ACTICOR BIOTECH

PRESS RELEASE

Acticor Biotech announces its 2022 half-year financial results and update on its clinical progress

- **Significant clinical progress in the treatment of stroke with glenzocimab:**
  - **Positive results from the ACTIMIS phase 1b/2a study**
  - **Patent granted to protect glenzocimab in thrombotic diseases in Europe until 2036**
  - **Obtained "PRIME" status from the European Medicines Agency**
  - **More than 150 patients enrolled to date in the ACTISAVE Phase 2/3 study in Europe and the US**

- **Strong outlook for portfolio development by the end of 2022:**
  - **Launch of the GREEN Phase 2/3 study in stroke**
  - **Launch of the LIBERATE phase 2 study in myocardial infarction**
  - **Initiation of regulatory reviews in Europe and the US**

Paris, France, 27 October 2022 – 6:00 pm CEST - Acticor Biotech, a clinical stage biotechnology company developing an innovative drug for the treatment of cardiovascular emergencies, today announced its half-year results for the period ended 30 June 2022, as approved by the Board of Directors on 27 October 2022, and provides an update on its clinical progress.

The 2022 half-yearly financial report is made available to the public and is accessible on the Investors/Regulated Information section of the company's website: https://www.acticor-biotech.com/investors/regulated-information-2/regulated-information.

Gilles Avenard, Chief Executive Officer and founder of Acticor Biotech, comments: "*During the first semester of this year, Acticor Biotech demonstrated the full potential of its drug candidate, glenzocimab, with very promising clinical results in the ACTIMIS Phase 1b/2a trial in stroke. We have since accelerated our clinical development plan around this first indication in our ACTISAVE Phase 2/3 study, which is well underway with more than 150 patients enrolled to date across Europe and the United States. We are also preparing for the launch of a second Phase 2/3 GREEN study sponsored by Assistance Publique-Hôpitaux de Paris (AP-HP) by the end of this year. Our interactions with regulatory authorities for glenzocimab in stroke have strengthened, with the European Medicines Agency granting PRIME status, and we have filed for Fast Track status with the US FDA. We look forward to deploying our clinical and regulatory strategy to address the important medical challenge of stroke and cardiovascular emergencies more broadly.*"

Main financial information *(limited review – in accordance with IFRS)*

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

Research and development costs[1] amounted to €4,918 thousand at 30 June 2022, compared with €4,379 thousand in the first half of 2021. This slight increase is mainly due to the progress of the ACTISAVE clinical trial in phase 2/3.

Operating and administrative expenses amounted to €1,917 thousand at 30 June 2022, compared to €1,258 thousand at 30 June 2021. These expenses include, in particular, personnel costs and expenses related to the Company's listing.

The operating loss for the period was €7,270 thousand, compared with €5,741 thousand at 30 June 2021.

As a result, the Company recorded **a net loss** of €7,310 thousand at 30 June 2022, compared to €5,906 thousand at the same period in 2021.

At 30 June 2022**, cash and cash equivalents** amounted to €4.9 million, compared with €11.3 million at 31 December 2021.

On October 17, 2022, the Company issued €3.9 million in bonds convertible into shares from existing shareholders and €2.0 million in simple bonds with warrants attached from a French investment company.

Progress of Acticor Biotech's clinical portfolio in the first half of 2022

- **Positive results of the ACTIMIS phase 1b/2a clinical trial on patients presenting with Acute Ischemic Stroke (AIS)**

The positive results of the ACTIMIS phase 1b/2a clinical trial evaluating glenzocimab in combination with the reference treatment (thrombolysis with or without thrombectomy) in patients presenting with acute ischemic stroke (AIS) demonstrated glenzocimab's very favourable safety profile by meeting the main criterion of the trial as well as a significant reduction in the number of intracerebral haemorrhages and mortality in the group treated with glenzocimab.

These positive results were the subject of an oral presentation at ESOC 2022 by Professor Mikael Mazighi, MD, PhD, Coordinating Investigator for ACTIMIS.

The efficacy of glenzocimab is now being evaluated in an international ACTISAVE phase 2/3 study, which will include 1,000 patients.

- **Clinical development in other cardiovascular emergency indications**

The results of the GARDEN phase 2 clinical trial in Covid-19-related respiratory distress syndrome confirmed the good safety profile of glenzocimab, dosed at 1000 mg for three consecutive days. However, it was not possible to show a difference on the primary efficacy endpoint. In addition, Acticor Biotech has decided to postpone the launch of its phase 2 BREATH study in pulmonary embolism to focus its resources on the two phase 2/3 studies in stroke, ACTISAVE and GREEN.

