ACTICOR BIOTECH

PRESS RELEASE

Acticor Biotech publishes its half-year results for 2023 and provides an update on its clinical progress

- **Adaptation of the development plan for the ACTISAVE phase 2/3 study, with clinical results expected as early as Q2 2024, to register glenzocimab in Europe and the United States by 2028 at the latest**

- **UK regulatory agency (MHRA) approves protocol for LIBERATE phase 2b study, first clinical trial to evaluate glenzocimab in myocardial infarction**

- **Cash and cash equivalents of €8 million at June 30, 2023**

Paris, France, October 26, 2023 - 6:00 PM CEST - Acticor Biotech, (ISIN: FR0014005OJ5 - ALACT), a clinical stage biopharmaceutical company developing glenzocimab, an innovative drug for the treatment of cardiovascular emergencies, today publishes its half-year results to June 30, 2023, approved by the Board of Directors on October 26, 2023, and provides an update on its latest progress.

The 2023 half-year financial report is available to the public on the Investors/Regulated Information section of the company's website. The review of the half-year financial statements has been completed. The limited review report is in the process of being issued.

Financial highlights *(limited review - prepared in accordance with IFRS)*

Given the Company's stage of clinical development, it does not generate revenues.

Research and development costs[1] amounted to €5,918 thousand euros at June 30, 2023, compared with €4,918 thousand euros at June 30, 2022. This increase is mainly due to progress in recruitment for the ACTISAVE phase 2/3 clinical trial.

Operating and administrative expenses amounted to 2,093 thousand euros at June 30, 2023, compared with 1,917 thousand euros at June 30, 2022.

The operating loss amounted to 8,821 thousand euros over the six-month period, compared with 7,270 thousand euros over the same period in 2022.

As a result, the Company recorded a **net loss** of 10,081 thousand euros at June 30, 2023, compared with 7,310 thousand euros for the same period in 2022.

At June 30, 2023, cash and cash equivalents amounted €8 million, compared with €6.6 million at December 31, 2022.

[1] *Net of research tax credit and grants.*

ELIGIBLE PEA PME

On March 9, 2023, the Company announced that it had **successfully raised €12.2 million** to pursue its registration ambition for glenzocimab in stroke.

At the date of preparation of these financial statements, the Board of Directors considers that the Company will be able to cover the financing requirements of its operating activities until at least the beginning of the second quarter of 2024, based on the following factors:

- Net cash and cash equivalents (including bank overdrafts) at June 30, 2023, of 7,955 thousand euros;
- Receipt in October 2023 of the balance of the recoverable BPI France advance of 1,200 thousand euros granted in November 2022 to finance the development of glenzocimab;
- End of patient enrolment in the ACTISAVE study in October 2023, leading to a sharp reduction in financing requirements from that date onwards;
- Expected consumption of cash by the Company's activities over the second half of 2023 and 2024.
- Ability of the Company to pre-finance its 2023 CIR;
- Ability of the Company to modulate its variable operating expenses within the framework of its studies.

Beyond its liquidity horizon, the Company will need additional funds to continue financing the development of its activities. Management has already taken steps to seek additional financing.

Major clinical and regulatory advances in 2023

- **Adaptation of the ACTISAVE phase 2/3 clinical trial in the treatment of acute ischemic stroke**

In September 2023, following consultations with the European (EMA) and US (FDA) regulatory agencies, and in agreement with ACTISAVE's scientific committee, Acticor Biotech decided to change the primary endpoint of this study to a single, unique endpoint, namely the reduction in the number of patients who died or suffered severe disability as a result of the stroke (mRS score 4-6 at 90 days).

This modification of the primary endpoint, reducing the size of the study to 400 patients from the 1,000 initially planned, will thus enable clinical results to be obtained as early as the second quarter of 2024.

To date, the ACTISAVE trial in the USA, Europe, Israel, and the UK has enrolled over 430 patients.

Regarding the pharmaceutical development plan, Acticor received the opinion of the EMA and FDA agencies in the summer of 2023. The authorities confirmed the relevance of the registration strategy in terms of validation of the production process and characterization of glenzocimab. Recommendations have been proposed and will be considered in the roadmap, with no impact on the registration plan.

