

Acticor Biotech announces the conclusions of the interim futility analysis in the GREEN study

Paris, France, July 26, 2024 – 8:00 a.m. CEST - ACTICOR BIOTECH (FR00140050J5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, announces the conclusions of the futility analysis of the phase 2/3 GREEN study evaluating glenzocimab as an adjunct to mechanical thrombectomy in acute ischemic stroke.

In the light of the information provided to the members of the Independent Monitoring Committee (IMC), and in accordance with the futility criteria defined in the protocol, the IMC recommends that the GREEN study be discontinued.

In light of the Committee's recommendations, sponsor Assistance Publique Hôpitaux de Paris (APHP), in agreement with Professor Mikaël Mazighi, principal investigator of the study, has decided to stop the GREEN study and halt enrolment. To date, 108 patients have been included in the study, the futility analysis only covered the first 78 patients, and all included patients will be analysed after the 90-day protocol follow-up.

The GREEN study, sponsored by Assistance Publique - Hôpitaux de Paris, is part of the RHU BOOSTER program, with financial support from the Agence Nationale de la Recherche and the Programme Investissements d'Avenir.

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 the first 24 hours of acute ischemic stroke.

About RHU BOOSTER

The RHU BOOSTER, Brain cIoT personalized therapeutic Strategies for sTroke Emergent Reperfusion, winner of the fourth call for Hospital-University Research (RHU) projects in healthcare under the future investment program, is led by Professor Mikael Mazighi, Interventional Neuroradiology Department at Hôpital Fondation Adolphe de Rothschild and Head of the Neurology Department at Hôpital Lariboisière, has given itself 5 years (2019-2025) to develop personalized medicine for ischemic stroke in emergency situations. The RHU BOOSTER coordinated by the AP-HP brings together a transdisciplinary consortium of 15 internationally renowned partners with different areas of expertise: 5 experimental research laboratories, 4 clinical research and imaging teams, 2 universities, 4 industrial partners <https://rhubooster.for.paris/>

About GREEN

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.

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. Martin 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 also being evaluated in a Phase 2b LIBERATE clinical trial initiated by academic teams 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: FR00140050J5 - ALACT).

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