ABIVAX REPORTS 2022 FINANCIAL RESULTS AND OPERATIONS UPDATE

Obefazimod global pivotal phase 3 program (ABTECT program) in moderate to severe ulcerative colitis (UC) early enrollment progressing according to plan

Abivax reports promising Phase 2b maintenance results with 52.5% of UC patients in clinical remission after two years of continued oral daily treatment with 50mg obefazimod (ITT-Analysis)

US Food and Drug Administration (FDA) and the European Medicine Agency (EMA) provided their agreement on the pediatric study plans for the development of obefazimod in UC in children aged 2 to 17

Scientific articles published in the peer-reviewed journals "The Lancet Gastroenterology & Hepatology" and "Clinical and Translational Gastroenterology" highlighting obefazimod's capacity to treat patients with moderate to severe UC and its novel mechanism of action

Appointment of Marc de Garidel as new Chief Executive Officer and Interim Board Chair, Sheldon Sloan, M.D., M. Bioethics, as new Chief Medical Officer and Michael Ferguson as new Chief Commercial Officer

Financing of EUR 49.2M secured in September 2022, complemented by another EUR 130M oversubscribed capital increase in February 2023, at market price, subscribed by new and existing high-quality US and European biotech specialist investors

Cash resources fund operations throughout Q2 2024

PARIS, FRANCE, April 19, 2023 – 9.00 p.m. (CEST) – Abivax (Euronext Paris: FR0012333284 – ABVX) (the "**Company**"), a Phase 3 clinical-stage biotechnology company focused on developing therapeutics that modulate the immune system to treat patients with chronic inflammatory diseases, today announces its 2022 annual financial results, as of December 31, 2022, and provides an update on the progress of its product pipeline. The financial statements for 2022 have been audited and approved by the Company's Board of Directors on April 18, 2023. The audit procedures on the consolidated financial statements have been performed and the certification report is being prepared by the Company's external auditors.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax said: *"2022 was another eventful and successful year for Abivax. We made great progress in advancing our lead product candidate obefazimod into a Phase 3 clinical program for the treatment of UC patients. Our new CMO, Sheldon Sloan, and new CCO, Michael Ferguson, under the leadership of our newly appointed CEO Marc de Garidel, will play critical roles in the successful conduct and completion of these clinical trials, as well as in the subsequent global submissions and commercial launch preparations. As already observed in our previously conducted Phase 2a and Phase 2b trials, we believe that the results of our ABTECT program will confirm the rapid onset of action- and long-term efficacy and safety profile of obefazimod. The trust of our new and existing investors, as well as the increased interest of the scientific and medical community in obefazimod, encourages Abivax to stay focused and committed to make our drug candidate rapidly available to all the patients in need."*

Didier Blondel, CFO of Abivax, added: *"Our successful financing round of EUR 49.2M, concluded in 2022, and the pricing of another EUR 130M capital increase, at market price in February this year, fund the Company's operations throughout Q2 2024. These new financial resources will be mainly used to continue our Phase 3 clinical program with obefazimod for the treatment of UC patients. The successful conduct of this program, along with the maximization of shareholder value, continue to be Abivax's top priorities for 2023 and beyond. We are focusing to securing the full funding of the ABTECT program in due course through additional non-dilutive and/or dilutive financial resources."*

2022 Financial Highlights

Items in the Income Statement *in millions of Euros*	FY 2022	FY 2021	Change
Total operating income	0.1	9.7	(9.6)
Total operating expenses	(56.7)	(52.2)	(4.5)
of which Research and Development costs	*(48.7)*	*(47.2)*	*(1.5)*
of which administrative costs and overheads	*(8.0)*	*(5.0)*	*(3.0)*
Operating result	**(56.6)**	**(42.6)**	**(14.1)**
Financial result	(3.8)	(3.1)	(0.7)
Ordinary result	**(60.5)**	**(45.7)**	**(14.8)**
Extraordinary result	(13.9)	0.1	(14.0)
Tax on income	4.5	4.2	0.3
Result for the period	**(69.8)**	**(41.4)**	**(28.5)**

