Abivax reports 2023 financial results and operational update

April 2, 2024

- *Raised EUR 500M in 2023, including a EUR 130M capital increase, two structured debt financing transactions aggregating EUR 150M and EUR 223.3M initial public offering on the Nasdaq Global Market*
- *Sufficient funds to finance operations into Q4 2025, including through the announcement of top-line data from the Phase 3 ABTECT induction trials of obefazimod in ulcerative colitis (UC)*
- *Implementation of U.S. and European operational infrastructure to progress the Company's ongoing clinical and preclinical programs*

PARIS, France, April 2, 2024, 8:30 a.m. CEST – Abivax SA (Euronext Paris & Nasdaq: ABVX) ("Abivax" or the "Company"), a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory mechanisms to stabilize the immune response in patients with chronic inflammatory diseases, today announced its 2023 annual financial results, as of December 31, 2023, and provided an update on the progress of its development programs. The financial statements for 2023 have been audited and approved by the Company's Board of Directors on March 28, 2024, and the financial reports are planned to be filed with the French and U.S. securities regulatory authorities, respectively, on April 5, 2024. The audit procedures on the consolidated financial statements have been performed and the certification report is being prepared by the Company's external auditors.

The Company will organize a webcast on the 2023 financial results on Monday, April 8, 2024, at 2:30 p.m. CEST (8:30 a.m. EST).

Marc de Garidel, Chief Executive Officer of Abivax, said: *"In 2023, Abivax accomplished several major milestones and made significant progress on its ongoing clinical and preclinical projects. Beyond executing one of the top worldwide financing raises in the biotech sector last year, the company implemented a strategy designed to take advantage of obefazimod's unique and differentiated profile for the treatment of IBD. We believe we built the necessary U.S and European operational infrastructure to conduct the Phase 3 ABTECT program in UC and the planned Phase 2b Crohn's Disease trial, potentially expanding the long-term use of obefazimod for a large patient population in a field with high unmet medical needs. In 2024, the execution of this strategy is underway by advancing our UC and CD clinical programs and, in parallel, strengthening our pipeline by evaluating a potential combination therapy with obefazimod in UC as well as advancing research on a follow-on candidate. Abivax's scientific excellence has further been highlighted by several abstracts presented by leading U.S. and European KOLs at major scientific congresses. In addition, we continue to reinforce our Board of Directors after notable changes in 2023 and I am glad to welcome Camilla Soenderby as a new member of the Abivax Board. We are very much looking forward to working with Camilla and to benefiting from her expertise."*

Didier Blondel, Chief Financial Officer of Abivax, added: *"The past year was also very successful looking at the trust that our existing and new U.S. and European investors placed in us, reflected in the significant capital raises in 2023. With the successful Nasdaq IPO last year, the largest Nasdaq IPO of a French-listed biotech company, we continue to implement our multi-pronged financial strategy to fund our projects in 2024 and beyond. Abivax has secured more than EUR 500M financing in 2023 and we expect to have sufficient funds to finance our operations into Q4 2025, including through the anticipated release of top-line Phase 3 induction data from the ABTECT program."*

2023 financial highlights (IFRS figures)

Income Statement	**FY 2023**	**FY 2022**	**Change**
in millions of euros			
Total operating income	4.6	4.6	0.0
Total operating expenses			
of which Research and Development costs	(103.2)	(48.3)	(54.9)
of which Sales and Marketing costs	(6.4)	0.0	(6.4)
of which General and Administrative costs	(22.4)	(7.5)	(14.9)
of which Goodwill impairment loss	(0.0)	(13.6)	13.6
Operating loss	**(127.4)**	**(64.8)**	**(62.6)**
Financial (loss) gain	(20.4)	4.1	(22.3)
Net loss for the period	**(147.4)**	**(60.7)**	**(84.9)**

