PRESS RELEASE

Acticor Biotech: progress in discussions with EU and US Regulatory Agencies

- **The FDA has provided valuable feedback to reinforce the proposed clinical development plan of glenzocimab in acute ischemic stroke (AIS)**
- **A new Type C consultation with the FDA has been granted on the pharmaceutical development plan**
- **In Europe additional scientific advice requests under the PRIME program have been validated by the EMA**
- **In ACTISAVE study, 300 patients have already been recruited and 100 patients have been treated with thrombolysis and thrombectomy, reaching the target for the first futility analysis.**

Paris, France, May 30, 2023 – 06:30pm CEST - Acticor Biotech, (ISIN: FR0014005OJ5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, is discussing with the FDA and the EMA its development program for the acute ischemic stroke (AIS) indication.

In the US, Acticor Biotech was granted FDA Type C consultation on its non-clinical and clinical developments for its first-in-class drug candidate, glenzocimab. Written responses were received by the end of May 2023 on a list of questions regarding potential future marketing authorization (BLA) of glenzocimab in AIS indication. The FDA provided valuable feedback to reinforce the proposed development plan and to best address US requirements on the expected design of a pivotal study. These recommendations will be evaluated in an aim to adjust some parameters of the ongoing ACTISAVE study, taking into account both US and EU opinions to propose a single acceptable development plan up to registration.

In parallel, a new FDA Type C consultation was granted on the pharmaceutical development with written answers expected by end of July 2023.

In Europe, Acticor continues to discuss the clinical and pharmaceutical developments for registration with the EMA as part of the PRIME designation program. Additional scientific advice requests under this program have been validated by the EMA including the pharmaceutical development plan.

As a reminder, the positive results of the ACTIMIS phase 1b/2a clinical trial evaluating glenzocimab in combination with the reference treatment (thrombolysis with or without thrombectomy) in patients presenting with AIS demonstrated glenzocimab very favorable safety profile by meeting the primary end-point of the trial, as well as by showing a significant reduction in the number of intracerebral hemorrhages and mortality in the group treated with glenzocimab.

To date, the ACTISAVE study has enrolled more than 300 patients across 10 countries in the world. Out of them, 100 have been treated with thrombolysis with thrombectomy, reaching the target for the first futility analysis. The Independent Data Meeting Committee (IDMC) will gather in Q4 2023 to confirm safety and ascertain that preliminary results are aligned with the initial trial assumptions.

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.

The positive results from its Phase 1b/2a study, ACTIMIS, confirmed the safety profile and showed 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 (Mediolanum farmaceutici, Karista, Go Capital, Newton Biocapital, CMS Medical Venture Investment (HK) Limited, A&B (HK) Limited, Anaxago, 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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