PRESS RELEASE

Acticor Biotech obtains "PRIME" status from the European Medicines Agency for glenzocimab in the treatment of stroke

- **Strengthening discussions with regulatory authorities to accelerate the clinical development of glenzocimab for its potential benefit in the treatment of stroke**

- **87 patients already enrolled in Europe in the ACTISAVE Phase 2/3 registration study in stroke patients**

Paris, France, July 21, 2022 - 7:00 PM CEST - ACTICOR BIOTECH (ISIN: FR0014005OJ5 - ALACT), a clinical-stage biotechnology company developing innovative drugs for the treatment of cardiovascular emergencies, in particular stroke, announced today that it has received "PRIority Medicines" status from the European Medicines Agency (EMA) for its drug candidate, glenzocimab, for the treatment of patients with stroke.

The "PRIME" status granted by the European Medicines Agency (EMA) allows to reinforce the support for the development of drugs that target an unmet medical need. This status will allow Acticor Biotech to strengthen interactions and obtain early dialogues with regulatory authorities in order to confirm the clinical development plan for glenzocimab in the treatment of stroke.

Glenzocimab is currently being evaluated in the Phase 2/3 registration ACTISAVE study in stroke patients. This study started in Q3 2021, with the inclusion of the first patient in Europe. In parallel, ACTICOR had obtained an IND for this study from the U.S. *Food and Drug Administration* (FDA) in November 2021. To date, 87 patients have already been enrolled in Europe.

A total of 1,000 patients will be included in the United States and Europe. An interim futility analysis is planned after inclusion of the first 200 patients to confirm the baseline hypotheses.

Yannick Pletan, General Manager & CMO of Acticor Biotech, said: *"We are delighted that the European Medicines Agency has granted "PRIME" status to glenzocimab. This designation is both a recognition of the significant unmet medical need for stroke and a validation of the relevance of the positive clinical results of our Phase 1b/2a ACTIMIS study with glenzocimab in stroke patients. We will now be able to more easily pursue our discussions with regulatory authorities and ensure the smooth continuation of the ACTISAVE Phase 2/3 clinical trial, conducted in the United States and in Europe. To date, 87 patients have already been enrolled across Europe, which is perfectly in line with our theoretical inclusion curve. The good recruitment momentum in this study will lead, as previously announced, to the interim futility analysis, scheduled after the inclusion of the 200 patients, in the first half of 2023."*

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.

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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