Balance Sheet	**FY2023**	**FY2022**	**Change**
in millions of euros			
Net financial position	**203.2**	**(14.5)**	**217.7**
of which other financial assets and other receivables and assets*	28.3	8.3	20.0
of which fixed-term deposits (maturing in > 1 year)	0.0	0.0	0.0
of which fixed-term deposits (maturing in < 1 year)	9.0	0.0	9.0
of which available cash and cash equivalents	251.9	26.9	225.0
(of which financial liabilities)**	(77.0)	(49.8)	(27.2)
Total Assets	**327.1**	**75.5**	**251.5**
Total Shareholders' Equity	**196.0**	**7.2**	**191.0**

* Excluding items of the liquidity contract (liquidity and own shares) and prepaid expenses

** Financial liabilities include borrowings, convertible loan notes, derivative instruments, royalty certificates and other financial liabilities

- Operating loss increased by EUR 62.6M to EUR -127.4M compared to EUR -64.8M as of December 31, 2022. Operating income, consisting predominantly of Research Tax Credit, was comparable between both financial periods. The increase in operating loss was driven by operating expenses as described further below.
- Research and development (R&D) expenses increased by EUR 54.9M to EUR -103.2M in 2023 compared to EUR -48.3M in 2022. This increase was predominantly driven by a EUR 45.2M, or 117%, increase in expenses related to:
    - Our UC clinical program, driven by the progression of Phase 3 clinical trials for obefazimod in UC (where Phase 3 clinical trial costs were significantly higher than in Phase 2);
    - A EUR 2.7M increase in expenses related to our Crohn's disease (CD) clinical program, driven by planning costs incurred for the Phase 2b CD trial; and
    - A EUR 4.5M, or 71%, increase related to the overall expansion of the research and development headcount to support our organizational growth and the issuance of new equity awards to officers and employees in research and development.
- Sales and marketing (S&M) expenses were EUR -6.4M for 2023. We did not incur any sales and marketing expenses in 2022. These expenses consist primarily of consulting costs associated with market research, re-branding of our company in preparation of our U.S. initial public offering and listing on Nasdaq, as well as an early team build out in preparation for our future sales and commercialization efforts in the U.S.
- General and administrative (G&A) expenses increased to EUR -22.4M compared to EUR -7.5M for 2022 (excluding the one-time goodwill impairment charge taken in 2022 of EUR -13.6M to ABX196 for the treatment of hepatocellular cancer). This increase was primarily due to:
    - An increase in personnel costs of EUR 11.7M, resulting from the issuance of new equity awards to our officers and employees;
    - Management changes that occurred during the period and an increased G&A headcount to support the expansion of the company; and
    - Increased legal and professional fees and other costs associated with operating as a dual-listed public company.
- Total number of employees at the end of December 2023 was 61 and significantly increased compared to 2022, due to the implementation of the U.S. and European operational infrastructure.
- For the year ended December 31, 2023, our EUR -20.4M net financial loss was driven primarily by the following items:
    - Interest expenses of EUR -4.7M relation to borrowings and loans;
    - Non-cash expense of EUR -8.9M in relation to the fair value of our royalty certificates;
    - Non-cash expense of EUR -3.4M related to the derecognition of certain financial liabilities;
    - Non-cash expense of EUR -3.0M in relation to an increase in the fair value of warrant derivatives issued in relation to the Kreos/Claret financing; and
    - Foreign exchange losses of EUR -5.6M (including the EUR -3.2M non-cash impact of the year-end revaluation of

