ACTICOR BIOTECH

PRESS RELEASE

Acticor Biotech publishes its 2022 annual results and provides an update on its clinical progress

- **Key milestones achieved in the two Phase 2/3 studies in stroke with glenzocimab:**
  - **ACTISAVE study: more than 240 patients enrolled to date**
  - **GREEN study: enrollment of the first patients**
- **Exchanges between the University of Birmingham and the UK regulatory authorities for the LIBERATE study in the treatment of myocardial infarction**
- **Cash of €6.6 million as of December 31, 2022**
- **Successful capital increase of €12.2 million in March 2023**

Paris, France, March 23, 2022 - 6:15 p.m. CET - ACTICOR BIOTECH (FR0014005OJ5 - ALACT), a clinical-stage biotechnology company focused on the development of innovative drugs for the treatment of cardiovascular emergencies, in particular stroke, today released its annual results for the year ended December 31, 2022, as approved by the Board of Directors on March 23, 2023, and provided an update on its latest progress.

The annual financial report will be included in a Registration Document, scheduled for publication at the end of April 2023.

Gilles AVENARD, Chief Executive Officer and founder of Acticor Biotech said: *"2022 and the first months of 2023 are an extremely structuring period for Acticor Biotech. In 2022, we have reached our enrollment objectives in our international phase 2/3 study ACTISAVE in the treatment of stroke and have involved new countries and hospitals in 2023. The GREEN study in collaboration with the Assistance Publique-Hôpitaux de Paris also started in early 2023 with the enrollment of the first patients. In parallel, we are preparing the start of the Phase 2b study conducted in collaboration with the University of Birmingham in the treatment of myocardial infarction. On the regulatory front, discussions with the EMA within the framework of the PRIME program have been initiated, with France designated as the rapporteur country for the dossier, and a consultation schedule has been approved. In the United States, FDA's written responses in a Type C meeting are expected in May 2023. Finally, at the beginning of 2023, we have strengthened our financial structure by successfully completing a capital increase of 12.2 million euros. I would like to thank once again our historical shareholders, in particular Mediolanum Farmaceutici S.p.a, and also the many new institutional and individual shareholders for their support. We are perfectly in line with our strategy to pursue the development of glenzocimab towards its registration in the treatment of cardiovascular emergencies."*

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Financial highlights (audited[1] - prepared under IFRS)

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

Research and development costs[2] amounted to 10,454 thousand euros at December 31, 2022, compared to 8,035 thousand euros at December 31, 2021. This increase is mainly due to the acceleration of enrollment in the ACTISAVE Phase 2/3 clinical trial.

Operating and administrative expenses amounted to 3,622 thousand euros at December 31, 2022, compared with 3,480 thousand euros at December 31, 2021.

The operating loss for the year was 15,121 thousand euro, compared with 11,889 thousand euro at December 31, 2021.

As a result, the Company recorded **a net loss** of 15,878 thousand euros at December 31, 2022, compared with 12,608 thousand euros at 2021.

At December 31, 2022, cash and cash equivalents amounted to €6.6 million, compared with €11.3 million at December 31, 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.

On March 9, 2023, the Company announced **the successful completion of a €12.2 million fundraising** to pursue its registration ambition for its drug glenzocimab in stroke.

As of the date of preparation of these financial statements, the Board of Directors believes that the Company will be able to cover the financing needs of its operations through December 31, 2023 on the basis of the following elements:

- Cash and cash equivalents (including bank overdrafts) at December 31, 2022 amounted to € 6.6 million;
- Capital increase in March 2023 of €12.2 million, of which €4.1 million by offsetting receivables against amounts due by the Company under the convertible bonds in shares issued on October 17, 2022;
- Pre-financing of the 2022 research tax credit for an amount of €2.1 million, of which €1.8 million was received in March 2023;
- Collection of the balance of repayable advances scheduled for 2023:
    - €1.2 million for the BPI recoverable advance granted in November 2022 to finance the development of glenzocimab;
    - €126 thousand for the recoverable advance and €252 thousand for the grant for the finalization of the iNov project for the development of glenzocimab
- Ability of the Company to modulate its variable operating expenses in the context of its studies.

The company estimates that it will be able to meet the financing needs of its operational activities until March 31, 2024 with the financial support of historical shareholders.

