



Acticor Biotech selects Catalent GPEX® Cell Line Development Technology to develop ACT-017

Acticor Biotech is developing an antibody fragment (Fab) considered as a first-in-class anti-thrombotic agent without bleeding risk in the primary treatment of ischemic strokes.

Paris, March 1st, 2016 – Acticor Biotech today announced that it selected Catalent's proprietary GPEX® technology for the development of its Fab candidate, ACT-017, targeting the platelet glycoprotein VI (GPVI).

The GPEX platform creates stable, high-yielding mammalian cell lines with high speed and efficiency and the advantages of applying GPEX technology span from early feasibility studies, to clinical manufacturing, through to commercial scale production. To date, seven GPEX based antibody and protein products are approved and marketed, and 34 therapeutic candidates are currently undergoing clinical trials across the world.

Catalent's high-performance expression platform was chosen following a thorough evaluation, whereby the use of GPEX for the manufacture of ACT-017 was benchmarked against another proprietary mammalian cell line technology, an *E. coli* bacterial platform, and a *Pichia pastoris* yeast expression system.

Using GPEX technology enabled the optimised production of ACT-017, which displayed excellent functionality evaluated upon collagen induced platelet aggregation inhibition, as well as a productivity level aligned with the manufacturing scales required for further clinical and commercial development stages.

« We are extremely pleased to have passed this critical milestone for the development of our Fab candidate and have selected a cell line development technology which is recognized by the Regulatory Authorities and has enabled clinical and commercial developments of a number of biologic products» commented Dr. Gilles Avenard, CEO of Acticor Biotech.

“GPEX technology was designed to offer clients and partners advantages over conventional cell line engineering systems, including increased flexibility and higher, more stable yields,” commented Mike Riley, Vice President and General Manager of Catalent Biologics. *“We are pleased to be able to partner with Acticor Biotech in order to bring this important new therapeutic to market.”*

About GPEX® technology

Catalent's proprietary GPEX® technology creates stable, high-yielding mammalian cell lines with high speed and efficiency. The advantages of applying GPEX technology span from early feasibility studies, to

clinical manufacturing, through to commercial scale production. To date, seven GPEX based antibody and protein products are approved and marketed and 34 therapeutic candidates are currently in the clinic across the world.

Catalent performs GPEX® programs at its state-of-the-art biomanufacturing facility in Madison, WI., which was completed in June 2013. Designed for flexible cGMP production from 10 L up to 1,000 L, and non-GMP production up to 250 L, the site features extensive single-use technologies and unidirectional flow to maximize efficiency and safety.

About Ischemic stroke and ACT-017

Stroke is the second most common cause of death in Europe, causing 1.1 million deaths each year and is the leading cause of acquired handicap in adults. Occurrence of stroke is increasing with the growth of the aging population: 800,000 new or recurrent strokes occur per year in the US and about 1 million in Europe.

ACT-017 is positioned as a first-line anti-thrombotic treatment, to be combined or not with thrombolysis or mechanical thrombectomy, in the therapy of acute ischemic stroke. The Fab targets GPVI, a platelet transmembrane protein which is essential to thrombus formation and growth in artery but not required for physiological hemostasis. Animal models and observation of patients naturally deficient in GPVI (by autoimmunity or genetic mutation) show that GPVI inhibition does not trigger bleeding risk.

About ACTICOR-BIOTECH

Acticor Biotech is an Inserm spin-off. Founded in late 2013, the company's mission is primarily to develop the anti-GPVI antibody as a platelet-aggregation inhibitor for acute thrombotic pathologies. Acticor Biotech's project is based on scientific research from two Inserm units and was lead by Drs Martine Jandrot-Perrus (U1148) and by Pr. Philippe Billiald from the Institut Paris-Sud d'Innovation Thérapeutique. Acticor Biotech raised 670k€ from Business Angels and crowdfunding on February 2015. For more information, visit www.acticor-biotech.com

For safe and effective treatment of strokes

About Catalent

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics, consumer health and animal health products. With over 80 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs approximately 8,700 people, including over 1,000 scientists, at 31 facilities across 5 continents, and in fiscal 2015 generated more than \$1.8 billion in annual revenue. Catalent is headquartered in Somerset, N.J. For more information, visit www.catalent.com

More products. Better treatments. Reliably supplied.™

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