ACTICOR BIOTECH

PRESS RELEASE

Acticor Biotech: Results of the Phase 2 GARDEN study in COVID-19-related acute respiratory distress syndrome

Paris, France, February 2, 2022, at 06:00pm CET – Acticor Biotech, a clinical stage biotechnology company developing an innovative drug for the treatment of cardiovascular emergencies, announced today the results of its GARDEN clinical study evaluating glenzocimab (ACT017), a humanised monoclonal antibody fragment targeting the platelet glycoprotein VI (GPVI), for the treatment of acute respiratory distress syndrome (ARDS) in COVID-19 patients.

GARDEN *(NCT04659109)* is a Phase 2 multinational, multicentre, randomised, double-blind, placebo-controlled, parallel-group clinical study, evaluating the safety and efficacy of glenzocimab administered at a daily dose of 1000 mg for three consecutive days.

This exploratory study was conducted in France and in Brazil between December 2020 and June 2021, in a total of 62 randomised patients (30 to glenzocimab and 32 to placebo).

The safety data analysis confirmed the good tolerability of glenzocimab administered at a daily dose of 1000 mg for three consecutive days, i.e. three times the dose used in ischemic stroke. In spite of the severity of the ARDS and comorbidities, no serious drug-related side effect and no bleeding were observed, even in patients given anticoagulant or anti-inflammatory treatments.

No difference was shown for the primary efficacy endpoint of progression from moderate to severe respiratory distress between glenzocimab and the placebo, both administered in conjunction with the standard of care. An imbalance in major risk factors at inclusion was observed between the two groups, with a higher prevalence of hypertension, diabetes and more advanced age in the glenzocimab group than in the placebo group.

"When the pandemic broke out in 2020, the evaluation of an antithrombotic therapy, not associated with a bleeding risk, opened up interesting treatment perspectives for patients with severe forms of COVID-19-related ARDS. However, in spite of the clear evidence of the importance of major thrombotic events related to platelet hyperactivity in these patients, this exploratory study was not able to show that GPVI inhibition with a specific antibody improved the respiratory function of COVID-19 patients. In these very complex conditions, many other pathophysiological hypotheses have been explored to date, but none have produced significant results," declared Prof. Julien POTTECHER, Global Coordinator of the GARDEN Study and Head of the Department of Anaesthesiology-Critical Care & Perioperative Medicine at the Hautepierre Hospital, Strasbourg University Hospitals.

"*This result could be caused by a sampling bias due to the small size of the study population, to the higher prevalence of risk factors at inclusion in the glenzocimab group, or to a platelet desensitisation of GPVI in patients infected with SARS-COV-2, as shown in a recent publication,*[1]" commented Yannick

[1] *Leopold V. et al. Thromb Haemost 2021; 121: 1258-1262*

Pletan, Chief Medical Officer and General Manager of Acticor Biotech. "*As planned in the protocol, we will continue to analyse the biological data, such as soluble GPVI measurements and glenzocimab pharmacokinetic parameters, and we expect to publish these results given their value for the international scientific community*."

Acticor Biotech is finalising the analysis of its Phase 2a clinical study ACTIMIS (NCT03803007), conducted in 160 randomised patients in six European countries to evaluate the safety of glenzocimab for the treatment of ischemic stroke in combination with the standard of care. Final results are expected by the end of Q1 2022. Unlike in COVID-19-related ARDS, platelet GPVI is overexpressed in stroke patients[2]. Stroke is one of the leading causes of adult disability and the second cause of death worldwide, and it is the main indication developed by Acticor.

For more information,

click here to watch the exclusive interview with Acticor Biotech management

Gilles AVENARD, Chief Executive Officer
Yannick PLETAN, General Manager and Chief Medical Officer
Sophie BINAY, General Manager and Chief Scientific Officer

[2] *Induruwa I. et al. Plos One 2022 ; 17 : e0262695*

About ACTICOR BIOTECH

Acticor Biotech is a clinical stage biopharmaceutical company, spin-off from INSERM (the French National Institute of Health and Medical Research), aiming to develop an innovative treatment for cardiovascular emergencies, including ischemic stroke.

Acticor Biotech is developing glenzocimab (ACT017), a humanised monoclonal antibody (mAb) fragment directed against a novel target of major interest, the platelet glycoprotein VI (GPVI). Glenzocimab inhibits platelet binding to the thrombus without affecting physiological haemostasis, 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 is 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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