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[1] *The audit procedures on the accounts have been performed. The audit report is being issued.*

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

Recent major clinical and regulatory advances with glenzocimab

- **Enrollment of more than 240 patients in the ACTISAVE Phase 2/3 study in stroke and regulatory progress with the EMA and FDA**

ACTISAVE (NCT05070260), which will be launched in Europe in the third quarter of 2021, has so far enrolled more than 240 patients. As a reminder, this international Phase 2/3 study with glenzocimab in the acute phase of stroke is planning to recruit 1,000 patients in approximately 80 centers in the United States, European Union (France, Germany, Belgium, Spain, Slovakia, Denmark, Czech Republic), Great Britain and Israel.

From a regulatory perspective, the European Medicines Agency (EMA) approved the adaptive design strategy and validated the choice of a dual primary endpoint: an ordinal endpoint of the difference between the Modified Rankin Scale (mRS) groups[3] , and a binary endpoint of the percentage of patients with severe disability or death, i.e. mRS score 4-6. Recognition of the design of this pivotal study supports a future application for marketing authorization (MA) for glenzocimab in stroke in Europe. In the context of the "PRIME" status received in July 2022, a program recognizing unmet medical need and aimed at optimizing the development plan and speeding up access to the drug candidate for patients, the Company continues its interactions with the EMA.

In the United States, written responses from the FDA in a Type C meeting are expected in May 2023 to validate the design and statistical analysis of the study, and to support a future application for marketing authorization, via a Biologic License Application (BLA) in the United States. An amendment to the study protocol allowing the use of the two thrombolytic agents in stroke management, tenecteplase (TNK) and alteplase, was submitted to the FDA in November 2022, and approved by a Central Ethics Committee (IRB). First patients have been included to date and Acticor estimates that this amendment should accelerate patient enrollment in the study, given the massive use of TNK in U.S. hospitals.

- **Initiation of patient enrollment in the GREEN Phase 2/3 study in stroke**

Conducted under the auspices of the Assistance Publique - Hôpitaux de Paris, and part of the RHU BOOSTER, with the financial support of the Agence Nationale de la Recherche and the Programme Investissements d'Avenir, the GREEN study (NCT05559398) has started 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 the 90-day functional outcome (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 (SAEs), serious unexpected adverse events (SUSARs) and quality of life. This study will include nearly 260 patients eligible for mechanical thrombectomy in 11 French neurovascular units and institutions of excellence.

- **Discussions with the UK regulatory authorities for the LIBERATE study for the treatment of 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 the *University Hospitals Birmingham NHS Foundation Trust,* is currently being submitted to the UK regulatory authorities (MHRA).

[3] *7-point ordinal scale (categories 0 to 6) to measure the degree of disability of a person who has had a stroke*

This is a randomized, double-blind, phase 2b study that will include 212 patients in the acute phase of myocardial infarction to test the safety and efficacy of glenzocimab 1000 mg versus placebo on reducing cardiac damage remote from the infarction.

Governance

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

Patricia Zilliox has joined the Board of Directors of Acticor Biotech as an independent director, replacing Corinne Le Goff, whose multiple directorships in the United States meant that she was no longer able to carry out her duties at Acticor Biotech. This appointment will be proposed for ratification at the next Annual General Meeting of Shareholders on May 12, 2023.

Outlook for 2023

With a strengthened financial position, Acticor Biotech continues to develop its strategic plan to demonstrate the efficacy of its drug glenzocimab and to 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:** A first futility analysis will be conducted once 100 patients have been treated by both thrombolysis and thrombectomy and followed for 90 days to confirm the safety of the treatment and to ensure that the preliminary results are consistent with the trial's initial assumptions. Results of this futility study are expected in **Q3 2023**.

- **GREEN Phase 2/3 study in stroke:** an interim analysis will be performed after the inclusion of the first 78 patients and is expected by the **end of 2023**.

- **Phase 2b LIBERATE study in the treatment of myocardial infarction:** inclusion of the first patient is planned for the **second quarter of 2023**.

Next financial event: General Meeting of Shareholders, May 12, 2023

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.

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, 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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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	31/12/2022 12 months €'000	31/12/2021 published 12 months €'000
Research and development costs, net	(10,454)	(7,766)
Of which research and development costs	*(13,132)*	*(10,770)*
Of which grants	*2,678*	*3,004*
Operating and administrative expenses	(3,622)	(3,749)
Costs relating to share-based payments	(1,045)	(375)
Operating income (loss)	**(15,121)**	**(11,889)**
Financial expenses	(766)	(721)
Financial income	8	2
Income (loss) before tax	**(15,878)**	**(12,608)**
Income tax		-
Net profit (loss) for the period	**(15,878)**	**(12,608)**
Attributable to shareholders of the parent company	(15,878)	(**12,608**)
Non-controlling interests		-

	31/12/2022	31/12/2021
Weighted average number of shares in circulation (pro forma) (1)	10,545,776	7,780,292
Basic earnings per share (€/share) - pro forma (1)	(1.49)	(1.62)
Diluted earnings per share (€/share) - pro forma (1)	(1.49)	(1.62)

(1) The General Meeting of October 4, 2021 decided to split the nominal value of the shares by 20 from €1.00 to €0.05. As a result, the number of shares has been multiplied by 20. For comparison purposes, the weighted average number of shares outstanding has been restated to take account of this transaction as if this change had already taken place at the beginning of the years presented.

