GIMEMA ALL 2418

A Phase IIA Study of Feasibility and Effectiveness of Inotuzumab Ozogamicin (IO) in Adult Patients with B-Cell Acute Lymphoblastic Leukemia with positive Minimal Residual Disease before any Hematopoietic Stem Cell Transplantation

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Trattamento: Inotuzumab

Sindromi target: acute lymphoblastic leukemia

Criteri Inclusione:

1. To be classified as having ALL according to WHO classification of haematological neoplasms, patients must have >20% blasts in bone marrow at the time of diagnosis.

2. Blasts at the diagnosis or in any timepoint had to be CD22+.

3. To have a measurable BCR-ABL1 fusion transcript (cohort 1) or a measurable IG/TCR specific rearrangement (cohort 2)

4. To have any measurable MRD positivity after at least

a. 3 months of therapy for Ph+ ALL, or the failure of at least 2nd line TKI (cohort 1)

b. 2 courses of therapy for Ph- ALL (cohort 2)

5. and to not have more than 5% of bone marrow blasts. Patients has to be in 1st or 2nd complete remission.

6. Patients ≥ 18 years old with no upper age limit.

7. Patients with a life expectancy >12 weeks

Criteri esclusione:

1. More than 5% of BM blasts

2. WHO performance status ≤ 50% (Karnofsky) or ≥ 3 (ECOG).

3. Active HBV or HCV hepatitis, or AST/ALT ≥ 2.5 x ULN and bilirubine ≥ 1.5 x ULN.

4. Evidence of liver fibrosis, portal hypertension or other clinically relevant liver abnormalities at screening liver ultrasonography

5. History of alcohol abuse.

6. Burkitt lymphoma and active CNS leukemia.

8. Uncontrolled hypertriglyceridemia (triglycerides >450 mg/dL).

9. Clinically significant, uncontrolled, or active cardiovascular disease