PRESS RELEASE

Acticor Biotech announces the enrollment of the first US patient in its Phase 2/3 study ACTISAVE for the treatment of stroke

Paris, France, September 26, 2022 – 06:00pm CEST - ACTICOR BIOTECH (ISIN: FR0014005OJ5 - ALACT), a clinical-stage biotechnology company developing innovative drugs for the treatment of cardiovascular emergencies, particularly stroke, today announced the enrollment of the first patient in the USA in its Phase 2/3 registration study ACTISAVE, which is evaluating glenzocimab in patients with acute ischemic stroke.

This first US patient was enrolled at the CHI Memorial Stroke and Neuroscience Center, Chattanooga, Tennessee, by **Dr. Ruchir A. Shah, MD, Neurologist who said**: *"I am very happy with this first patient inclusion in the United States in ACTISAVE study. Glenzocimab has significant potential for improvement in patients with ischemic stroke, especially those undergoing mechanical thrombectomy. We urgently need new drugs in this indication, and glenzocimab presents an innovative and promising mechanism of action on recanalization and on the downstream microcirculation. Chattanooga CHI Memorial is a state-of-the-art stroke unit that receives 1,400 stroke patients per year in unprecedented medical conditions, with a large part given to research. "*

ACTICOR had obtained an IND[1] for this study from the U.S. Food and Drug Administration (FDA) in November 2021 and had initiated enrollment in Europe in the third quarter of 2021. To date, the study has enrolled 130 patients.

The clinical trial is planned for 1,000 patients treated at approximately 80 centers in the USA, Europe (France, Germany, Belgium, Spain, Slovakia, Denmark, Czech Republic), Great Britain and Israel. A first futility analysis is planned after the inclusion of the first 200 patients to confirm the initial hypotheses.

Dr. Yannick PLETAN, Chief Operating Officer, and Chief Medical Officer of Acticor Biotech added: *"The opening of the first U.S. centers, in addition to those already active in Europe, marks another important milestone for our ACTISAVE Phase 2/3 study. The cumulative incidence of ischemic stroke in the USA, Europe, Japan, and China will approach 4 million patients by 2026[2], highlighting the urgent need for an effective treatment to address this major public health problem with a strong societal and economic impact."*

In July 2022, Acticor Biotech was granted Priority Medicines (PRIME) status by the European Medicines Agency for glenzocimab in the treatment of stroke, recognizing the potential clinical benefit of glenzocimab and its relevance to the unmet medical need in this disease. Because efficacy data were a secondary endpoint of the Phase 1b/2a ACTIMIS study, glenzocimab was not eligible for Breakthrough Therapy status despite significant data on mortality and reduction of cerebral hemorrhage. Nevertheless, these data and the inclusion of patients in the USA will allow Acticor Biotech to apply for Fast Track status with the FDA in the coming weeks.

[1] *Investigational New Drug Application*

[2] *Global data AIS Epidemiology forecast to 2022*

About ACTISAVE

ACTISAVE (NCT05070260) is a multinational, adaptive, multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 2/3 study evaluating the safety and efficacy of a single dose of glenzocimab used in combination with standard of care (thrombolysis +/- thrombectomy) for acute ischemic stroke.

About ACTICOR BIOTECH

Acticor Biotech is a clinical stage biopharmaceutical company, a spin-off from INSERM (the French National Institute of Health and Medical Research), which is aiming to develop an innovative treatment for cardiovascular emergencies, including ischemic stroke.

Acticor Biotech is developing glenzocimab (ACT017), a humanized monoclonal antibody (mAb) fragment directed against a novel target of major interest, platelet glycoprotein VI (GPVI). Glenzocimab inhibits platelet binding to the thrombus without affecting physiological hemostasis, thereby limiting the bleeding risk, particularly in the brain.

In May 2022, Acticor Biotech presented positive results from its Phase 1b/2a study, ACTIMIS, at the ESOC, confirming the safety profile and showing a reduction in mortality and intracerebral hemorrhage in the glenzocimab-treated group in patients with stroke. The efficacy of glenzocimab is now being evaluated in an international Phase 2/3 study, ACTISAVE, which will include 1,000 patients. In July 2022, Acticor Biotech was granted "PRIME" status by the European Medicines Agency (EMA) for glenzocimab in the treatment of stroke. This designation will allow the company to strengthen its interactions and obtain early dialogues with regulatory authorities.

Acticor Biotech is supported by a panel of European and international investors (Karista, Go Capital, Newton Biocapital, CMS Medical Venture Investment (HK) Limited, A&B (HK) Limited, Mirae Asset Capital, Anaxago, Primer Capital, Mediolanum farmaceutici and the Armesa foundation). Acticor Biotech is listed on Euronext Growth Paris since November 2021 (ISIN: FR0014005OJ5 – ALACT).

For more information, visit: www.acticor-biotech.com

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