PRESS RELEASE

Acticor Biotech updates its glenzocimab clinical development plan for the treatment of cardiovascular emergencies

- **New analyses of ACTISAVE phase 2/3 study show positive trends for glenzocimab in subpopulations of patients**

- **Continuation of clinical studies: Phase 2/3 GREEN in Ischemic stroke and Phase 2b LIBERATE in myocardial infarction**

- **Launch of GALICE, a Phase 2/3 study in severe ischemic stroke, sponsored by the Hôpital Fondation Adolphe de Rothschild and funded by a public grant (national PHRC[1] in 2023)**

Paris, France, June 3, 2024 – 6:00 CEST - ACTICOR BIOTECH (FR0014005OJ5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, provides an update on the clinical development of glenzocimab following the release of results from its phase 2/3 ACTISAVE study.

Gilles Avenard, Chief Executive Officer, explains: *" We are pleased with the additional analyses carried out on the ACTISAVE study and with the opinion from scientists and clinicians. This reinforces our conviction that, despite the results presented at ESOC, glenzocimab still has a place in the treatment of cardiovascular emergencies in particular in the treatment of the acute phase of ischemic stroke. The spectacular evolution in patient management since the advent of thrombectomy should encourage us to be more precise in selecting patients likely to benefit from new treatments, and reminds us of the heterogeneity of this pathology, both in terms of aetiology and because of the extreme disparity of patients. The search for partners is now our priority to pursue product development, discussions have been initiated in this way."*

Clinical development plan in the acute phase of ischemic stroke

ACTIMIS and ACTISAVE: 2 clinical studies conducted by Acticor Biotech in the treatment of ischemic stroke

The Company has conducted and completed two clinical studies in the treatment of acute stroke:

- **ACTIMIS**, a Phase 1b/2a study with glenzocimab in ischemic stroke, showing positive results presented at scientific congresses in 2022 and 2023 and published in the Lancet Neurology journal in February 2024.

[1] *Hospital program for clinical research*

- **ACTISAVE**, a Phase 2/3 efficacy study, that recruited from 7 European countries in Europe, Israel, the UK and the USA. The results of the 400-patient ACTISAVE trial were presented at the European Congress (ESOC) in May 2024.

The negative results of ACTISAVE on the primary and secondary endpoints led the Company to conduct analyses on patient sub-populations showing positive trends for glenzocimab on the mRS 0-1 score (pre-specified analysis), i.e., a return to normal life, the endpoint recommended by the FDA.

These analyses identified an imbalance in several key factors at inclusion likely to explain why the reference treatment was seemingly outperforming glenzocimab, particularly in patients treated by mechanical thrombectomy in addition to thrombolysis. This imbalance concerned the percentage of diabetic patients, whose ultimate prognosis is poorer, the severity score at inclusion (NIHSS) and the respective administration times of the reference treatment and glenzocimab. A post-hoc statistical analysis with an adjustment for these imbalanced prognostic factors showed a much more favorable result for glenzocimab on the mRS 0-1 score. It was also shown that patients with concomitant antithrombotic had a better outcome in the glenzocimab group, as did fully recanalized patients (eTICI 3) after mechanical thrombectomy and patients with a high severity score at inclusion.

In addition, it should be noted that the ACTIMIS and ACTISAVE studies can hardly be compared on several criteria, including patient severity at inclusion, overall evolution of stroke management, and percentage of patients with intracerebral hemorrhage leading to death.

Considering the results of these two studies, glenzocimab continues to be an attractive candidate for the treatment of the acute phase of ischemic stroke. The Company therefore intends to pursue the development of glenzocimab in this indication, particularly in patients eligible to thrombectomy and in very severe ones.

Finally, numerous world leading experts in stroke treatment emphasize the product's excellent tolerability, and a potential benefit in other conditions 1) before any treatment; 2) in those patients who have received fibrinolytic and glenzocimab simultaneously, and that these options are complementary development opportunities for the product.

The design of a new Phase 2/3 study evaluating glenzocimab in patients requiring thrombectomy is currently being drawn up by the Company.

GREEN and GALICE: ACTICOR is also continuing its collaboration with French stroke experts with 2 academically sponsored clinical studies in thrombectomized patients:

GREEN: Phase 2/3 clinical study in stroke treatment

GREEN (Glenzocimab for REperfusion in the setting of Endovascular therapy for brain infarctioN) is a randomized, double-blind, multicenter, placebo-controlled Phase 2/3 study of the efficacy and safety of glenzocimab as an adjunct to mechanical thrombectomy in acute ischemic stroke. The GREEN study is being conducted under the auspices of Assistance Publique - Hôpitaux de Paris, and is part of the RHU BOOSTER program, with financial support from the Agence Nationale de la Recherche and the Programme Investissements d'Avenir.

