PRESS RELEASE

ACTICOR adapts its ACTISAVE clinical study to prepare the registration of glenzocimab for the treatment of stroke

- **Clinical results from ACTISAVE phase 2/3 study now expected in the second quarter of 2024**

- **Optimised development plan to register glenzocimab in Europe and the United States projected no later than 2028**

Paris, France, September 14, 2023 - 5.45 pm CEST - Acticor Biotech, (ISIN: FR0014005OJ5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, announced today its optimised development plan for Acute Ischemic Stroke (AIS) to register glenzocimab in Europe and the United States.

ACTISAVE (NCT05070260) is an international phase 2/3 study, adaptive, multicentre, randomised, double-blind, placebo-controlled, parallel-group evaluating the safety and efficacy of a single dose of glenzocimab used in combination with the reference treatment (thrombolysis with or without mechanical thrombectomy) for acute ischaemic stroke.

After consultation with the European (EMA) and US (FDA) regulatory agencies, in agreement with ACTISAVE's scientific committee, Acticor Biotech has decided to change the dual primary endpoint of this study to a single endpoint, namely the reduction in the number of patients who died or suffered from severe disability as a result of the stroke (mRS score 4-6 at 90 days). This modification of the primary endpoint, reducing the size of the study to 400 patients compared to 1,000 initially planned, will enable clinical results to be obtained as early as in the second quarter of 2024.

Amending ACTISAVE study protocol should enable:
1) a quicker confirmation of the efficacy and safety results obtained in February 2022 in the ACTIMIS study (and recently confirmed by the Brainomix study);
2) a simplification of the evaluation, replacing the interim futility analyses planned by a final analysis;
3) an opportunity to evaluate additional endpoints and several subpopulations, optimally supporting the best possible design and making it possible to identify those patients who should draw the best benefit from glenzocimab.

To date, the ACTISAVE study deployed in the United States, Europe, Israel, and the United Kingdom, has recruited more than 380 patients, 35% of whom have undergone a mechanical thrombectomy. Comparison of the patient populations included in ACTISAVE and ACTIMIS studies suggests that ACTISAVE patients will be more representative, in terms of severity at inclusion, of the general population of patients treated in hospital for a stroke.

Regarding the pharmaceutical development plan, Acticor received the opinion from EMA and FDA during the summer. The authorities confirmed the relevance of the registration strategy in terms of production process validation and glenzocimab characterization. Recommendations have been proposed and will be implemented in the roadmap, without impacting the registration plan.

Based on the results of the ACTISAVE phase 2/3 study and on recommendations from world leading stroke experts, Acticor plans to consult the EMA and FDA again during 2024 to confirm that the phase 3 design will support registration in both Europe and the United States, projected no later than 2028.

Gilles Avenard, Chief Executive Officer of Acticor Biotech, commented: *"We are very pleased with this strategic decision, which will enable us to obtain clinical results as early as mid-2024. We will then have two independent studies showing the efficacy of our drug and we will be able to define, in consultation with the FDA and the EMA, the design of phase 3 for the registration of this promising drug in the treatment of the acute phase of stroke. This evolution of our clinical strategy also has the advantage of reducing our current costs and consequently our financing requirements for 2024"*

Watch exclusive interview with Gilles Avenard

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. 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

Contacts

ACTICOR BIOTECH
Gilles AVENARD, MD
CEO and Founder
gilles.avenard@acticor-biotech.com
T. : +33 (0)6 76 23 38 13

Sophie BINAY, PhD
General Manager and CSO
Sophie.binay@acticor-biotech.com
T. : +33 (0)6 76 23 38 13

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

NewCap
Arthur ROUILLÉ
Media Relations
acticor@newcap.eu
T. : +33 (0)1 44 71 00 15

Disclaimer

This press release contains certain forward-looking statements concerning Acticor Biotech and its business. Such forward-looking statements are based on assumptions that Acticor Biotech considers to be reasonable. However, there can be no assurance that such forward-looking statements will be verified, which statements are subject to numerous risks, including the risks set forth in the Document de référence registration document as approved by the Autorité des marchés financiers under number R. 22-011 on 26 April 2022 and to the development of economic conditions, financial markets and the markets in which Acticor Biotech operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Acticor Biotech or not currently considered material by Acticor Biotech. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Acticor Biotech to be materially different from such forward-looking statements.