

Press Release

# Acticor Biotech Announces the Completion of Enrollment in ACTIMIS, its Key Phase 1b/2a Safety Study

Paris, July 1st, 2021 – Acticor Biotech, a clinical stage biotechnology company involved in the acute phase of thrombotic diseases, today announces the end of recruitment in ACTIMIS, its phase 1b/2a study with glenzocimab (ACT017), a novel humanized monoclonal antibody fragment for use in patients with acute ischemic stroke.

ACTIMIS (NCT03803007) is a multinational, multicenter, randomized, double-blind, placebo-controlled, single-parallel, escalating dose phase 1b/2a safety and efficacy study of glenzocimab used as an add-on to standard of care therapy for acute ischemic stroke.

"We are proud to have completed patient recruitment for phase 1b/2a of the ACTIMIS study in Acute Ischemic Stroke with glenzocimab. This is a novel first-in-class treatment in this indication, which inhibits GPVI without increasing the risk of bleeding, and thus a source of new perspectives in the field. The development of several other drug candidates has failed in recent years, mainly due to safety concerns that included excessive bleeding risks. We are particularly grateful to all the investigators who have coped with such fast-paced recruitment despite the current COVID-19 pandemic. We would also like to seize this opportunity to applaud all healthcare providers who have stepped up during the pandemic to serve their patients." says Prof. Mikael Mazighi, M.D., Ph.D., Coordinating Investigator for ACTIMIS.

In September 2020, Acticor Biotech had announced that the Target Dose of 1000mg in the first 60 patients of the study had been reached and this was confirmed by the Drug Safety Monitoring Board (DSMB).

**The primary objective** of this additional 100-patient group randomized to either 1000mg glenzocimab or its matching placebo was to evaluate the safety of glenzocimab as an add-on to thrombolysis alone or thrombolysis plus thrombectomy.

Six countries (France, Spain, Belgium, Germany, Switzerland and Italy) have actively participated in including a total of 166 patients for the ACTIMIS trial. No safety issues have so far been detected by the Drug Safety Monitoring Board (DSMB) at any point during this study.

## About glenzocimab (ACT017), the Therapeutic Candidate

Acticor is developing glenzocimab (ACT017), a humanized monoclonal antibody fragment (Fab). This therapeutic candidate is directed against a novel target of major interest, platelet glycoprotein VI (GPVI), and inhibits its action. Evidence of the antithrombotic efficacy of glenzocimab and the safety of its inhibition of GPVI has been established both *ex vivo* and *in* 



*vivo*. This target is involved in growth of the thrombus but not in physiological hemostasis, which thus limits the bleeding risk associated with its inhibition.

https://acticor-biotech.com/ourproduct

## About glenzocimab and COVID-19

Glenzocimab is also being assessed as a treatment for Acute Respiratory Distress Syndrome in COVID-19-infected patients (SARS-Cov-2) to contain the contribution of platelets to uncontrolled lung inflammation and thus prevent downstream complications due to prothrombotic conditions without inducing bleeding.

The primary objective of GARDEN (NCT04659109) - <u>G</u>lenzocimab in SARS-Cov-2 <u>A</u>cute <u>Respiratory DistrEss</u> sy<u>N</u>drome study is to evaluate the effect of glenzocimab in preventing the clinical progression of disease when added to standard of care in COVID-19 patients presenting with Acute Respiratory Distress Syndrome.

#### **About Acticor Biotech**

Acticor Biotech is a clinical stage biotechnology company, a spin-off of INSERM, dedicated to developing an innovative treatment for acute thrombotic diseases, including ischemic stroke. Acticor Biotech has been built on the expertise and research conducted by the co-founders: Dr. Martine Jandrot-Perrus at INSERM Paris and Prof. Philippe Billiald at Paris-Sud University.

Acticor Biotech is a partner in the BOOSTER consortium, dedicated to the management of, and new treatments for, cerebrovascular accidents in emergency situations.

Acticor Biotech is backed by a syndicate of European and International investors: Karista, Go Capital, Newton Biocapital, CMS Ventures, Mirae Asset Capital, Anaxago, Primer Capital, Mediolanum farmaceutici & Armesa Foundation.

For more information, go to: <a href="https://acticor-biotech.com/">https://acticor-biotech.com/</a>

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