SELECT-AML-1

SYROS is currently investigating **tamibarotene, a selective oral RARα agonist,** in certain patients with **AML**

~30% of patients with AML are positive for *RARA* gene overexpression[1]

TRIAL INFORMATION

Tamibarotene plus venetoclax/azacitidine in patients with newly diagnosed AML who are positive for *RARA* overexpression

STUDY POPULATION / Patients with newly diagnosed unfit AML who are positive for *RARA* overexpression
STUDY TREATMENT / Patients randomized 1:1 to receive either tamibarotene + venetoclax/azacitidine or venetoclax/azacitidine

KEY STUDY CRITERIA /
Inclusion*:

1. *RARA*-positive, as determined by an investigational blood test for *RARA* overexpression
2. Must have newly diagnosed, previously untreated non-acute promyelocytic leukemia (APL) AML with a bone marrow or peripheral blood blast count ≥20% and be unlikely to tolerate standard intensive chemotherapy at the time of study entry due to age, performance status, or comorbidities based on at least one of the following criteria:
   - Age ≥75 years old
   - Age <75 years old, with ≥1 of the following:
     - ECOG performance status of 3
     - cardiac history of CHF or documented EF ≤50%
     - pulmonary disease with DLCO ≤65% or FEV1 ≤65%
     - creatinine clearance ≥30 mL/min to <45 mL/min per Cockcroft-Gault estimation
     - hepatic impairment with total bilirubin >1.5 to ≤3.0 ULN
     - any other comorbidity that the investigator judges to be incompatible with intensive chemotherapy

Exclusion*:

1. Has APL
2. Has known active central nervous system involvement with AML
3. Prior treatment for the diagnosis of AML, MDS, or antecedent hematologic malignancy with any hypomethylating agent, venetoclax, chemotherapy, or HSCT, with the exception of prior treatment with hydroxyurea

PRIMARY ENDPOINT / CR/CRi
SECONDARY ENDPOINTS / AEs, CR, CR/CRh, DOCR, DOCR/CRi, DOCR/CRh, TTCR, TTCR/CRi, TTCR/CRh, ORR, plasma concentration of tamibarotene

ClinicalTrials.gov Identifier: NCT04905407

Tamibarotene is an investigational therapy and is not approved for use in any indication in the U.S. or Europe.

REQUEST TRIAL DETAILS

*Additional criteria apply.

AE, adverse event; AML, acute myeloid leukemia; APL, acute promyelocytic leukemia; CHF, congestive heart failure; CR, complete remission; CRh, complete remission with partial hematologic recovery; CRi, complete remission with incomplete count recovery; DOCR, duration of complete remission; DLCO, diffusing capacity of the lungs for carbon monoxide; ECOG, Eastern Cooperative Oncology Group; HSCT, hematopoietic stem cell transplantation; ORR, overall response rate; RARα, retinoic acid receptor alpha; TTCR, time to complete remission; ULN, upper limit of normal.

Reference: 1. Clinical Study SY-1425-201 Protocol. Syros Pharmaceuticals, Inc.

SYROS