Based on the results of the ACTISAVE phase 2/3 study and the recommendations of international stroke experts, Acticor plans to consult the EMA and FDA again during 2024 to confirm that the phase 3 design will support registration in both Europe and the United States, envisaged no later than 2028.

- **Complementary results from AI-enhanced brain imaging data confirm the mode of action of glenzocimab in stroke patients in the ACTIMIS study**

To better understand glenzocimab's mode of action in reducing intracranial hemorrhage, a collaboration has been set up with Brainomix, a UK-based company specializing in the evaluation of AI-powered imaging biomarkers, to further analyze the brain imaging results of the ACTIMIS study.

Using AI software developed by Brainomix, ischemic lesion and hemorrhagic transformation volumes were measured and quantified. This objective assessment of the evolution of the cerebral lesion caused by the stroke was then compared with the clinical results. Initial results obtained using these biomarkers showed that, after treatment, patients receiving glenzocimab had lower volumes of brain damage than patients receiving placebo (standard treatment only), mainly due to a significant reduction in volumes of hemorrhagic transformation. The benefit of glenzocimab appears more pronounced in patients who underwent mechanical thrombectomy after initial treatment with a thrombolytic agent.

- **UK regulatory agency (MHRA) approves protocol for LIBERATE study, the first clinical trial evaluating glenzocimab in myocardial infarction**

The LIBERATE study (IRAS -1005400), conducted in partnership with *the University of Birmingham* (UK), and expert clinicians from *the Institute of Cardiovascular Sciences* and *University Hospitals Birmingham NHS Foundation Trust*, received all regulatory approvals to launch the study in August 2023.

This randomized, double-blind Phase 2b study will include over 200 patients with ST-segment elevation myocardial infarction (STEMI) scheduled for percutaneous coronary intervention. The aim of the study is to assess the safety and efficacy of glenzocimab 1000 mg versus placebo in reducing myocardial infarction size after 90 days. The study will be conducted at two UK hospitals: Queen Elizabeth Hospital, Birmingham and Northern General Hospital, Sheffield. Patient enrolment is due to begin by the end of 2023.

- **Start of patient enrolment in Phase 2/3 GREEN stroke trial**

Conducted under the auspices of Assistance Publique - Hôpitaux de Paris, and part of the RHU BOOSTER program, with financial support from the Agence Nationale de la Recherche and the Programme Investissements d'Avenir, the GREEN study (NCT05559398) has begun with the enrollment of the first patients at the beginning of 2023.

As a reminder, the primary objective of this study is to evaluate the efficacy of glenzocimab in combination with endovascular thrombectomy (EVT) versus EVT alone within the first 24 hours, on functional outcome at 90 days (mRS). Secondary objectives are to evaluate the impact of glenzocimab on overall survival, reperfusion, clinical improvement at 24 hours, symptomatic and asymptomatic intracerebral hemorrhage, serious adverse events (SAE), serious unexpected adverse events (SUSAR) and quality of life. The study will include nearly 260 patients eligible for mechanical thrombectomy in 11 French neurovascular units and institutions of excellence.

The interim analysis, to be carried out after inclusion of the first 78 patients will take place in the first half of 2024.

Governance

- **Appointment of Patricia Zilliox to the Board of Directors as an independent director**

Patricia Zilliox has joined Acticor Biotech's Board of Directors as an independent director, replacing Corinne Le Goff, whose multiple directorships in the United States meant that she was no longer able to fulfill her role with Acticor Biotech. This appointment was ratified by the Annual General Meeting of Shareholders on May 12, 2023.

Outlook

Acticor Biotech continues to develop its strategic plan to demonstrate the efficacy of its drug glenzocimab and bring it to registration for the treatment of stroke. The next clinical steps in the treatment of cardiovascular emergencies are:

- **ACTISAVE phase 2/3 study in stroke: final results expected in Q2 2024.**
- **Phase 2b LIBERATE study in the treatment of myocardial infarction:** inclusion of the first patient is scheduled **before the end of 2023.**
- **Phase 2/3 GREEN study in stroke:** an interim analysis will be carried out after inclusion of the first 78 patients **in H1 2024.**

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), which is aiming to develop an innovative treatment for cardiovascular emergencies, including ischemic stroke.