USD-denominated cash and cash equivalents);
    - Partially offset by interest income of EUR 2.4M in relation to the invested proceeds from our U.S. initial public offering and listing on Nasdaq and decrease in the fair value of the Heights convertible notes by EUR 3.2M.
- Cash position (including other financial assets of EUR 9.0M) at the end of 2023 was EUR 261.0M, compared to EUR 27.0M at the end of 2022. The increase was due to a EUR 130M gross equity financing (EUR 123M net proceeds) concluded in February 2023, and two additional structured debt agreements (EUR 27M net proceeds from the first tranches) signed in August 2023. In addition, in October 2023 the Company completed its Nasdaq IPO with gross proceeds of EUR 223.3M.
- As part of the structured debt financing transaction for a total amount of up to EUR 75M with Kreos Capital and Claret European Growth Capital entered into on August 21, 2023 (the "Kreos/Claret financing"), Abivax proceeded with the drawdown of the second tranche of the Kreos/Claret financing for EUR 25M.
    - This second tranche consists of 25,000,000 senior secured non-convertible bonds with a par value of EUR 1.00 each, which will not be listed on any market;
    - The issuance of the Kreos/Claret non-convertible bonds occurred on March 28, 2024;
    - A variable interest rate of 7.5% European Central Bank Base Rate (MRO) (with a floor at 2.5% and a cap at 4%) applies to such tranche. These non-convertible bonds will be repaid monthly through March 31, 2027, after a deferred repayment of the principal until February 1, 2025.

Based on the currently available funds, including the drawdown of the second tranche Kreos/Claret financing described above, Abivax expects to be able to finance its operating cash flow requirements into Q4 2025.

Operating highlights - Ongoing clinical trials

Obefazimod Phase 3 program in UC (ABTECT)

The obefazimod Phase 3 ABTECT program investigating efficacy and safety in adults with moderately to severely active UC is progressing. Recruitment into both induction trials, ABTECT-1 and ABTECT-2, is ongoing in all designated regions.

The ABTECT program is designed for 1,200 UC patients across 36 countries with more than 600 trial sites taking part in the pivotal Phase 3 program that covers North America, Europe, Latin America, and Asia Pacific. Clinical remission is the primary endpoint for the 8-week induction trials as well as for the 52-week maintenance trial (which is week 44 of the maintenance trial).

Anticipated milestones:

- Q4 2024: ABTECT planned enrollment of last patient into induction trials
- Q1 2025: ABTECT planned top-line induction data read-out after eight weeks of treatment
- Q1 2026: ABTECT planned top-line maintenance results after one year of treatment

Objectives:

- Obtain robust Phase 3 data for obefazimod in moderately to severely active UC as a potentially differentiated oral treatment option
- Establish obefazimod as a potential first-line advanced therapy for the treatment of UC

Obefazimod 25 mg long-term extension trial in UC

UC patients initially treated with 50 mg of oral, once-daily obefazimod and who completed the Phase 2a or Phase 2b maintenance trials could roll over into a follow-on, open-label long-term extension trial with a reduced dose of 25 mg.

In an interim analysis as of July 31, 2023, of the 71 eligible patients, 63 completed their 48-week visit, with a demonstrated disease control rate (stable or improved Modified Mayo Score) of 84% (53 of 63 patients) with the 25 mg once-daily dose of obefazimod. No new safety signals were detected in UC patients treated up to five years with oral, once daily obefazimod.

Anticipated milestones:

- Q3 2024: New obefazimod UC extension trial read-out after one and two years of continued treatment with reduced dose of 25 mg

Objectives:

- Confirm safety and efficacy data of Phase 2 maintenance trials and long-term extension trial interim analysis
- Confirm safety and efficacy results for reduced dose of 25 mg obefazimod for chronic long-term use

Operating highlights - Planned clinical trials

Obefazimod Phase 2b trial in Crohn's disease (ENHANCE-CD)

The obefazimod Phase 2b clinical trial in moderately to severely active CD is a double-blind placebo-controlled trial, evaluating three obefazimod doses. The CD investigational new drug (IND) application was filed with the FDA and cleared to proceed in Q4 2023. The trial design consists of a 12-week induction period and a subsequent 40-week maintenance period.

In alignment with FDA feedback on the Company's initial Phase 2a IND application submission, the CD trial design was adapted to be a dose ranging Phase 2b clinical trial. These adjustments to the obefazimod CD clinical program are not expected to have an impact on the overall program budget and projected supplemental New Drug Application (sNDA) submission timeline.

