

# ACTICOR BIOTECH announces its projected IPO on the Euronext Growth® market in Paris

- ACTICOR BIOTECH is developing a "first-in-class" drug to treat cardiovascular emergencies, including ischemic strokes
- Stroke is one of the primary causes of disability in adults and the second largest cause of death in the world
- Two clinical programs in Phase 2/3 registration for the treatment of ischemic stroke
- Two other Phase 2 trials addressing major cardiovascular emergencies with clinical results expected in Q1 2022, in ischemic stroke and Covid-19 respiratory distress syndrome
- IPO supported by its historical shareholders

**Paris, France, September 28, 2021 – ACTICOR BIOTECH,** a clinical stage biopharmaceutical company specialized in the development of drugs for treating the acute phase of thrombotic diseases, announces the approval of its registration document by the French stock market authority (AMF) under number I.21-054 on September 27, 2021.

The approval of the registration document is the first step towards ACTICOR BIOTECH's projected IPO on the Euronext Growth® market in Paris, subject to favorable market conditions and the AMF's approval of the prospectus relating to the public offering and the listing of the company's shares on Euronext Growth and consisting of the registration document, the note pertaining to the securities offered and the summary of the prospectus (included in the securities note).

The Company's historical shareholders have given their support to the projected IPO and some of them have committed to subscribe to the transaction, thus demonstrating their confidence in the Company's strategy and the potential of its drug candidate.

For Gilles AVENARD, Chief Executive Officer and co-founder of ACTICOR BIOTECH: "This IPO project is a new key step in the development of ACTICOR BIOTECH and its first-in-class drug, glenzocimab. This drug, which is currently in two Phase 2 clinical trials, has already demonstrated its good safety profile in combination with standard of care. Glenzocimab is also being studied in a Phase 2/3 trial in acute ischemic stroke, with enrollment of the first patient in Europe scheduled for late September 2021. This drug has the potential to improve the care of patients in the acute phase of stroke, which remains one of the leading causes of death and disability in adults. The potential of glenzocimab also extends to other thrombotic diseases such as pulmonary embolism and myocardial infarction, for which we expect to initiate Phase 2 studies in 2022. At the same time, we expect results from our clinical trial in COVID-19-related acute respiratory distress syndromes in early 2022."

## What is Ischemic Stroke?

Acute Ischemic Strokes (AIS), which account for 85% of all strokes<sup>1</sup>, occur when blood flow through a brain artery is blocked by a clot. The main objective of treatments for patients who have been victims of an AIS is to rapidly restore the blood flow to preserve brain tissue that has not yet been damaged. Hemorrhagic Strokes (15% of strokes) occur when a brain artery wall ruptures.



# **ACTICOR BIOTECH: missions and expected clinical outcomes**

Currently, despite Best of Care, almost 50% of patients who have had an Acute Ischemic Stroke still have disabilities. Furthermore, the major complication of AIS and its current treatment is cerebral hemorrhages. There is therefore an urgent need for new drugs to improve this prognosis without running the risk of provoking cerebral hemorrhages.

ACTICOR BIOTECH is developing a first-in-class drug candidate, glenzocimab, with no hemorrhage risk, for which two Phase 2 clinical trials have already demonstrated good tolerance. ACTICOR BIOTECH started a Phase 2/3 trial (ACTISAVE) in September 2021 and plans to participate in another Phase 2/3 trial (GREEN) initiated by researchers at the Assistance Publique des Hôpitaux de Paris, which is expected to start in the 4<sup>th</sup> quarter of 2021, in view to registering and commercializing glenzocimab in acute ischemic stroke. The projected clinical objectives are to significantly reduce the number of patients with severe disability and increase the number of patients without sequelae.

## 1. Acute Ischemic Stroke: a major unmet medical need

Stroke is one of the leading causes of acquired disability in adults<sup>1</sup> and the second largest cause of death in the world<sup>2</sup>.

