PRESS RELEASE

Update on Acticor Biotech's clinical developments with glenzocimab in the treatment of cardiovascular emergencies

- **Enrollment of the 200th patient in the ACTISAVE study**
- **Initiation of patient enrollment in the GREEN Phase 2/3 study in stroke**
- **Update on the clinical evaluation of glenzocimab in stroke and myocardial infarction**

Paris, France, January 09, 2023 – 06:00pm CET - ACTICOR BIOTECH (ISIN: FR0014005OJ5 - ALACT), a clinical-stage biotechnology company focused on the development of innovative drugs for the treatment of cardiovascular emergencies, in particular stroke, today provides an update on the progress of its clinical programs with glenzocimab, its lead drug candidate.

Gilles AVENARD, Chief Executive Officer and co-founder of Acticor Biotech, said: *"The beginning of this year is an opportunity to review the progress of our clinical program portfolio, which has reached crucial milestones since our IPO a little over a year ago. Our clinical and regulatory development teams have done a remarkable job, particularly in discussions with the European regulatory authorities (EMA) for our Phase 2/3 study ACTISAVE, in order to advance the preparation of a marketing authorization application for glenzocimab in stroke. We have fully met our patient enrollment goals in 2022 and are involving new countries and hospitals in 2023. We are proud that the enrollment of patients in the Phase 2/3 GREEN study, promoted by the AP-HP in the framework of the RHU BOOSTER, has started. We look forward to continuing the clinical development of glenzocimab in the treatment of myocardial infarction in partnership with the University of Birmingham (UK). We will keep up our efforts to provide a therapeutic solution to this unmet medical need in cardiovascular emergencies."*

1) ACTISAVE: Phase 2/3 clinical study in stroke

Study design and regulatory discussions

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. The study is being conducted in 7 European countries, UK, Israel, and the USA.

The European Medicines Agency (EMA) approved the adaptive design strategy and validated the choice of a dual primary endpoint: an ordinal endpoint of the difference between the Modified Rankin Scale (mRS)[1] and a binary endpoint of the percentage of patients with severe disability or death, i.e. an mRS score of 4-6. The recognition of this pivotal study design supports a future application for marketing authorization for glenzocimab in stroke in Europe.

[1] *7-point ordinal scale (categories 0 to 6) to measure the degree of disability of a person who has had a stroke*

In the context of the "PRIME" status received in July 2022, a program aimed at optimizing the development plan to speed up patient access to the drug candidate, the company is continuing its interactions with the EMA.

In the United States, discussions are underway with the American regulatory agency (FDA) to set up a Type C meeting to validate the design and statistical analysis of the study in support of a future Biologic License Application (BLA) in the United States. An amendment to the study protocol allowing the use of the two recognized thrombolytic agents in stroke management, tenecteplase (TNK) and alteplase, was submitted to the FDA in November 2022, and is awaiting approval by the Ethics Review Board (IRB). Two patients have been enrolled to date. This amendment should accelerate enrollment, given the massive use of TNK in U.S. hospitals.

Number of patients recruited to date: 203 patients.

Next clinical step: an initial futility analysis is planned when 100 patients will be enrolled with thrombolysis + thrombectomy, treated and followed for 90 days to confirm the safety of the study and ensure that the preliminary results are consistent with the original trial assumptions. Results of this futility study are expected in the 3rd quarter 2023.

2) GREEN: Phase 2/3 clinical trial in stroke

Study design

GREEN (NCT05559398) is a randomized, double-blind, multicenter, placebo-controlled Phase 2/3 study of the efficacy and safety of glenzocimab as an adjunct to mechanical thrombectomy in acute ischemic stroke. The GREEN study is conducted under the auspices of the Paris Public Hospitals (*Assistance Publique – Hôpitaux de Paris*), and is part of the RHU BOOSTER, receiving financial support from the French National Research Agency (*Agence Nationale de la Recherche*) and the Government's 'Investments for the Future' program (*Programme Investissements d'Avenir*).

The primary objective of this study is to evaluate the efficacy of glenzocimab in combination with endovascular thrombectomy (EVT) versus EVT alone on 90-day functional outcome (mRS). Secondary objectives are to evaluate the impact of glenzocimab on overall survival, reperfusion, clinical improvement at 24 hours, symptomatic and asymptomatic intracerebral hemorrhage, serious adverse events (SAEs), serious unexpected adverse events (SUSARs) and quality of life. This study will include nearly 260 patients eligible for mechanical thrombectomy in 11 French neurovascular units and institutions of excellence.

Number of patients recruited to date: 1 patient.

Next clinical step: an interim analysis will be performed after the first 78 patients are included and is expected end of 2023.

3) LIBERATE: Phase 2b clinical trial in the treatment of myocardial infarction

Study design

LIBERATE (IRAS -1005400) is a randomized, double-blind, Phase 2b study that will include more than 200 patients in the acute phase of myocardial infarction to test the safety and efficacy of glenzocimab 1000 mg versus placebo in reducing cardiac damage remote from the infarction. This study is being conducted in partnership with the University of Birmingham (UK), with expert clinicians from the Institute of Cardiovascular Sciences and University Hospitals Birmingham NHS Foundation Trust.

Current status of the study: file being submitted to the UK regulatory authorities.

Next clinical step: Inclusion of the first patient planned for the second quarter of 2023.

4) Other indications for cardiovascular emergencies

At this stage of development, Acticor Biotech has decided to focus its efforts on the development of glenzocimab in stroke and myocardial infarction with three ongoing studies (ACTISAVE, GREEN and LIBERATE) and to postpone the launch of its Phase 2 study, BREATHE in pulmonary embolism.

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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