[1] *Net of research tax credit and subsidies*

- **Patent granted in Europe for glenzocimab for the treatment of cardiovascular emergencies**

The European Patent Office has granted a patent providing protection for glenzocimab in thrombotic diseases in Europe until 2036. This grant complements those already obtained in the United States, Singapore and other jurisdictions that also protect glenzocimab until 2036. Three patent families, comprising 4 issued patents and 33 pending patent applications, protect glenzocimab and its use.

Governance

- **Appointment of Corinne Le Goff to the Board of Directors as independent board member**

Corinne Le Goff has joined Acticor Biotech's Board of Directors as an independent board member. Her appointment will be submitted to the shareholder vote at the combined general meeting of 12 May 2022.

Other significant clinical developments after 30 June 2022

- **European Medicines Agency grants "PRIME" status to glenzocimab for the treatment of stroke**

The "PRIME" status granted by the European Medicines Agency (EMA) has recognised the unmet medical need and interest of glenzocimab in the disease. This status allows Acticor Biotech to strengthen its interactions and obtain early dialogues with regulatory authorities to confirm the clinical development plan for glenzocimab in stroke.

- **Enrolment of the first US patient in its Phase 2/3 study ACTISAVE for the treatment of stroke**

In September 2022, the first US patient was enrolled at the CHI Memorial Stroke and Neuroscience Center, Chattanooga, Tennessee, by Dr. Ruchir A. Shah, MD. ACTICOR had obtained an IND[2] for this study from the US Food and Drug Administration (FDA) in November 2021.

As a reminder, the international phase 2/3 study, ACTISAVE, plans to treat 1,000 patients in approximately 80 centres in the United States, Europe (France, Germany, Belgium, Spain, Slovakia, Denmark, Czech Republic), Great Britain and Israel. Enrolment in Europe began in the third quarter of 2021. To date, the study has enrolled more than 150 patients. A first futility analysis is planned after the inclusion of the first 200 patients to confirm the initial assumptions.

Outlook for 2022-2023

Acticor Biotech's clinical strategy is to develop its drug, glenzocimab, in several major indications in the treatment of cardiovascular emergencies: two phase 2/3 studies in stroke, including ACTISAVE, which started in Europe in 2021, and a phase 2 study in myocardial infarction, which is expected to start this year.

During the first semester of 2023, the Company will meet with the European (EMA) and US (FDA) regulatory agencies to confirm the overall development plan up to registration. Following the amendments filed on the ACTISAVE study, a futility analysis will be available in the second half of 2023 to confirm the assumptions made following the ACTIMIS results.

[2] *Investigational New Drug Application*

The Company commissioned an independent international company (IQVIA) to conduct a market and positioning study for glenzocimab in the treatment of ischemic stroke. In this study, three hypotheses were studied based on the clinical results obtained in the ACTIMIS study and the expected results of the ACTISAVE and GREEN studies. This qualitative and quantitative study gathered the opinions of numerous experts, clinicians, and payers in 5 European countries, in Japan and in the United States. The results confirm a potential sales figure well more than US$1 billion and a very high level of acceptability and interest in the product. A project value study was also provided.

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.

Acticor Biotech is developing glenzocimab (ACT017), a humanized monoclonal antibody (mAb) fragment directed against a novel target of major interest, platelet glycoprotein VI (GPVI). Glenzocimab inhibits platelet binding to the thrombus without affecting physiological hemostasis, thereby limiting the bleeding risk, particularly in the brain.

In May 2022, Acticor Biotech presented positive results from its Phase 1b/2a study, ACTIMIS, at the ESOC, confirming the safety profile and showing a reduction in mortality and intracerebral hemorrhage in the glenzocimab-treated group in patients with stroke. The efficacy of glenzocimab is now being evaluated in an international Phase 2/3 study, ACTISAVE, which will include 1,000 patients. 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 (Karista, Go Capital, Newton Biocapital, CMS Medical Venture Investment (HK) Limited, A&B (HK) Limited, Mirae Asset Capital, Anaxago, Primer Capital, Mediolanum farmaceutici 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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Disclaimer

This press release contains certain forward-looking statements concerning Acticor Biotech and its business. Such forward-looking statements are based on assumptions that Acticor Biotech considers to be reasonable. However, there can be no assurance that such forward-looking statements will be verified, which statements are subject to numerous risks, including the risks set forth in the Document de référence registration document as approved by the Autorité des marchés financiers under number R. 22-011 on 26 April 2022 and to the development of 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 not yet known to Acticor Biotech or not currently considered material by Acticor Biotech. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Acticor Biotech to be materially different from such forward-looking statements.

