PRESS RELEASE

Acticor Biotech announces positive results from its ACTIMIS phase 1b/2a study in patients with Acute Ischemic Stroke (AIS)

Results presentation webinar:
Wednesday 23 February at 11.00am CET Sign-up link

- **Achievement of the study's primary endpoint, confirming glenzocimab's very favorable safety profile**
- **Reduction in the number of intracerebral hemorrhages and mortality among patients treated with glenzocimab**

Paris, France, 22 February 2022 – 08.00 CET – Acticor Biotech, a clinical stage biotechnology company focused on the treatment of cardiovascular emergencies, is today announcing positive results from its ACTIMIS phase 1b/2a clinical trial using glenzocimab (an antibody targeting platelet GPVI ACT017) as an add-on to standard of care (thrombolysis with or without thrombectomy) in patients with Acute Ischemic Stroke (AIS).

ACTIMIS (NCT03803007) is an international, multi-center, randomized, double-blind, placebo-controlled study to evaluate the tolerability and efficacy of glenzocimab. Based on recommendations from the European Medicines Agency (EMA), the first part of the study (phase 1b) involved dose escalation and parallel groups (125, 250, 500, 1000 mg and placebo, 4:1), followed by a phase 2a study at a selected dose of 1000 mg versus placebo, as an add-on to standard of care. The study was carried out in six European countries and included 166 patients.

Achievement of the study's primary endpoint, confirming glenzocimab's very favorable safety profile

The study's primary endpoint was tolerability, including the occurrence of intracerebral hemorrhage and mortality. That endpoint was achieved for all patients in the study (phases 1b and 2a combined). The incidence of symptomatic intracerebral hemorrhage (*ICH*) was lower among patients treated with glenzocimab (across all doses) versus placebo and standard of care, with a 1% incidence of symptomatic *ICH* in the glenzocimab arm versus 8% in the placebo arm. Similarly, a lower incidence of asymptomatic *ICH* was observed with imaging, i.e. in 31% of patients treated with glenzocimab (across all doses) versus 48% in the placebo arm.

Furthermore, in the entire study population there was a lower incidence of deaths among patients receiving glenzocimab (8%) than in the placebo arm (19%).

As a result, glenzocimab has demonstrated a very favorable tolerability profile when administered in combination with reperfusion treatments in the acute phase, including thrombolysis with or without thrombectomy.

Reduction in the number of intracerebral hemorrhages and mortality among patients treated with glenzocimab

The study's secondary endpoint was the efficacy of glenzocimab as assessed in the phase 2a "intention to treat" population (53 patients receiving glenzocimab and 53 the placebo), measured via an early improvement in neurological symptoms at 24 hours (based on the NIHSS[1]) and functional autonomy at 90 days (mRS[2] score), as well as mortality.

Although the results of this study are not statistically significant, there was an improvement among patients receiving glenzocimab (and particularly older patients over 65 and over 80) in the most severe cases and in those who had undergone thrombectomy.

A survival analysis of the phase 2a findings revealed a roughly threefold reduction in the number of deaths, and a later occurrence of death, with glenzocimab (log-rank test stratified according to the presence/absence of thrombectomywithout adjustment for multiplicity: : $p < 0.05$). Overall, fewer patients suffering from severe disability and/or death were seen in the glenzocimab arm. These results will now be confirmed by phase 3 studies.

"This clinical study assessed glenzocimab as an add-on to standard of care, i.e. thrombolysis with or without thrombectomy, in patients with acute ischemic stroke. Across the entire treated population, a reduction in the number of intracerebral hemorrhages was seen with glenzocimab, and in phase 2a fewer patients experienced severe disability or death (mRS scores of 4, 5 or 6). The study has therefore confirmed the clinical benefit of inhibiting GPVI, and these findings tally with recently published laboratory data on the expression of platelet GPVI in patients in the acute phase of stroke[3]" **explained Dr. Yannick Plétan, Chief Medical Officer and General Manager at Acticor Biotech.**

"This is the first time that the results of a randomized clinical study to assess an antithrombotic agent in combination with thrombolysis during the acute phase of ischemic stroke have demonstrated a significant reduction in mortality; this is very likely due to fewer symptomatic intracerebral hemorrhages. These preliminary findings are very encouraging, particularly for patients who have undergone thrombectomy, and reinforce the hypothesis regarding the combination of glenzocimab with endovascular treatment, which will be assessed during the GREEN study," added **Professor Mikael Mazighi, MD, PhD, Coordinating Investigator for ACTIMIS.**

Dr Gilles Avenard, Chief Executive Officer of Acticor Biotech, went on: *"We are very pleased with these promising results, which have had no equivalent in recent years and only make us more enthusiastic about pursuing our development of glenzocimab in this indication. We will continue to analyze the data more closely in order to hone future development, and will be publishing all the results in an international review. We would like to take this opportunity to thank the patients who took part in the study, along with their families, and also all the healthcare professionals who showed great dedication in helping to recruit and monitor patients under working conditions that were rendered very difficult by the pandemic."*

Results presentation webinar at 11.00am CET on 23 February

Mikael Mazighi, Principal Investigator and Coordinator of the ACTIMIS study at Hôpital Lariboisière in Paris, along with members of Acticor Biotech's management team – Gilles Avenard, CEO and founder, Yannick Plétan, Chief Medical Officer and General Manager, Sophie Binay, Chief Scientific Officer and

[1] *National Institute of Health Stroke Score*
[2] *Modified Ranking Scale*
[3] *Indurawa I et al. Platelet surface receptor glycoprotein VI-dimer is overexpressed in stroke: The Glycoprotein VI in Stroke (GYPSIE) study results. PLoS One 18 January, 2022. https://doi.org/10.1371/journal.pone.0262695*

General Manager, and Eric Cohen, Chief Financial Officer – will be commenting on the results of this ACTIMIS phase 1b/2a clinical study.

The webinar will take place in French at 11.00am CET on Wednesday 23 February 2022, and be followed by a Q&A session.

To take part in the webinar, sign up here

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.

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 has been listed on Euronext Growth Paris since November 2021 (ISIN: FR0014005OJ5 – ALACT).

For further information, please go to www.acticor-biotech.com

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