As a reminder, the primary objective of this study is to evaluate the efficacy of glenzocimab in combination with endovascular thrombectomy (EVT) versus EVT alone, within the first 24 hours, on functional outcome at 90 days (mRS). Secondary objectives are to evaluate the impact of glenzocimab on overall survival, reperfusion, clinical improvement at 24 hours, symptomatic and asymptomatic intracerebral hemorrhage, serious adverse events (SAE), serious unexpected adverse events (SUSAR) and quality of life. The study will include 260 patients eligible for mechanical thrombectomy in 12 French neurovascular units and institutions of excellence. To date, over 85 patients have been included, and the results of the interim futility analysis are expected in Q4 2024.

GALICE: Phase 2/3 clinical study in stroke treatment

The GALICE study (Glenzocimab in Anterior stroke with Large Ischemic Core eligible for Endovascular therapy) is a randomized, double-blind, multicenter study that will include over 300 patients suffering from large ischemic stroke with proximal occlusion and eligible for mechanical thrombectomy. The objective of the study is to assess the efficacy and safety of glenzocimab versus placebo in improving neurological prognosis at 3 months.

The GALICE study is an academic study sponsored by the Adolphe de Rothschild Foundation Hospital and has received public funding through a national PHRC in 2023. This new clinical study is based on a long-standing collaboration between Acticor Biotech and the Hôpital Fondation Adolphe de Rothschild.

The study received approval from the French regulatory authorities (ANSM and CPP) in May 2024, and will take place in 15 French university hospitals. The first patients are expected to be enrolled in the 3rd quarter of 2024, for a 2-year recruitment period.

Other cardiovascular emergency indications

LIBERATE: Phase 2b clinical study in the treatment of myocardial infarction

The LIBERATE study, a randomized, double-blind Phase 2b trial, will enrol over 200 patients diagnosed with ST-elevation myocardial infarction (STEMI) and scheduled for percutaneous coronary intervention. The primary objective of the study is to evaluate both the safety and efficacy of glenzocimab at a dosage of 1000 mg compared to a placebo, specifically focusing on the reduction of myocardial infarct size at Day 90 post-treatment. The study is being conducted in partnership with the University of Birmingham (UK), and expert clinicians from the Institute of Cardiovascular Sciences and University Hospitals Birmingham NHS Foundation Trust. The two leading clinical research sites, Queen Elizabeth Hospital Birmingham and Northern General Hospital Sheffield, have been actively recruiting since January 2024. To date, 16 patients have been recruited, with results expected in Q4 2025.

Acticor Biotech is also exploring other cardiovascular emergency indications for glenzocimab. These indications could include situations such as pulmonary embolism, deep vein thrombosis, or other acute thrombotic events.

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.

The positive results of 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 hemorrhage in the glenzocimab-treated group of stroke patients. A post-hoc analysis of brain imaging at 0 and 24 hours using artificial intelligence confirmed these results, showing a reduction in the number and volume of intracerebral lesions in patients treated with glenzocimab.

On April 25, 2024, the company announced the initial results of the international phase 2/3 ACTISAVE study in the treatment of acute ischemic stroke, which showed no efficacy of glenzocimab on the primary endpoint, the proportion of patients with severe disability or death (mRS 4-6) 90 days after stroke, nor on the secondary endpoint, the proportion of patients returning to life without disability (mRS 0-2).

On May 15, 2024, Prof. Mikael Köhrmann (Principal Investigator of ACTISAVE) presented the main results of the study at the opening session of the European Stroke Organization Conference (ESOC), confirming the neutrality of the study on the primary and secondary endpoints, and showing trends in return to normal life (mRS 0-1), notably in sub-populations of patients with complete recanalization after mechanical thrombectomy.

Glenzocimab is being evaluated in 2 other clinical trials initiated by academic teams:

- GREEN: a phase 2/3 study in the treatment of stroke in thrombectomized patients, with a futility analysis after inclusion of the first 78 patients (30% of patients) expected in Q4 2024;
- LIBERATE: a Phase 2b LIBERATE trial in the treatment of myocardial infarction, with final results expected in Q4 2025.

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

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