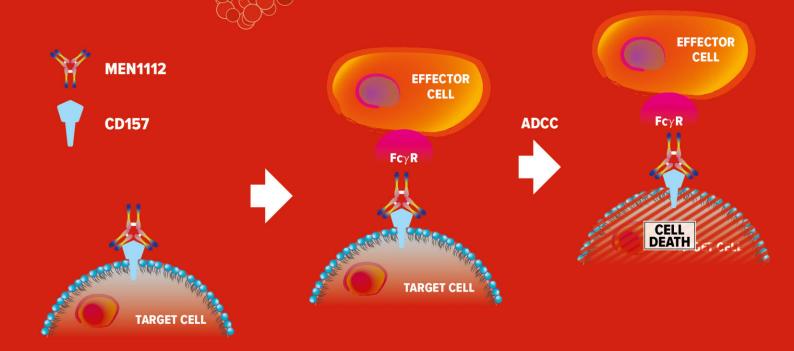


MEN1112, developed in the collaboration between Menarini and Oxford BioTherapeutics, is a defucosylated humanized monoclonal antibody specific for the receptor CD157, in clinical development for the Acute Myeloid Leukemia



MEN 1112

AML is an aggressive and frequently lethal hematologic malignancy, with a median age of presentation beyond the sixth decade. The age-adjusted incidence rate of AML in the US has been described as 3.4 in 100,000 and in Europe its incidence has been observed at approximately 5-8 per 100,000. In the Western world, AML accounts for a quarter of all leukemias in adults, making it the most common form of leukemia in these areas.

CTR

1K

600

200

38C-H

100

100

101

102

103

104

ENAST CELLS (0.57%)

MEN1112

1K

800

200

98C-M2

200

0,13333

0,13333

BLAST CELLS (0.13%)

Regardless specific prognostic factors, the overall 5-year survival for patients with AML is 25%, 40% for patients under age 60 years, and 10% for patients over age 60 years. Remission is achieved in the majority of patients, but relapse is common, particularly in older patients.

The target CD157 is highly expressed both at primary diagnosis and at relapse.

MEN1112 has demontrated promising ex-vivo blast depletion in AML peripheral blood samples.



"First in Man Study With **MEN1112**, a CD157 Targeted Monoclonal Antibody, in Relapsed or Refractory Acute Myeloid Leukemia" NCT02353143

This trial is designed as an open label, non randomised, dose escalation and cohort expansion, first administration to human study to be conducted in Europe.

The study is aiming to identify the Dose Limiting Toxicity (DLT) and Maximum Tolerated Dose (MTD), to assess the pharmacokinetics and to determine the clinical activity and potential immunogenicity of **MEN1112**, administered in patients with relapsed/refractory acute myeloid leukemia (AML).

