PRESS RELEASE

Acticor Biotech has just and timely completed patient recruitment of its phase 2/3 study in stroke

- **438 patients with stroke have been randomized in ACTISAVE study evaluating glenzocimab, in the United-States, Europe, Israel and United Kingdom**

- **Confirmation of clinical results communication for the second quarter 2024**

Paris, France, November 07, 2023 - 08h00 CET - ACTICOR BIOTECH (FR0014005OJ5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, today announces the timely completion of enrollment in the ACTISAVE Phase 2/3 clinical trial in patients with acute ischemic stroke (AIS).

Gilles Avenard, General Manager of Acticor Biotech, declares: *« We are pleased with the completion of the enrollment of our clinical study evaluating the efficacy of glenzocimab in 438 stroke patients exactly on schedule. We eagerly anticipate sharing the outcomes of this world-class study in the second quarter of 2024. This achievement bolsters our commitment to delivering an innovative drug for the treatment of cardiovascular emergencies, that is strengthened, moving forward at every milestone of development plan execution. »*

Adeline Meilhoc, Head of Global Clinical Development of Acticor Biotech, says: *« We extend our heartfelt gratitude to the patients and their families, as well as medical teams at about 70 clinical centers around the world for supporting this extraordinary study. The pace of recruitment and the quality of the data fill us with immense pride for our dedicated project teams, who were able to stay the course despite the constraints associated with conducting a trial in a medical emergency and the international context. All have already expressed their willingness to participate in the development of glenzocimab in future trials. »*

ACTISAVE (NCT05070260) is an international, 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 the standard of care (thrombolysis +/- thrombectomy) for acute ischemic stroke. Deployed in the United States, Europe, Israel, and United Kingdom, ACTISAVE has enrolled 438 patients, of whom about 40% have undergone mechanical thrombectomy.

As a reminder, following consultations with the European (EMA) and American (FDA) regulatory agencies, and in agreement with ACTISAVE Scientific Committee, Acticor Biotech decided in September 2023 to change the main endpoint of the study by retaining only one single endpoint, namely the reduction in the number of patients who died or suffered from severe disability as a result of AIS (mRS score 4-6 at 90 days).

As previously announced, phase 2/3 clinical results are expected in the second quarter of 2024.

Based on these results and the recommendations of international experts in stroke, Acticor Biotech plans to consult again with the EMA and the FDA in 2024 to confirm that the Phase 3 design will support final registration in both Europe and the United States, envisaged by 2028 at the latest.

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 of the phase 1b/2a study, ACTIMIS, confirmed the safety profile of glenzocimab and showed a reduction in mortality and intracerebral hemorrhage in the glenzocimab-treated group of stroke patients. The efficacy of glenzocimab is now being analyzed in an international Phase 2/3 study, ACTISAVE, with clinical results expected in Q2 2024.

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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