GIMEMA ALL2420

A Phase 2, prospective, multi-center intervention trial in patients with acute myeloid leukemia secondary to myeloproliferative neoplasms unfit for intensive chemotherapy investigating a treatment combination including decitabine and venetoclax
ENABLE (vENetoclax plus decitAbine treatment in Blastic phase of myeLoproliferative nEoplasms)

Contatti: Eloise Beggiato ebeggiato@cittadellasalute.to.it 0116334279

Inclusion criteria:

1. Patients with AML secondary to myeloproliferative neoplasms (sAML), untreated, newly diagnosed, according to WHO 2016 criteria based on conventional cytological, cytogenetic, and immunophenotypic disease characterization
2. Patients ≥ 60 years or adult patients unfit for intensive treatment modalities at the discretion of the investigator.
3. ECOG performance status 0-2 or disease-related reversible ECOG 3 score following adequate supportive care.
4. Signed written informed consent according to ICH/EU/GCP and national local laws.
5. Males enrolled in the study with partners who are women of childbearing potential, must be willing to use an acceptable barrier contraceptive method during the trial. Males should use contraception for 3 months after the last dose of decitabine. Females should use contraception for 1 month after the last dose of venetoclax or 6 months after the last dose of decitabine, whichever comes later.

Exclusion criteria:

1. Diagnosis of *de novo* AML
2. Pre-existing, uncontrolled pathology such as heart failure (congestive/ischaemic, acute myocardial infarction within the past 3 months, untreatable arrhythmias, NYHA classes III and IV), sever liver disease with total bilirubin ≥2,5 x ULN and/or ALT>3 ULN (unless attributable to AML), acute or chronic pancreatitis, kidney function impairment with Creatinine Clearance (CrCl) level <30ml/min (calculated by Cockcroft Gault formula) (unless attributable to AML) and severe neuropsychiatric disorder that impairs