The positive results of the phase 1b/2a study, ACTIMIS, confirmed the safety profile of glenzocimab and showed a reduction in mortality and intracerebral hemorrhage in the glenzocimab-treated group of stroke patients. The efficacy of glenzocimab is now being evaluated in an international Phase 2/3 study, ACTISAVE, which will include 400 patients, with clinical results expected in Q2 2024.

In July 2022, Acticor Biotech was granted "PRIME" status by the European Medicines Agency (EMA) for glenzocimab in the treatment of stroke. This designation will allow the company to strengthen its interactions and obtain early dialogues with regulatory authorities.

Acticor Biotech is supported by a panel of European and international investors (Mediolanum farmaceutici, Karista, Go Capital, Newton Biocapital, CMS Medical Venture Investment (HK) Limited, A&B (HK) Limited, Anaxago, and the Armesa foundation). Acticor Biotech is listed on Euronext Growth Paris since November 2021 (ISIN: FR0014005OJ5 – ALACT).

For more information, visit: www.acticor-biotech.com

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Forward-looking statements

This press release contains forward-looking statements about Acticor Biotech and its business. Acticor Biotech believes that these forward-looking statements are based on reasonable assumptions. However, there can be no assurance that the expectations expressed in these forward-looking statements will materialize as they are subject to risks, including those described in the Registration Document as approved by the Autorité des marchés financiers under number R. 22-011 on April 26, 2022, and to changes in economic conditions, financial markets and the markets in which Acticor Biotech operates. The forward-looking statements contained in this press release are also subject to risks that are unknown to Acticor Biotech or that Acticor Biotech does not currently consider material. The occurrence of some or all of these risks could cause Acticor Biotech's actual results, financial condition, performance or achievements to differ materially from those expressed in the forward-looking statements.

Appendix

Income statement in accordance with IFRS	**30/06/2023 6 months €'000**	**30/06/2022 6 months €' 000**
Research and development costs, net	(5,918)	(4,918)
Of which research and development costs	*(7,074)*	*(6,237)*
Of which grants	*1,156*	*1,320*
Operating and administrative expenses	(2,093)	(1,917)
Costs relating to share-based payments	(810)	(435)
Other operating income and expenses	-	-
Operating income (loss)	**(8,821)**	**(7,270)**
Financial expenses	(1,734)	(40)
Financial income	474	1
Income (loss) before tax	**(10,081)**	**(7,310)**
Income tax	-	-
Net profit (loss) for the period	**(10,081)**	**(7,310)**
Attributable to shareholders of the parent company	(10,081)	(7,310)
Non-controlling interests	-	-
Weighted average number of shares in circulation	11,631,540	10,545,776
Basic earnings per share (€/share)	(0.87)	(0.69)
Diluted earnings per share (€/share)	(0.87)	(0.69)

Statement of financial position in accordance with IFRS	30/06/2023	31/12/2022
	K€	K€
ASSETS		
Intangible assets	713	713
Property, plant and equipment	28	14
Non-current financial assets	522	479
Total non-current assets	**1,263**	**1,206**
Other receivables	4,428	4,840
Prepaid expenses	656	298
Cash and cash equivalents	7,955	6,599
Total current assets	**13,039**	**11,737**
Total Assets	**14,302**	**12,943**
LIABILITIES AND EQUITY		
Shareholders' equity		
Share capital	617	527
Issue or contribution premiums	35,155	23,327
Other comprehensive income	(11)	(10)
Accumulated losses attributable to owners of the Company	(25,312)	(10,209)
Net profit (loss) attributable to owners of the Company	(10,081)	(15,878)
Equity attributable to owners of the Company	**368**	**(2,243)**
Non-controlling interests	-	-
Total shareholders' equity	**368**	**(2,243)**
Non-current liabilities		
Employee benefit obligations	85	56
Non-current borrowings	4,342	7,062
Non-current derivative liabilities	901	1,367
Provisions	-	-
Total non-current liabilities	**5,328**	**8,485**
Current liabilities		
Current borrowings	2,706	801
Trade payables	5,265	5,141
Tax and social security liabilities	635	615
Other current liabilities	-	144
Total current liabilities	**8,606**	**6,701**
Total liabilities and equity	**14,302**	**12,943**