Two stroke treatments currently exist, but they have some limitations:

Alteplase is a thrombolytic treatment which purpose is to dissolve the clot and which cannot
be given to the patient more than 4.5 hours after symptoms appear because of the risk of
intracerebral hemorrhage. Alteplase only leads to a complete recanalization with restoration
of blood flow in only 38% of cases<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup> GBD 2016 Stroke Collaborators, "Global, Regional, and National Burden of Stroke, 1990-2016: A Systematic Analysis for the Global Burden of Disease Study 2016.," Lancet Neurology (May 2019).

<sup>&</sup>lt;sup>2</sup> Zinkstok SM, Roos YB, ARTIS investigators. Early administration of aspirin in patients treated with alteplase for acute ischaemic stroke: a randomised controlled trial. Lancet 2012; 380: 731–7

• Thrombectomy enables the clot to be extracted mechanically using a catheter inserted into the affected cerebral artery. However, this operation is only applicable in 5 to 10% of cases<sup>3</sup>. Its use is indeed limited by the clot's location, but also by access to specialized hospital departments.

There is therefore an urgent need for a treatment that can be combined with alteplase and/or a thrombectomy to improve their efficacy and prevent recurrences without increasing the risk of hemorrhage.

# 2. Glenzocimab: a first-in-class antithrombotic drug

Faced with this largely unmet medical need, ACTICOR BIOTECH is focusing its efforts on developing its drug candidate, glenzocimab, a humanized monoclonal antibody fragment (Fab), that targets a specific platelet glycoprotein, GPVI, whose inhibition does not carry hemorrhage risks<sup>4</sup>.

The development of glenzocimab is currently being considered in combination with alteplase with or without a thrombectomy. Glenzocimab is designed to be administered intravenously by infusion to cover the acute phase of stroke. In the longer term, the Company could also consider its clinical development in treating the post-acute phase, i.e. 6 to 24 hours after symptoms appear, for which there is currently no approved pharmacological treatment.

The Company has already anticipated the production of glenzocimab, which has a long shelf life (36 months of stability) and an easy storage (between 2 and 8°C), in view of its future commercialization.

#### 3 ACTICOR BIOTECH's clinical strategy in stroke

The Company has just completed the recruitment of a Phase IIa clinical trial (ACTIMIS) in 6 European countries with glenzocimab in Acute Ischemic Stroke combined with the standard of care. 160 patients were enrolled in the trial and the results are expected during the first quarter of 2022.

For the same indication, the Company initiated an adaptive Phase 2/3 study (ACTISAVE) in Europe during the third quarter of 2021, to evaluate the efficacy of glenzocimab in combination with the standard of care within 4.5h of symptom onset. The first patient was enrolled in France at the end of September 2021 and the start of enrollment in the United States is planned for the first half of 2022. This study will include 1,000 patients, the first 200 of whom will undergo a futility analysis.

Acticor Biotech is a partner in the BOOSTER consortium, winner of the 4<sup>th</sup> wave of University Hospital Research (RHU) projects led by the French National Research Agency. Within this framework, the launch of a phase 2/3 clinical trial in stroke (GREEN), which will include 400 patients, sponsored by the Assistance Publique-Hôpitaux de Paris (AP-HP) and which will evaluate the efficacy of glenzocimab in combination with thrombectomy, is planned for the 4<sup>th</sup> quarter of 2021. The Company's clinical development in AIS is supported by numerous leading international opinion leaders, thus confirming the relevance of the development of an antithrombotic drug for this indication.

<sup>&</sup>lt;sup>3</sup> Chia NH, Leyden JM, Newbury J, Jannes J, Kleinig TJ. Determining the Number of Ischemic Strokes Potentially Eligible for Endovascular Thrombectomy: A Population-Based Study. Stroke 2016; 47: 1377–80

<sup>&</sup>lt;sup>4</sup> M Zahid et al., "The Future of Glycoprotein VI as an Antithrombotic Target.," Journal of Thrombosis and Haemostasis (December 2012); Nigel Mackman et al., "Therapeutic Strategies for Thrombosis: New Targets and Approaches.," Nature Reviews. Drug Discovery (May 2020).

