Press Release

ACTICOR BIOTECH COMPLETED ITS PHASE I CLINICAL TRIAL WITH ACT017 ACHIEVING ITS SAFETY AND TOLERABILITY PRIMARY ENDPOINTS

Paris, February 5th, 2018 – Acticor Biotech, a clinical stage biotechnology company involved in the acute phase of thrombotic diseases, including stroke and other thrombosis disorders like pulmonary embolism, announced today the completion of its phase I clinical trial in healthy volunteers with its drug candidate, ACT017.

ACT017 is a humanized monoclonal antibody fragment (Fab) directed against a platelet glycoprotein (GPVI) involved in thrombosis.

The study, a randomized, double blind, placebo-controlled single escalating dose, conducted in the clinical research center of QPS (The Netherlands) enrolled 48 subjects in 6 dose level cohorts, with each cohort consisting of 8 subjects: 6 on active and 2 on placebo at subsequent doses of 62,5 – 125 – 250 – 500 – 1 000 and 2 000 mg.

The primary endpoint assessing safety and tolerability was achieved with no serious adverse event reported at any of the doses tested. The maximum tolerated dose was not reached, though the complete inhibition of collagen-induced platelet aggregation was observed, meaning that an acceptable phase 2 recommended dose is obtained. More detailed haemostasis and coagulation as well as pharmacokinetic parameters will be soon available, that will allow for PK-PD[1] simulation and dose optimization. The final report of the study is due in the coming weeks.

With the results of this study, the company will be able to determine the most appropriate ACT017 dosage for phase II studies.

Gilles Avenard, CEO of Acticor Biotech commented: *"The clinical trial went smoothly as planned thanks to the professionalism of QPS's team. We are pleased to confirm the safety profile of our*

[1] Pharmacokinetic/Pharmacodynamic

drug candidate in healthy volunteers at all dosages from 62.5mg up to 2000mg. While waiting for the full results of the clinical trial, which should be available in the coming weeks, we are working actively on the design and the organisation of the first Phase II clinical study with ACT017 in the acute phase of ischemic stroke".

Yannick PLETAN, Acticor Biotech's Chief Medical Officer added: *"With these encouraging results, it may become possible to overcome the safety issues that have long precluded the use of these agents in stroke, and ACT017 may well become the first-in-class of a brand new category of safe injectable anti-platelet drugs, with a potential to complete the very limited armamentarium in a dreadful condition like stroke, and in a few other severe vascular emergencies".*

Wim Tamminga, QPS's Vice President and Global Head of Early Phase added: *"The study was a very challenging one taking into account the type of compound, the infusion paradigm, the number of safety and PD[2] assessments and the dosing (sentinel approach) schedule. We are proud this study went so well without any problem. Thanks to all the volunteers who participated in the study and made it possible to run the study without any recruitment problem. In addition, in dose escalation decisions the Medical Ethic Committee was very cooperative. All these elements together have proven that our unit is experienced and dedicated to conduct complex first-in-man studies."*

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: https://acticor-biotech.com/

About QPS Holdings, LLC

Founded in 1995, QPS is a GLP/GCP-compliant[3] contract research organization (CRO) and life sciences products supplier supporting discovery, preclinical, and clinical drug development, providing quality services to pharmaceutical and biotechnology clients worldwide. QPS linearly

[2] Pharmacodynamics
[3] Good Laboratory Practice / Good Clinical Practice

integrated core competencies include: neuropharmacology, DMPK[4], liver research, toxicology, bioanalysis, translational medicine, and clinical research program management. QPS regional laboratories and testing facilities are located at company headquarters in Newark, DE; Springfield, MO; Fargo, ND; Hollywood, FL; South Miami, FL, USA; Groningen, The Netherlands; Graz, Austria; Hyderabad, India; Barcelona, Spain; and Taipei, Taiwan.
For more information, visit: **https://www.qps.com/**

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.

For more information: https://acticor-biotech.com/technology/

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