Financial Items from the Balance Sheet *in millions of Euros*	31/12/2022	31/12/2021	Change
Net Financial Position	**(19.8)**	**6.6**	**(26.4)**
of which financial fixed assets*	0.0	0.0	0.0
of which fixed-term deposits (maturing in > 1 year)	0.0	0.0	0.0
of which fixed-term deposits (maturing in < 1 year)	0.0	0.0	0.0
of which available cash	26.9	60.7	(33.8)
of which financial debts	(46.7)	(54.1)	7.4
Total Assets	**73.4**	**110.4**	**(37.0)**
Total Equity	**8.7**	**35.6**	**(26.9)**
of which equity capital	1.9	28.8	(26.9)
of which conditional advances	6.8	6.8	(0.0)
* Excluding items of the liquidity contract (liquidity and own shares) and deposits & guarantees			

- Operating loss EUR -56.6M (EUR -14.0M compared to EUR -42.6M as of December 31, 2021) which reflects the increasing investments in R&D (EUR -1.5M) and G&A expenses (EUR -3.0M). The remaining difference is mainly due to the one-off income recorded in 2021, resulting from Bpifrance grant, relating to the full completion of the obefazimod Covid-19 program (EUR +9.6M)
- R&D expenses remained stable at EUR -48.7M (EUR -1.5M compared to -47.2M in 2021), reflecting mainly the funding needs for the development of obefazimod (93% of the total R&D expenses), notably taking into account the progressive ramp up of the ongoing Phase 3 program for the treatment of ulcerative colitis
- G&A expenses increased to EUR -8.0M (14.1% of total operating costs) compared to 2021 at EUR -5.0M
- Total number of employees at the end of December 2022 was 22 and slightly decreased compared to 2021
- The extraordinary loss for 2022 at EUR -13.9M is mostly resulting from the full depreciation of ABX196 after deciding to put the program on hold
- Cash at the end of 2022 was EUR +26.9M, compared to EUR +60.7M at the end of 2021
- The Company's cash utilization rate during 2022 was EUR -7.3M per month (EUR -5.5M in 2021),
- The Company has successfully completed a fund raising in September 2022 (EUR +49.2M gross amount, EUR +46,0 net amount after deduction of transaction fees), composed of EUR +46.2M equity raise combined with EUR +2.9 royalty certificates; in addition, the Company completed another EUR +130M

oversubscribed capital increase at market price in February 2023 (EUR 123M after deduction of transaction fees). These financing rounds were both led by TCGX, with participation from existing investors such as Sofinnova Partners, Invus, Deep Track Capital, Venrock Healthcare Capital Partners, as well as from new investors such as Great Point Partners LLC, Deerfield Management Company, Commodore Capital, Samsara BioCapital, Boxer Capital and others.

- The Company is currently funded throughout Q2 2024, based on the following assumptions:
    - Assessment of planned R&D needs in 2023 and 2024, notably taking into account the conduct of the obefazimod Phase 3 program for the treatment of ulcerative colitis (ABTECT program)
    - 2023 opening cash
    - Additional cash resulting from the February 2023 capital raise
    - 2023 cash in resulting from the reimbursement of the 2022 Research Tax Credit
- As previously communicated, at this point of time, the prospective funding needs of Abivax consider the costs of the ongoing ulcerative colitis Phase 3 program with obefazimod, as well as on the running costs of the Company, as planned and assessed as of today. The following costs are not included:
    - Any costs related to the continued treatment of patients who are receiving clinical benefit beyond 52 weeks of the Phase 3 trial;
    - Costs relating to market access, pre-marketing and pre-commercial investments which will be required in due time for the appropriate preparation of the commercialization of obefazimod;
    - Any financing related to subsequent potential indications to be treated with obefazimod, such as Crohn's Disease and/or rheumatoid arthritis;
    - The Company will assess and plan for these funding requirements and will regularly update the market on its financing need projections. The potential impact for the operations throughout Q2 2024 is not expected to materially affect Abivax's current cash runway.

