Press Release

ACTICOR BIOTECH ANNOUNCES THAT THE EUROPEAN MEDICINES AGENCY CLEARS THE ROUTE FOR A PHASE II OF ITS ACT017 PRODUCT IN STROKE

Paris, April 25th, 2018 – Acticor Biotech, a clinical stage biotechnology company involved in the acute phase of thrombotic diseases, including stroke and pulmonary embolism, has discussed with the European Medicines Agency (EMA) the development of its drug candidate, ACT017. This meeting follows the completion of the first-in-human study in January 2018 which provided preliminary positive results especially in bleeding time and dose effect in platelet aggregation inhibition.

The discussion meeting took place in London on March 6th, 2018. Acticor Biotech provided a list of questions concerning the non-clinical development, including pharmacology and toxicology studies in animals, and the clinical development of ACT017.

The final advice given by the Committee for Medicinal Product for Human use (CHMP) based on the questions and supporting discussion was very positive.

It was acknowledged that further studies in animal stroke models are not likely to add conclusive information given the lack of available models that adequately mimics ischemic stroke and, hence, are not warranted at this stage of development.

Given the data presented, the non-clinical pharmacology and toxicology studies seems sufficient to support future marketing authorization.

The proposal to initiate a first-in-patient study appeared justified to the Agency, the phase IIa study design with ACT017 administered in association with standard of care was discussed such as thrombolysis and thrombectomy. Although national authorities remain the competent authorities for clinical trial authorisation, the feedback was constructive and allowed to refine endpoints and selection criteria.

Analysis of pharmacokinetics and pharmacodynamics (PK-PD) results from Phase I are ongoing and the final report of the study is due in the coming weeks. Once full results are available, the

protocol for the phase IIa study will be finalized. As such, Clinical Trial Authorization (CTA) application for Phase IIa in stroke patients in several European countries is planned for Q3 2018.

About ACT017, the Therapeutic Candidate

Acticor is developing 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 ACT017 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.

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 and pulmonary embolism. Acticor Biotech is built upon the expertise and the results of researches conducted by, the founders: Dr. Martine Jandrot-Perrus at INSERM Paris and Pr. Philippe Billiald at Paris-Sud University.

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

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