PRESS RELEASE

Acticor Biotech provides an update on the US regulatory discussion with the FDA

Paris, France, December 23, 2022 – 08:00 am CET - Acticor Biotech, (ISIN: FR0014005OJ5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, is discussing with FDA to set up a Type C meeting for early 2023 with the same objective as for the recent meeting with the European Agency EMA.

With this Type C meeting, Acticor Biotech intends to pursue the discussion with the FDA on its clinical development program. The objective will be to validate the design and statistical analysis of the international Phase 2/3 study, ACTISAVE to support a potential future marketing authorization application in the US, BLA (Biologic License Application), as it has been recently done with the EMA.

At the same time, although it was recognized by the FDA that acute ischemic stroke (AIS) is a serious condition and that glenzocimab development program is designed to demonstrate an effect on a serious aspect of the condition, additional clinical evidence is requested by the Agency to accept a Fast Track designation for glenzocimab, at this stage. This request for Fast Track designation was submitted to the FDA on October 11th, 2022 on the basis of the Phase 1b/2a ACTIMIS study results. The FDA acknowledged the conduct of the ongoing Phase 2/3 ACTISAVE and is encouraging Acticor Biotech to submit a new request for Fast Track with additional supportive data from the ACTISAVE study.

Gilles Avenard, Chief Executive Officer and founder of Acticor Biotech, comments: "*We are pleased to have met our overall enrollment goals with over 180 patients included and will continue our efforts to enroll patients in our Phase 2/3 ACTISAVE study in the U.S. We are pursuing our discussions with the FDA, despite the negative outcome on the Fast Track designation, at this stage. This does not call into question the fundamentals of our positive Phase 1b/2a ACTIMIS results and the ongoing enrollment in our Phase 2/3 ACTISAVE study. The design of the ACTISAVE study was approved by the European Medicines Agency (EMA) at the end of the year, supporting a future marketing authorization application for glenzocimab in stroke. We are fully confident in the future of the clinical development of our program and pursue our discussions with regulatory authorities in Europe and the United States."*

About ACTISAVE

ACTISAVE (NCT05070260) is a multinational, adaptive, multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 2/3 study evaluating the safety and efficacy of a single dose of glenzocimab used in combination with standard of care (thrombolysis +/- thrombectomy) for acute ischemic stroke.

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.

In May 2022, Acticor Biotech presented positive results from its Phase 1b/2a study, ACTIMIS, at the ESOC, confirming the safety profile and showing a reduction in mortality and intracerebral hemorrhage in the glenzocimab-treated group in patients with stroke. The efficacy of glenzocimab is now being evaluated in an international Phase 2/3 study, ACTISAVE, which will include 1,000 patients. In July 2022, Acticor Biotech was granted "PRIME" status by the European Medicines Agency (EMA) for glenzocimab in the treatment of stroke. This designation will allow the company to strengthen its interactions and obtain early dialogues with regulatory authorities.

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 more information, visit: www.acticor-biotech.com

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