OPERATING HIGHLIGHTS: PORTFOLIO UPDATE

Obefazimod global pivotal Phase 3 clinical program in ulcerative colitis (UC) – ABTECT program

At this time, priority is given to the Phase 3 program in moderate to severe UC (ABTECT program), which includes 1,200 patients suffering from moderate to severe UC at 600 investigator sites covering North America, Europe, Latin America and Asia Pacific. The ABTECT program was initiated in the first half of 2022 and the first patient in the United States was enrolled on October 11, 2022.

The ABTECT program consists of two 8-week induction trials followed by a 44-week maintenance trial. Abivax has committed to provide access to the study medication to patients who continue to experience clinical benefit beyond the end of the maintenance trial.

In December 2022, Abivax announced that the US Food and Drug Administration (the FDA) provided their agreement on the initial Pediatric Study Plan (iPSP) for the development of obefazimod in UC in children aged 2 to 17. The European Medicines Agency (EMA) also provided their green light for the pediatric investigation plan (PIP) with obefazimod for the treatment of Inflammatory Bowel Diseases (IBD) in children aged 2 to 17 in December 2022. Recognizing the impact in children and adolescents, Abivax is committed to the pediatric development of obefazimod for the treatment of IBD.

The next steps envisaged for the Phase 3 program of obefazimod for the treatment of UC are (i) obtaining the first results of the induction trials at the end of 2024, (ii) obtaining the first results of the maintenance trial at the end of 2025, and (iii) submission of marketing authorization applications in Europe and the United States by 2026.

Obefazimod Phase 2b maintenance trial in UC

Abivax recently reported the results of its Phase 2b maintenance trial of obefazimod in UC after two years of continued once-daily treatment with 50mg obefazimod.

Among the 217 patients who continued their treatment with 50mg once-daily oral obefazimod, 49 were already in clinical remission after the 8-week induction trial. 67.3% (n=33) out of these 49 patients stayed in clinical

remission during the maintenance treatment. Further, out of the 168 patients who were not in clinical remission at the end of the induction phase, 48.2% (n=81) showed a *de novo* clinical remission at the end of the two-year maintenance therapy with obefazimod.

Furthermore, the clinical remission rate for patients who did not show at least a clinical response at the end of the 8-week induction phase was 43.0% (n=40) after two years of treatment, demonstrating that long-term administration of obefazimod provided substantial clinical benefits also for these patients.

75% (n=164/217) of the patients included in the maintenance trial completed two years of once-daily oral dosing with 50mg obefazimod. 30 patients dropped out during the first year of treatment. 6 patients did not qualify for the second year due to non-response after the first year of treatment, and 17 patients dropped out during the second year. These patients were all considered as treatment failures in the ITT analysis.

During the induction and the maintenance treatments of the Phase 2b trial, the safety and tolerability profile observed was consistent with previous findings and no safety signals were observed.

As of November 2022 (last safety data cut-off), 1,074 patients and volunteers were treated with obefazimod, of which 209 patients have been treated with 50 mg obefazimod for one year or more. At present, no signal of opportunistic infections or malignancies were detected across all studies.

Obefazimod Phase 2a maintenance trial in UC

Further, 11 out of the 22 UC patients initially included in the Phase 2a maintenance trial recently completed the fourth year of continued daily treatment with 50mg obefazimod.

41% (n=9/22) of the patients were in clinical remission and 50% (n=11/22) showed a clinical response after four years. Further, 27% (n=6/22) of the patients were in endoscopic remission and 41% (n=9/22) had an endoscopic improvement after four years of treatment with obefazimod.

