

Acticor Biotech Announces FDA Acceptance of IND Application for glenzocimab in Acute Ischemic Stroke

Paris, France, November 4, 2021 at 06:30 pm CET – ACTICOR BIOTECH (ISIN: FR00140050J5 – ALACT), a clinical stage biotechnology company involved in the acute phase of thrombotic diseases, today announces that the U.S Food and Drug Administration (FDA) has provided clearance for the initiation of a clinical trial in US with glenzocimab, a novel humanized monoclonal antibody fragment, for use in patients with acute ischemic stroke.

This active IND represents a significant milestone and marks the launch in the US of the Phase 2/3 clinical trial with glenzocimab in acute ischemic stroke as an add-on therapy to standard of care for this indication.

“The development of new therapeutic options for the treatment of the acute phase of ischemic stroke without increasing the bleeding risk, is a major medical need of the coming years. The FDA acceptance of an IND application for glenzocimab and the clinical program that will be conducted by Acticor Biotech in the US constitute important steps to offer new safe treatments to stroke patients” says **Pr. James Grotta, M.D., Memorial Hermann Hospital, Texas Medical Center, Global Coordinating Investigator for ACTISAVE.**

“We are very pleased with the achievement of this milestone which materializes our clinical objective stated at the time of our IPO which took place a few days ago, to enroll a first US patient in Q1 2022, following the enrollment of a first patient in Europe at the end of September 2021” concluded **Gilles Avenard, Chief Executive Officer of Acticor Biotech.**

ACTISAVE (NCT05070260) is an adaptive Phase 2/3 multinational, randomized, double-blind, multicenter, placebo-controlled, parallel group, single dose, efficacy and safety study, where patients are randomized to either 1000mg glenzocimab or its matching placebo. Its primary objective **is to evaluate the efficacy of glenzocimab** in addition to standard of care, thrombolysis only or thrombolysis plus thrombectomy, with specific focus on the Day 90 modified Rankin Scale score (mRS), for acute ischemic stroke.

Started at the end of September 2021 in Europe, ACTISAVE follows the end of recruitment of ACTIMIS study, a phase 1b/2a dose escalation and safety study in 160 patients (NCT03803007), that permitted the selection of the recommended dose of 1000 mg and the confirmation of the favorable safety profile of glenzocimab (complete results are expected by the first quarter of 2022). Eight countries are expected to be involved with a total of 1000 patients. An initial futility analysis is planned after 200 patients have been enrolled.

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 (ARDS) 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 bleeding. The primary objective of GARDEN (NCT04659109) 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 ARDS. In July 2021, the 60 patients of the study have been enrolled and complete results are expected by the first quarter 2022.

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), that is developing an innovative treatment for acute thrombotic diseases, including ischemic strokes.

At the end of October 2021, Acticor biotech has been awarded the prix Galien Medstartup Award in the category “best collaboration in the pharmaceutical or biotechnology industry” for its collaboration with Pr James Grotta at the Memorial Hermann Hospital, TX.

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 since November 2021 (ISIN: FR00140050J5 – ALACT).

For further information, please go to www.acticor-biotech.com

Contacts

ACTICOR BIOTECH
Gilles AVENARD, M.D.
CEO and Founder
gilles.avenard@acticor-biotech.com

Sophie BINAY, PhD
General Manager and CSO
Sophie.binay@acticor-biotech.com

NewCap
Mathilde BOHIN / Olivier BRICAUD
Investor Relations
acticor@newcap.eu
Tel.: +33 (0)1 44 71 94 95

NewCap
Annie-Florence LOYER
Media Relations
afloyer@newcap.fr
Tel.: +33 (0)1 44 71 00 12

Forward-Looking Statements

Certain information included in this press release are not historical facts but are forward-looking statements. These forward-looking statements are based on current beliefs, expectations and assumptions, including,

without limitation, assumptions regarding present and future strategy of Acticor Biotech and the environment in which Acticor Biotech operates, and involve known and unknown risks, uncertainties and other factors, which may cause actual results, performance or achievements, or industry results or other events, to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include those set out and detailed in Chapter 3 “Risk Factors” of the registration document of Acticor Biotech which was approved by the French *Autorité des marchés financiers* on September 27, 2021 under number I.21-054.

Forward-looking statements speak only as of the date of this press release and Acticor Biotech expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements included in this press release to reflect any change in expectations or any change in events, conditions or circumstances on which these forward-looking statements are based. Forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Acticor Biotech. Actual results could differ materially from those expressed in, or implied or projected by, forward-looking information and statements.