Anticipated milestones:

- Q3 2024: ENHANCE-CD planned start of patient enrollment

- 2H 2026: ENHANCE-CD planned 12-week induction data read-out

Objectives:

- Reproduce obefazimod UC Phase 2 safety and efficacy data for the treatment of CD

Operating highlights - Ongoing R&D work

- **Obefazimod in combination therapy:** Based on its early clinical profile, the formal process evaluating combination therapy of oral and injectable candidates with obefazimod in UC is ongoing in preclinical models. Preclinical data to support decision-making on a combination agent is expected in 2H 2024.
- **Obefazimod follow-on candidate selection from miR-124 library:** R&D work on potential follow-on drug candidates from Abivax's compound library is ongoing. Selection of the first follow-on drug candidate to further strengthen the Abivax pipeline is expected in Q3 2024.

Anticipated milestones:

- 2H 2024: Disclosure of preclinical data of obefazimod combination therapy for the treatment of moderately to severely active UC
- Q3 2024: Selection of first obefazimod follow-on drug candidate from Abivax's miR-124 library

Objectives:

- Strengthen Abivax product pipeline with 1) additional opportunities to use obefazimod in a combination therapy; and 2) additional compounds in the field of chronic inflammatory diseases

Congress participation

Abivax participated at all major IBD conferences in 2023 and Q1 2024. The submitted abstracts were accepted by the conference hosts and presented by leading U.S. and European KOLs. The potential of obefazimod to become a safe and long-term effective treatment option in IBD, as well as its novel mechanism of action, gains increasing interest among the scientific community and the industry.

Abivax plans to participate and present at all major upcoming congresses in 2024:

Digestive Disease Week (May 18-21, 2024, Washington, D.C., U.S.)

- Four submitted Abivax abstracts were accepted for presentation at DDW 2024
- Visit the Abivax booth at the DDW exhibitor hall (booth #529)

United European Gastroenterology Week (October 12-15, 2024, Vienna, Austria)

- Visit the Abivax booth at the UEGW exhibitor hall

American College of Gastroenterology Scientific Meeting (October 25-30, 2024, Philadelphia, U.S.)

- Visit the Abivax booth at the ACG exhibitor hall

Abivax appoints Camilla Soenderby as Independent Board Member

Abivax announces today the appointment of Camilla Soenderby as an Independent Board Member, in replacement of Santé Holdings S.R.L. which has resigned from its position as Board member.

Camilla Soenderby brings 25 years of international leadership experience from executive roles in top ten biopharma companies in the EU, United States and Asia. Ms. Soenderby was most recently a corporate officer at Takeda, leading global portfolio commercialization and commercial excellence, overseeing global brands and a large pipeline, working in close partnership with R&D. Prior to that, she worked as SVP, Head of Global Product Strategy for Shire, having previously held regional- and general management positions at Roche Pharma, Abbott (now AbbVie) and Schering Plough. Ms. Soenderby has a proven international P&L track record of developing and growing businesses. She also has extensive experience in leading worldwide cross functional teams to drive portfolio strategy and commercialization of therapies to treat rare diseases, oncology and specialty conditions, including inflammatory bowel diseases. In the IBD field, Ms Soenderby has notably been involved in the strategic development and the commercialization of Humira (adalimumab) and Entyvio (vedolizumab). She began her career as a management consultant at McKinsey & Company focused on healthcare.

Currently, Ms. Soenderby is a member of the Board of Directors for the investment company BB Biotech and two biotech companies, F2G and Affibody. In addition, she is a member of Novo Holdings Advisory Group and industrial advisor for the private equity group EQT.

Santé Holdings S.R.L., represented by Mr. Paolo Rampulla, an historical investor in Abivax, will continue to contribute to the work of the Board of Directors as an observer alongside Mr. Maurizio PetitBon from Kreos Capital/Blackrock.

Ms. Soenderby has also been appointed as a member of the Nomination and Compensation Committee, which now comprises four members: June Lee (Chair), Sofinnova Partners (represented by Kinam Hong), Truffle Capital (represented by Philippe Pouletty) and Camilla Soenderby.