Scientific publications and presentations on obefazimod UC clinical trial results and its novel mechanism of action

In September 2022, Abivax published a scientific article in the peer-reviewed journal "The Lancet Gastroenterology & Hepatology", the world-leading gastroenterology and hepatology research journal. The title of the article is *"ABX464 (obefazimod) for moderate to severe active ulcerative colitis: a randomised, placebo controlled phase 2b induction trial and 48-week, open-label extension".*[1]

The publication highlights that all doses of obefazimod tested during the induction study (25mg, 50mg and 100mg) significantly improved the condition of patients suffering from moderate to severe, active ulcerative colitis compared to placebo, as measured by changes in Modified Mayo Score from baseline at week 8. Further, the data show that patients on continuous daily treatment with 50mg obefazimod during the 48 weeks maintenance trial experienced new or maintained clinical response, clinical remission, endoscopic improvement and endoscopic remission.[2]

These safety and efficacy results after 48-week of treatment with obefazimod in the Phase 2b maintenance trial were also selected as "one of the best abstracts" for a presentation at the UEG (United European Gastroenterology) Week 2022, that took place in October 2022 in Vienna, Austria.

In January 2023, the Company announced the publication of a scientific article in the peer-reviewed journal "Clinical and Translational Gastroenterology (CTG)" entitled: *"ABX464 (obefazimod) up-regulates miR-124 to reduce pro-inflammatory markers in inflammatory bowel diseases."* [3]

[1] Severine Vermeire et al.: ABX464 (obefazimod) for moderate-to-severe, active ulcerative colitis: a phase 2b, double-blind, randomised, placebo-controlled induction trial and 48-week, open-label extension, Lancet Gastroenterol Hepatol, published online on Sept. 5, 2022.

[2] The extension efficacy set in the publication includes 78 patients who either completed 48 weeks (73 patients) or were scheduled to complete 48 weeks (5 patients had discontinued).

[3] Apolit et al.: ABX464 (obefazimod) up-regulates miR-124 to reduce pro-inflammatory markers in inflammatory bowel diseases, CTG, published online Jan. 2023.

The publication highlights obefazimod's novel mechanism of action (MoA) and its capacity to treat patients with moderate to severe UC. The article extends the observations reported in Abivax's previous publications on the Phase 2a and Phase 2b clinical trials conducted in UC, including patients who failed to respond or stopped responding to currently available therapies.

The data from blood and rectal tissue from UC patients published in CTG were also selected for a presentation at the 18th Congress of ECCO in March 2023 in Copenhagen, Denmark.

Obefazimod Phase 2b/3 trial for the treatment of Crohn's disease (CD)

At this stage, the Company's program of obefazimod for the treatment of CD is suspended until the necessary financing is obtained. The Company will seek such financing once it has been able to complete the financing of the entire Phase 3 program for UC. Therefore, the Company does not currently have an established timetable for the advancement of its CD clinical program with obefazimod.

Obefazimod Phase 2a trial in rheumatoid arthritis (RA)

In June 2022, the safety and efficacy study results of the obefazimod Phase 2a trial in RA patients were published in the renowned and peer-reviewed journal "Annals of the Rheumatic Diseases (ARD)"[4] and presented at the Annual European Congress of Rheumatology, EULAR 2022.

The publication and EULAR presentation cover the promising top-line results of the induction phase of its Phase 2a clinical trial of obefazimod administered in combination with methotrexate (MTX) for the treatment of active moderate to severe RA. 60 patients who had either an inadequate response to methotrexate and/or TNFα inhibitors participated in the study.

In March 2022, Abivax announced its Phase 2a maintenance trial results of obefazimod in RA. Out of the 40 patients who enrolled into the maintenance trial, 23 patients had reached the first year of treatment and all achieved at least an ACR20[5], with 19 and 12 patients achieving ACR50 and ACR70 respectively. Further, the long-term safety profile (50mg obefazimod once daily + MTX) was consistent with previous observations.

The Phase 2a data along with the scientific validation in the ARD journal and at EULAR, clearly support moving obefazimod into a subsequent Phase 2b trial for the treatment of RA. Given the priority on the Phase 3 clinical program with obefazimod in UC, the Company's program for the treatment of RA is suspended until the necessary financing is obtained.

ABX196 Phase 1/2 clinical trial in hepatocellular carcinoma (HCC)

In January 2022, Abivax presented the results of the dose escalation phase of its Phase 1/2 clinical trial in HCC at the ASCO GI Cancers Symposium.

