

Press Release

Acticor Biotech Announces the Success of the First Phase of its ACTIMIS study with Glenzocimab In Patients with Acute Ischemic Stroke

- Dose Escalation of Glenzocimab as Add-on to Thrombolysis and/or Mechanical Thrombectomy Successfully Completed with 60 evaluable patients.
- The Drug Safety Monitoring Board (DSMB) confirmed the safety of the 1000mg Target Dose.

Paris, October 1st, 2020 – Acticor Biotech, a clinical stage biotechnology company involved in the acute phase of thrombotic diseases, including acute ischemic stroke, today announced the completion of its ACTIMIS Dose Escalation Phase of Glenzocimab Study as add-on to standard of care in Patients with acute ischemic stroke.

This Dose Escalation Phase was successfully completed with 60 patients enrolled from 6 European countries (France, Belgium, Germany, Spain, Switzerland and Italy).

5 cohorts of patients presenting with an acute ischemic stroke episode of moderate to severe intensity were enrolled in this study and randomly received glenzocimab at one of 4 ascending doses or a placebo, in a blind fashion as a 6-hour single-dose infusion. Patients were evaluated continuously for 24 hours, then 7 and 90 days after the episode. Approximately 50% were also treated with the thrombolytic agent rtPA (ACTILYSE®), and the other 50% received rtPA and underwent a mechanical thrombectomy. The DSMB met on 5 occasions in between each cohort and at the end of the last administration, and they analyzed the safety data with a particular focus on the advent of intra-cerebral hemorrhages and other bleeding related events. The last analysis performed after the target dose of 1000mg had been administered to 12 patients confirmed both the absence of increased bleeding when glenzocimab is added to rtPA and to rtPA and thrombectomy, and the absence of any dose-related trend in the number and nature of adverse events recorded.

The green light received from the DSMB will allow ACTICOR to launch the second part of this ACTIMIS study (phase 2) in an additional 100-patient group dosed and randomized with either 1000mg of glenzocimab or its matching placebo. It will also allow starting other clinical projects at this selected dose, which will address other acute ischemic stroke population subsets under various therapeutic options.



"We are very pleased to have completed the dose escalating phase of ACTIMIS in a pathology where most drug candidates have failed in the past years for safety reasons and specifically due to a higher bleeding risk. This is an important milestone for the company and an important progress in the emergency treatments of ischemic stroke. Glenzocimab is a first-in-class treatment in this indication, where no new treatment has been approved in recent decades. "
says Dr Gilles Avenard, CEO and founder of Acticor Biotech.

About glenzocimab (ACT017), the Therapeutic Candidate

Acticor is developing glenzocimab (ACT017), a humanized Antibody Fragment (Fab). The therapeutic candidate is directed against a novel target of major interest, platelet glycoprotein VI (GPVI), and inhibits its action. Evidence of antithrombotic efficacy of glenzocimab and safety of inhibition of GPVI have been established both *ex vivo* and *in vivo*. The target is involved in the growth of the thrombus, but not in physiological haemostasis. This limits the bleeding risk associated with its inhibition.

<https://acticor-biotech.com/our-product>

About Acticor Biotech

Acticor Biotech is a clinical stage biotechnology company, spin-off of INSERM, dedicated to developing an innovative treatment in the therapy of acute thrombotic diseases, including ischemic stroke. Acticor Biotech is built upon the expertise and the results of research conducted by the founders: Dr. Martine Jandrot-Perrus at INSERM Paris and Pr. Philippe Billiald at Paris-Sud University.

Acticor Biotech is a partner in the BOOSTER consortium, dedicated to the management and new treatments of cerebrovascular accidents (CVA) in emergency situations.

Acticor Biotech is backed by a syndicate of European and International investors: Karista, Go Capital, Newton Biocapital, CMS Ventures, Mirae Asset Capital, Anaxago, Primer Capital & Armesa Foundation.

For more information, go to: <https://acticor-biotech.com/>

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