Press Release

Acticor Biotech Announces the First Patient in ACTISAVE, its adaptive Phase 2/3 Efficacy Study in Acute Ischemic Stroke

Paris, October 13, 2021 – Acticor Biotech, a clinical stage biotechnology company working on treatment for the acute phase of thrombotic diseases, today announces that it started at the end of September 2021 the recruitment in ACTISAVE, its international phase 2/3 adaptive study on glenzocimab (ACT017), a novel humanized monoclonal antibody fragment for use in patients with acute ischemic stroke.

ACTISAVE (NCT05070260) is an adaptive phase 2/3, multinational, randomized, double-blind, multicenter, placebo-controlled, parallel group, single dose, efficacy and safety study of glenzocimab used as an add-on to standard of care therapy for acute ischemic stroke.

"We are very excited to have included the first patient in ACTISAVE, the new adaptive phase 2/3 study in Acute Ischemic Stroke using glenzocimab. Favourable safety and bounding of the bleeding risk shown in the first part of the ACTIMIS dose escalating study support the potential of this novel first-in-class treatment in AIS. I am particularly grateful to my team at Pellegrin Hospital in Bordeaux – France for working with such dedication in the context of COVID-19." says Prof. Igor Sibon, *Pellegrin Hospital in Bordeaux*, Coordinating Investigator in France for ACTISAVE.

The primary objective of ACTISAVE, where patients are randomized to either 1000mg glenzocimab or its matching placebo, is to evaluate the efficacy of glenzocimab in addition to standard of care, thrombolysis only or thrombolysis plus thrombectomy, with specific focus on the modified Rankin Scale score (mRS) at Day 90. Eight countries will be involved in including a total of 1000 patients. An initial futility analysis is planned after 200 patients have been enrolled.

In July 2021, Acticor Biotech announced the end of recruitment for ACTIMIS, its phase 1b/2a dose escalation and safety study in 160 patients (NCT03803007); the target dose of 1000mg was reached and confirmed by the Drug Safety Monitoring Board (DSMB). No safety issues were detected by the DSMB at any point during this study. The complete results of ACTIMIS are expected by the first quarter 2022.

About glenzocimab (ACT017), the Therapeutic Candidate

Acticor Biotech 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 pro-thrombotic conditions without inducing unwanted bleeding.

The primary objective of GARDEN (NCT04659109) - **G**lenzocimab in SARS-Cov-2 **A**cute **R**espiratory **D**istr**E**ss sy**N**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. By July 2021, the 62 patients had been enrolled in the study and complete results are expected by the first quarter 2022.

Availability of Acticor Biotech registration document

The registration document of Acticor Biotech approved by the AMF on September 27, 2021 under number I.21-054, is available on the Company's website (www.acticor-biotech.com) and on the AMF website (www.amf-france.org). It is also available free of charge, upon request, at the Company's registered office, 46 rue Henri Huchard, Bâtiment INSERM U698HP Bichat, 75877 Paris cedex 18. The public's attention is drawn to chapter 3 "Risk Factors" of the registration document.

About Acticor Biotech

Acticor Biotech is a clinical stage biotechnology company, a spin-off of INSERM (the French National Institute of Health and Medical Research), dedicated to developing an innovative treatment for cardiovascular emergencies, including ischemic stroke. Acticor Biotech has been built on the expertise and research undertaken by its co-founders: Dr. Martine Jandrot-Perrus at INSERM Paris and Prof. Philippe Billiald at Paris-Sud University and Dr Gilles Avenard.

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

Acticor Biotech is supported by a panel 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: https://acticor-biotech.com/

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