This trial was conducted at the Scripps MD Anderson Cancer Center in San Diego and the MD Anderson Cancer Center in Houston. In this proof-of-concept study, heavily pre-treated hepatocellular cancer patients who previously failed on checkpoint inhibitor treatments were dosed with ABX196, a synthetic invariant Natural Killer T cell (iNKT) agonist, in combination with checkpoint inhibitor nivolumab (Opdivo®, Bristol Myers Squibb).

The results of the dose escalation phase support the further clinical development of ABX196 in the HCC setting. However, in the absence of progress on partnership discussions in the second half of 2022, the Company has decided to put the ABX196 program on hold.

[4] Daien C, Krogulec M, Gineste P, et al.: "Safety and efficacy of the miR-124 upregulator ABX464 (obefazimod, 50 and 100 mg per day) in patients with active rheumatoid arthritis and inadequate response to methotrexate and/or anti-TNFα therapy: a placebo-controlled phase II study", Ann Rheum Dis 2022;81:1076–1084.

[5] The American College of Rheumatology ACR score measures the efficacy of treatments for rheumatoid arthritis patients. The ACR20/50/70 measures a 20/50/70% improvement in the tenderness and swelling in designated joints and a 20/50/70% improvement in at least 3 of the 5 following measures: investigator's and patient's reported global assessment of disease scales, patient's reported pain scale, CRP level, healthy assessment questionnaire.

FURTHER ANNOUNCEMENTS

Appointment of Sheldon Sloan, M.D., M. Bioethics, as Chief Medical Officer

In January 2023, Abivax announced the appointment of Dr. Sheldon Sloan, M.D., M. Bioethics, as new Chief Medical Officer, effective on March 1, 2023. Dr. Sloan will be involved in the successful conduct and completion of the ongoing Phase 3 global clinical program with obefazimod for the treatment of UC, as well as in the subsequent global submissions and commercial launch preparations.

Appointment of Marc de Garidel as Chief Executive Officer and Interim Board Chair

In April 2023, the Company announced the appointment of Marc de Garidel as new Chief Executive Officer and Interim Board Chair, effective on May 5, 2023. His appointment bolsters Abivax's position as a leader in the field of chronic inflammatory bowel diseases. Marc de Garidel has an extensive track record in the biopharma sector and he will lead obefazimod towards commercialization and execute on Abivax's clinical and financial strategy.

Appointment of Michael Ferguson as Chief Commercial Officer

In April 2023, Abivax announced the appointment of Michael Ferguson as new Chief Commercial Officer, effective immediately. He has a strong track record in the biopharmaceutical industry, having held senior positions for commercialization and marketing of drugs in the field of Gastroenterology and specifically in IBD. As CCO of Abivax, Michael Ferguson will be leading the market development of obefazimod in IBD.

Appointment of Pierre Courteille Ferguson as Chief Business Officer

In parallel to the appointment of Michael Ferguson as new CCO, Pierre Courteille was appointed Chief Business Officer of Abivax in April 2023.

Abivax Board of Directors recomposition

As from May 5, 2023, Mr. Marc de Garidel will join the Board of Directors and serve as Chairman on an interim basis. Dr. Philippe Pouletty will become Truffle Capital's permanent representative on the Board in replacement of Mr. Christian Pierret. Ms. Corinna zur Bonsen-Thomas will cease to act as Chairman but will retain her functions as director.

Financial Calendar 2023

- **Friday April 28, 2023:** Publication of the 2022 annual financial report
- **Monday June 5, 2023:** Annual Shareholders Meeting
- **Thursday September 14, 2023:** Publication of financial statements as of June 30, 2023
- **Friday September 29, 2023:** Publication of 2023 half year financial report

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About Abivax (www.abivax.com)

Abivax is a Phase 3 clinical stage biotechnology company, focused on developing therapeutics that modulate the immune system to treat patients with chronic inflammatory diseases. Abivax, founded by Truffle Capital, is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax's lead drug candidate, obefazimod (ABX464), is in Phase 3 clinical trials for the treatment of ulcerative colitis. More information on the Company is available at www.abivax.com. Follow us on Twitter @ABIVAX_.

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