

## Topline results of ACTISAVE phase 2/3 study in stroke treatment

- **Analysis of the primary and secondary endpoints of the phase 2/3 ACTISAVE study showed no improved efficacy with glenzocimab**
- **Key results from this study will be presented at ESOC on May 15, 2024, at 11:00 am**

**Paris, France, April 25, 2024 – 8:00 am CEST** - ACTICOR BIOTECH (FR00140050J5 - ALACT), a clinical-stage biotechnology company focused on the development of glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, today announced the first results of its ACTISAVE phase 2/3 study in the treatment of acute ischemic stroke.

Analysis of the first results shows no evidence of efficacy for either the primary endpoint, the proportion of patients with severe disability or death (mRS 4-6) at 90 days after the stroke, or for the secondary endpoint, the proportion of patients with no disability (mRS 0-2) at 90 days.

As a reminder, ACTISAVE (NCT05070260), an international, adaptive, multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 2/3 study, evaluated the safety and efficacy of a single dose of glenzocimab used in combination with the standard of care (thrombolysis +/- thrombectomy) for acute ischemic stroke. The study was deployed in the United States, Europe (8 countries), Israel and the United Kingdom.

**Yannick PLETAN, General Manager & Chief Medical Officer, comments:** *"These results obtained with glenzocimab in combination with the reference stroke treatment are extremely disappointing and in contradiction with the results of the previous phase 1b/2a ACTIMIS study and pharmacological studies. The ACTISAVE study included 438 patients, of whom 421 were treated, including 211 in the glenzocimab arm. Treatment was systematically combined with thrombolysis, and for just over 30% of patients with mechanical thrombectomy. The study population proved to be significantly less severe than that of ACTIMIS, with a very high percentage of patients returning to near-normal life. This negative result for Acticor is also negative for the medical community awaiting new treatments. It contradicts the results of previous pharmacological studies and clinical data. Main quality aspects of the study were analysed and found to be compliant. ACTICOR is currently investigating any influencing factors that may have accounted for these results. We're also assessing the potential impact on the 2 other clinical studies currently underway: GREEN in stroke patients undergoing mechanical thrombectomy and LIBERATE in myocardial infarction (STEMI). We would like to thank all the patients who took part in the ACTISAVE study, as well as their doctors and hospital teams. The full data will be presented on May 15 at a plenary session of the European Stroke Organization Conference (ESOC) by Professor Martin Köhrmann, coordinating investigator."*

**Gilles AVENARD, Chief Executive Officer explains:** *"We will continue to investigate these results to better understand and evaluate consequences of this study with the investigators, the US and European regulatory agencies and our Board of Directors, to determine what further action should be taken. As previously announced, the Company is able to finance its operations until October 2024."*

**The ESOC oral presentation (abstract n°357)** is entitled “*ACTISAVE Clinical Trial: Efficacy and Safety of Glenzocimab on Top of Thrombolysis with or without Mechanical Thrombectomy*” and will be held on May 15, 2024, at 11:00 am.

Glenzocimab is currently evaluated in two other clinical studies sponsored by academic teams:

- A Phase 2/3 GREEN study in stroke patients undergoing mechanical thrombectomy, with a futility analysis following the inclusion of the first 78 patients (30% of patients) expected in Q4 2024.
- A phase 2b LIBERATE study in the treatment of myocardial infarction, with final results expected in Q4 2025.

As reminder, the Company will publish its 2023 Full-Year Results and the URD on April 30, 2024, the General Meeting will take place on June 21, 2024.

### About ACTICOR BIOTECH

Acticor Biotech is a clinical-stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, particularly ischemic stroke.

Positive results from the phase 1b/2a study, ACTIMIS, published in January 2024 in the Lancet Neurology ([link to publication](#)) confirmed the safety profile of glenzocimab and showed a reduction in mortality and intracerebral haemorrhage in the glenzocimab-treated group of stroke patients. These results were confirmed by a post-hoc analysis of brain imaging at 0 and 24 hours using artificial intelligence (Brainomix, UK). This independent analysis confirmed the reduction in the number and volume of intracerebral lesions in patients treated with glenzocimab.

In July 2022, Acticor Biotech obtained "PRIME" status from the European Medicines Agency (EMA) for glenzocimab in the treatment of stroke. This designation enables the company to strengthen its interactions and obtain early dialogues with regulatory authorities.

Acticor Biotech is backed 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) and has been listed on Euronext Growth Paris since November 2021 (ISIN: FR00140050J5 - ALACT).

For further information, please visit: <https://www.acticor-biotech.com/>

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