Balance sheet

Statement of financial position in accordance with IFRS	31/12/2022	31/12/2021
	K€	K€
ASSETS		
Intangible assets	713	713
Property, plant and equipment	14	98
Non-current financial assets	479	197
Total non-current assets	**1,206**	**1,008**
Trade receivables and related accounts		-
Other receivables	4,840	4,281
Current financial assets	-	-
Prepaid expenses	298	1,244
Cash and cash equivalents	6,599	11,348
Total current assets	**11,737**	**16,873**
Total Assets	**12,943**	**17,881**
LIABILITIES AND EQUITY		
Shareholders' equity		
Share Capital	527	527
Additional paid-in capital	23,327	23,319
Other comprehensive income	(10)	(32)
Accumulated losses - attributable to shareholders of the parent	(10,209)	(188)
Net profit (loss) - attributable to equity holders of the parent	(15,878)	(12,608)
Equity attributable to shareholders of the parent company	**(2,243)**	**11,018**
Non-controlling interests		-
Total shareholders' equity	**(2,243)**	**11,018**
Non-current liabilities		
Obligations to employees	56	53
Non-current financial debts	7,062	2,200
Non-current derivative liabilities	1,367	
Provisions	-	553
Total non-current liabilities	**8,485**	**2,806**
Current liabilities		
Current financial debts	801	507
Trade payables	5,141	3,027
Social and fiscal debts	615	522
Other current liabilities	144	-
Total current liabilities	**6,701**	**4,057**
Total liabilities and equity	**12,942**	**17,881**

Cash flow statement

Statement of cash flows in accordance with IFRS	31/12/2022	31/12/2021
	K€	K€
Cash flows from operating activities		
Net income for the period	**(15,878)**	**(12,608)**
(-) Elimination of depreciation on property, plant and equipment	(86)	(96)
(-) Unrealized foreign exchange gains and losses	-	4
(-) Provision for pension obligations	(25)	(32)
(-) Provision for risks and charges	559	(127)
(-) Share-based payment expense	(1,045)	(375)
(-) Gain (loss) on disposal of fixed assets	3	-
(-) Elimination of the cost of net financial debt	(758)	(719)
(-) Elimination of subsidy on repayable advances	325	73
Cash flow from operations before cost of net financial debt and taxes	**(14,851)**	**(11,336)**
(-) Change in working capital	(2,748)	2,415
Taxes paid		-
Cash flows from operating activities	**(12,104)**	**(13,750)**
Cash flows from investing activities		
Acquisition of property, plant and equipment	(6)	(13)
Acquisition of financial assets	(66)	-
Reduction of financial assets	6	-
Disposal price of assets sold	-	1
Interest earned on term deposits	-	-
Change in scope of consolidation (1)	-	-
Cash flows from investing activities	**(66)**	**(12)**
Cash flows from financing activities		
Capital increase	-	12,133
Capital increase costs	-	(1,959)
Subscription of warrants	8	14
Issuance of simple and convertible bonds	5,900	7,835
Gross financial interests paid	(109)	(13)
Collection of advances	2,028	275
Repayment of advances	(293)	(100)
Issuance of a bank loan	-	-
Repayment of bank loan	(67)	-
Decrease in financial debt related to lease obligations	(46)	(62)
Payment into the liquidity contract	-	(600)
Cash flows from financing activities	**7,421**	**17,523**
Increase (decrease) in cash	**(4,749)**	**3,761**
Cash and cash equivalents at beginning of year	11,348	7,587
Cash and cash equivalents at end of year	6,599	11,348
Increase (decrease) in cash	**(4,749)**	**3,761**

Cash and cash equivalents (including bank overdrafts)	**31/12/2022**	**31/12/2021**
Cash and cash equivalents	6,599	11,348
Current bank loans		-
Cash and cash equivalents at the end of the year (including current bank loans)	**6,599**	**11,348**