APPENDICES

Income statement in accordance with IFRS	30/06/2022 6 months €'000	30/06/2021 6 months €'000
Net Research and development costs	(4,918)	(4,379)
Including Research and development costs	*(6,237)*	*(5,663)*
Including Grants	*1,320*	*1,284*
Operating and administrative expenses	(1,917)	(1,258)
Costs relating to share-based payments	(435)	(95)
Other operating income and expenses	-	(9)
Operating income (loss)	**(7,270)**	**(5,741)**
Financial expenses	(40)	(167)
Financial income	1	2
Profit (loss) before tax	**(7,310)**	**(5,906)**
Income tax	-	-
Net profit (loss) for the year	**(7,310)**	**(5,906)**
Attributable to shareholders of the parent company	(7,310)	(5,906)
Non-controlling interests	-	-
Weighted average number of shares in circulation (pro forma) (1)	10,545,776	7,853,512
Basic earnings per share (€ per share) (pro forma) (1)	(0.69)	(0.75)
Diluted earnings per share (€ per share) (pro forma) (1)	(0.69)	(0.75)

BALANCE SHEET

Statement of financial position in accordance with IFRS	30/06/2022	31/12/2021

	€'000	€'000
ASSETS		
Intangible assets	713	713
Tangible assets	50	98
Non-current financial assets	325	197
Total non-current assets	**1,088**	**1,008**
Other receivables	4,562	4,281
Prepaid expenses	772	1,244
Cash and cash equivalents	4,894	11,348
Total current assets	**10,228**	**16,873**
Total assets	**11,316**	**17,881**
LIABILITIES AND EQUITY		
Shareholders' equity		
Share capital	527	527
Additional paid-in capital	23,327	23,319
Other components of comprehensive income	(3)	(32)
Accumulated losses attributable to shareholders of the parent company	(12,232)	(188)
Net profit (loss) attributable to shareholders of the parent company	(7,310)	(12,608)
Equity attributable to shareholders of the parent company	**4,309**	**11,018**
Non-controlling interests	-	-
Total equity	**4,309**	**11,018**
Non-current liabilities		
Obligations to employees	43	53
Non-current debt	1,948	2,200
Provisions	553	553
Total non-current liabilities	**2,544**	**2,806**
Current liabilities		
Current debt	634	507
Trade payables	3,261	3,027
Tax and social security liabilities	568	522
Total current liabilities	**4,463**	**4,057**
Total liabilities and equity	**11,316**	**17,881**

Cash flow statement under IFRS	30/06/2022	30/06/2021
	€'000	€'000
Cash flow from operating activities		

Net profit for the period	**(7,310)**	**(5,906)**
(-) Elimination of depreciation of tangible assets	(54)	(51)
(-) Unrealised foreign exchange difference	1	-
(-) Provision for pension liabilities	(19)	(26)
(-) Provision for risks and charges	-	(4)
(-) Share-based payment expense	(435)	(95)
(-) Elimination of net finance costs	(39)	(115)
Cash flow before cost of net financial debt and taxes	**(6,763)**	**(5,614)**
(-) Change in working capital	(472)	43
Taxes paid		
Cash flow from operating activities	**(6,292)**	**(5,658)**
Cash flow from investing activities		
Acquisition of tangible assets	(7)	(6)
Disposal price of the assets sold	-	1
Cash flow from investing activities	**(7)**	**(5)**
Cash flow from financing activities		
Capital increase	-	5,055
Capital increase costs	-	(94)
Subscription of warrants	8	-
Gross financial interest paid	(10)	-
Repayment of advances	(123)	(50)
Convertible bond issue	-	1,962
Decrease in financial debt related to lease obligations	(31)	-
Cash flow from financing activities	**(155)**	**6,873**
Increase (decrease) in cash	**(6,454)**	**1,210**
Opening cash and cash equivalents	11,348	7,587
Cash and cash equivalents at end of year	4,894	8,796
Increase (decrease) in cash	**(6,454)**	**1,209**
Cash and cash equivalents (including current bank loans)	**4,894**	**8,796**
Cash and cash equivalents	4,894	8,796
Current bank loans	-	-
Cash and cash equivalents at the end of the year (including current bank loans)	**4,894**	**8,796**