



*Press Release*

## **ACTICOR BIOTECH FIRST-IN-HUMAN CLINICAL TRIAL IN HEALTHY VOLUNTEERS**

**Paris, October 17<sup>th</sup>, 2017** – Acticor Biotech, a clinical stage biotechnology company involved in the acute phase of thrombotic diseases, including stroke and myocardial infarction, today announced the agreement of Dutch Authorities for the initiation of a phase I clinical trial in healthy volunteers with its drug candidate, ACT017. ACT017 is a humanized fragment of monoclonal antibody (Fab) directed against a platelet glycoprotein (GPVI) involved in thrombosis.

The study is a randomized, double blind, placebo-controlled single escalating dose, conducted in the clinical research center of QPS, in The Netherlands. On time with the development plan announced a year ago, the first cohort of volunteers will be enrolled end of October 2017. The clinical study will include 48 subjects in 6 escalating dose level cohorts, with each cohort consisting of 8 subjects: 6 on active and 2 on placebo at the following planned doses: 62,5 – 125 – 250 – 500 – 1 000 and 2 000 mg.

The primary endpoint is to assess safety and tolerance. Bleeding time, and parameters of haemostasis and coagulation will also be determined as well as pharmacokinetic and pharmacodynamics parameters.

The results of this first-in-human study are expected for Q1 2018, and will be used to determine the appropriate ACT017 dosage for phase II studies.

In preparation of the first phase II, positive data from a pharmacology study in primates associating ACT017 with rtPA (Actilyse<sup>®</sup>), the only approved fibrinolytic drug for acute ischemic stroke, were obtained. This study demonstrated that there is no interference between ACT017 and rtPA given together compared with ACT017 or rtPA given alone. These results are paving the way for the first phase II in patients in the acute phase of ischemic stroke in association with rtPA.

The company also reports positive safety data in a stroke animal model in primates. In the group treated with ACT017, 3 hours after the induction of cerebral thrombosis with ACT017 there is no additional intracerebral bleeding compared with the control group of primates. A decrease of

the infarct volume in the cortex was also observed in the group treated 1 hour after the induction.

**Pr. Michael Mazighi, Neurologist, Hospital Lariboisière, Paris, France:** “We consider that these results provide enough data to make the assumption that ACT017 will have a positive effect in human on micro-thrombosis downstream to proximal large vessel occlusion; and as a consequence with an expected benefit in the setting of acute ischemic stroke patients’ reperfusion.”

### **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 (U1148 – Bichat Hospital, Paris, France) founded late 2013, dedicated to developing an innovative treatment in the therapy of acute thrombotic diseases, a Fab directed against platelet glycoprotein GPVI. Acticor Biotech is built upon the expertise and the results of researches conducted by, the founders: Dr. Martine Jandrot-Perrus at INSERM Paris and Professor Philippe Billiald at Paris-Sud University.

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

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