Webcast on 2023 financial results

A webcast will be organized on Monday, April 8, 2024, at 2:30 p.m. CEST (8:30 a.m. EST) following the announcement of the 2023 yearly results. The Abivax management will give an overview of the Company's 2023 highlights and projects going forward, followed by a live Q&A session.

To participate and ask questions during the webcast, please register via the Abivax website.

Financial calendar 2024

- April 5, 2024: Planned Filing of the financial reports with the French (URD) and U.S. (20-F) securities regulatory agencies
- May 30, 2024: 10:00 a.m. CEST: Shareholders' Meeting
- September 9, 2024: First Half Business and Financial Report 2024 (as of June 30, 2024)
- November 7, 2024: Third Quarter 2024 Financial Information (as of September 30, 2024)

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About Abivax

Abivax is a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory mechanisms to stabilize the immune response in patients with chronic inflammatory diseases. Based in France and the United States, Abivax's lead drug candidate, obefazimod (ABX464), is in Phase 3 clinical trials for the treatment of moderately to severely active ulcerative colitis. More information on the Company is available at www.abivax.com. Follow us on LinkedIn and on X, formerly Twitter, @ABIVAX.

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FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, forecasts and estimates, including those relating to the Company's business and financial objectives. Words such as "design," "expect," "forward," "future," "potential," "plan," "project," "will" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning or implying the therapeutic potential of Abivax's drug candidates, Abivax's expectations regarding the availability of data and timing of reporting results from its clinical trials, including its Phase 3 ABTECT-1 and ABTECT-2 induction trials, obefazimod extension trials in UC, and obefazimod Phase 2b trial in CD, the availability and timing of preclinical data to support decision-making on therapy candidates for use in combination with obefazimod in UC, as well as the availability and timing of disclosure of preclinical data of any such combination therapy, the selection of an obefazimod follow-on drug candidate from Abivax's miR-124 library, the impact of the adjustments to the obefazimod CD clinical program on the overall program budget and projected supplemental New Drug Application (sNDA) submission timeline, obefazimod's potential to provide meaningful benefit to patients suffering from UC, CD, IBD or other indications, and enrollment of patients in clinical trials, Abivax's plans to strengthen its product pipeline with additional opportunities to use obefazimod in a combination therapy and additional compounds in the field of chronic inflammatory diseases, Abivax's cash runway and strategy to extend its cash runway, and other statements that are not historical fact. Although Abivax's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks, contingencies and uncertainties, many of which are difficult to predict and generally beyond the control of Abivax, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. A description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the French Autorité des Marchés Financiers pursuant to its legal obligations including its universal registration document (Document d'Enregistrement Universel). These risks, contingencies and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug candidate, as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates. Special consideration should be given to the potential hurdles of clinical and pharmaceutical development including further assessment by the Company and regulatory agencies and IRBs/ethics committees following the assessment of preclinical, pharmacokinetic, carcinogenicity, toxicity, CMC and clinical data. Furthermore, these forward-looking statements, forecasts and estimates are made only as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. Abivax disclaims any obligation to update these forward-looking statements, forecasts or estimates to reflect any subsequent changes that the Company becomes aware of, except as required by law. Information about pharmaceutical products (including products currently in development) that is included in this press release is not intended to constitute an advertisement. This press release is for information purposes only, and the information contained herein does not constitute either an offer to sell, or the solicitation of an offer to purchase or subscribe securities of the Company in any jurisdiction. Similarly, it does not give and should not be treated as giving investment advice. It has no connection with the investment objectives, financial situation or specific needs of any recipient. It should not be regarded by recipients as a substitute for exercise of their own judgment. All opinions expressed herein are subject to change without notice. The distribution of this document may be restricted by law in certain jurisdictions. Persons into whose possession this document comes are required to inform themselves about and to observe any such restrictions.