular ejection fraction (LVEF) ≥institutional lower limit of normal as measured by multigated acquisition (MUGA) scan or 2-dimensional (2-D) echocardiography (ECHO) within 21 days before start of therapy and no clinically significant abnormalities on a 12-lead electrocardiogram (ECG). -ECG: QTcF≤450 male ≤480 female -Serum creatinine ≤ 1.5 x ULN or an estimated glomerular filtration rate of > 50 mL/min as calculated by the Modification of Diet in Renal Disease equation -Bilirubin ≤3 times the upper limit of normal ULN mg/dL except for Gilbert's condition -Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤3 times the upper limit of normal (ULN)., except if due to leukemic involvement Patient is positive at diagnosis for FLT3 activating mutation in bone marrow or whole blood. Diagnosis of untreated AML according to WHO 2016, non-APL If the patient is a woman of childbearing potential (WOCBP), she must have a negative serum or urine pregnancy test at screening within 1 week before treatment. The patient (male and female) agrees to use two acceptable contraceptive methods for the duration of time

	on the study and continue to use acceptable contraceptive methods for 6 months after the end of treatment The patient has signed informed consent before initiation of any study-specific procedures or treatment The patient is able to adhere to the study visit schedule and other protocol requirements, including follow-up for survival assessment
Principali criteri di esclusione:	Patient has congestive heart failure New York Heart Association (NYHA) class 3 or 4 or patient with a history of congestive heart failure NYHA class 3 or 4 in the past, unless a screening echocardiogram performed within 1 month prior to study entry results in a left ventricular ejection fraction that is ≥ 45% Patient has an active uncontrolled infection. Patient has active human immunodeficiency virus infection. Patient has active hepatitis B or C or other active hepatic disorder. Chronic conditions previously cured or in active prophylaxis are allowed in the study Patient has infections, comorbidities or any disease, condition or alteration that per judgment of the investigator may be jeopardized by therapy Patients receiving any other investigational or commercial agents or therapies administered with the intention to treat their malignancy with the exception of Hydroxyurea (HU) or 6- Mercaptopurine (6MP) in patients who need to continue this agent to maintain WBC count ≤10,000/mm3. HU and 6MP must be discontinued at the time of initiation of study medications
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