The regulatory strategy for the ACTISAVE 2/3 adaptative study has been deployed, with a first request for approval submitted in France in May 2021. Submissions in the other countries and the regulatory consultation with the FDA in the United States are planned for early 2022. In addition, initial contacts have been established in Japan, a heavily stroke impacted market, with experts and regulatory consultants. In China, development will be initiated by the Company's industrial partner, China Medical System (CMS), as soon as the first Phase 2 clinical results are available.

The cumulative incidence of AIS in the USA, Europe, Japan and China is estimated at 4 million patients by 2026<sup>5</sup>. The Company has based its assumptions on around 20% of these patients arriving in hospital within 4.5 hours to be treated either solely with alteplase or solely with a thrombectomy, i.e. the two current treatments. Glenzocimab could potentially therefore address an annual market of approximately 800,000 patients per year. If the treatment window is extended to 6 hours, then 25% of patients could be treated.

The Company considers that initial estimates of the size of the addressable market of for glenzocimab appear to be in excess of \$1 billion, assuming administration within a therapeutic window of 0 to 4.5 hours and sales prices close to those of alteplase in Europe and the US. These estimates are obviously conditioned by the risks associated with the clinical development of glenzocimab. In particular, the clinical results of tolerance and efficacy will be decisive in determining the price of glenzocimab by the health authorities.

# 4. A pipeline with a promising potential product for treating a number of indications and results expected from the first quarter of 2022



The Company is also extending its clinical development program to other indications such as pulmonary embolism and myocardial infarction, for which it is planning to launch clinical studies during 2022.

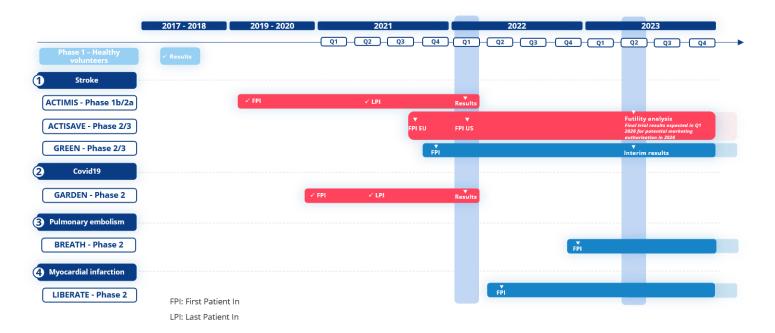
A Phase II clinical trial in France and Brazil has been undertaken on 60 patients with COVID-19 related acute respiratory distress syndrome (ARDS), the results of which are expected in Q1 2022.

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<sup>&</sup>lt;sup>5</sup> Global data AIS Epidemiology forecast to 2022

The pulmonary embolism study is planned to start in Q4 2022 and the myocardial infarction study, sponsored by the University of Birmingham, during Q2 2022.

The Company's strategy consists in developing its drug, glenzocimab, for a number of major indications and seeking one or more pharmaceutical partners liable to be able to ensure its marketing.



# Availability of the registration document

The registration document of ACTICOR BIOTECH approved by the AMF on September 27, 2021 under numberl.21-054, is available on the Company's website (www.acticor-biotech.com) and on the AMF website (www.amf-france.org). It is also available free of charge, upon request, at the Company's registered office, 46 rue Henri Huchard, Bâtiment INSERM U698HP Bichat, 75877 Paris cedex 18. The public's attention is drawn to chapter 3 "Risk Factors" of the registration document.

# **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), that is developing an innovative treatment for acute thrombotic diseases, including ischemic strokes. Acticor Biotech builds on the expertise and research undertaken by its co-founders Doctor Martine Jandrot-Perrus, of INSERM Paris, and Professor Philippe Billiald, of Paris-Sud University and doctor Gilles Avenard. Acticor Biotech is a partner of the BOOSTER consortium devoted to the management and novel treatments of strokes in emergency situations. Acticor Biotech is supported by a panel of European and International Investors: Karista, Go Capital, Newton Biocapital, CMS Ventures, Mirae Asset Capital, Anaxago, Primer Capital, Mediolanum farmaceutici and Armesa Foundation.

For further information, please go to <a href="https://acticor-biotech.com/">https://acticor-biotech.com/</a>

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