PRESS RELEASE

Acticor Biotech receives European Medicines Agency (EMA) endorsement on key parameters of ACTISAVE, its pivotal Phase II/III study for registration in Stroke

- **Approval of ACTISAVE design by the EMA to support a potential future marketing authorization application (MAA) for glenzocimab in Stroke**

- **Validation of the choice of two dual primary endpoints:**
  - **Modified Rankin Scale (mRS)**[1]
  - **Failure (versus success) define as severe disability or death i.e. mRS 4-6 (versus mRS 0-3)**

Paris, France, December 05, 2022 – 06:00pm CET - Acticor Biotech, (ISIN: FR0014005OJ5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, has discussed with the European Medicines Agency (EMA) the design of its pivotal Phase II/III study to support a potential future marketing authorization application (MAA) for its first-in-class drug, glenzocimab.

The discussion meeting took place remotely in October 2022, and Acticor Biotech provided a list of questions concerning the non-clinical development and the study design of the ACTISAVE study.

The final advice given by the Committee for Medicinal Product for Human use (CHMP) based on the questions and supporting discussion was very positive. The Agency endorsed the strategy of an adaptive design and validated the choice of two dual primary endpoints: the modified Rankin Scale as an ordinal scale in 7 categories from 0 to 6 and the binary endpoint defined as severe disability or death, i.e., mRS 4-6 (versus mRS 0-3).

Other key features of the study design were also endorsed, such as the two futility interim analyses proposed with their go/no go rules, the prespecified analysis in the promising subgroup of patients with thrombectomy and the adaptive reassessment of the sample size at the second futility analysis. Although CHMP recommendations were issued to further detail some analyses, the statistical methodology was therefore endorsed on its general principles.

In addition, the CHMP agreed that reproductive and developmental toxicity studies are not requested to support a future MAA, considering glenzocimab profile and safety results on previous nonclinical studies.

As 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 acute ischemic stroke (AIS) demonstrated glenzocimab very favorable safety profile by meeting the main criterion 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.

[1] *as an ordinal scale in 7 categories from 0 to 6 to measure the degree of disability of a stroke patient*

Glenzocimab was granted PRIME designation in July 2022, and frequent interactions with the EMA will be planned under the PRIME scheme to optimize the development plan and facilitate quicker access for patients of the drug candidate. To date, the ACTISAVE study has enrolled more than 180 patients. A first futility analysis is planned after 200-300 patients will have been recruited, treated, and monitored for 90 days to confirm safety and ascertain that preliminary results are aligned with the initial trial assumptions.

Dr. Yannick PLETAN, Chief Medical Officer of Acticor Biotech comments: *"It is presumably the first time that such an adaptive protocol is developed and regulatorily endorsed in acute ischemic stroke. It testifies to the urgent need to develop innovative designs to support the rapid advent of novel solutions to cure that terrible condition. We're very proud that glenzocimab can benefit from this recognition."*

Pr Jean-Marie GROUIN, Expert Statistician, added: *"The adaptive design proposed in ACTISAVE study optimizes the chances of proving glenzocimab efficacy for the benefit of patients who suffer from this dramatic condition."*

Laurie Jullien, Head of Regulatory Affairs of Acticor Biotech concluded: "*This new interaction with the EMA paves the way of a reinforced dialogue to build an efficient development up to the marketing authorization application. We look forward to having additional consultations in 2023 under the PRIME scheme and discuss further our proposed registration strategy. "*

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. 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 (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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