Abivax presents first-half 2022 financial results and operations update

September 15, 2022

Obefazimod global pivotal phase 3 clinical program in ulcerative colitis on track with US IRB approval granted and first-patient-in expected end of September 2022

Excellent results from the obefazimod phase 2b open-label maintenance study in moderate to severe ulcerative colitis (UC), including the full set of 217 patients who completed one year of once-daily oral treatment with 50mg, showing best-in-class clinical remission rate of 55.3%

Publication of a scientific article on obefazimod phase 2b induction and 48-week extension study results in UC in the peer-reviewed journal "The Lancet Gastroenterology & Hepatology"

Cash for operations strengthened in September with a cross-over financing of EUR 49.2M, extending the cash runway until the end of Q1 2023

PARIS, France, September 15, 2022 – 6:00 p.m. (CEST) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a phase 3 clinical-stage biotechnology company developing novel therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, announces today its 2022 half-year financial results, as of June 30, 2022, and provides an update on its clinical development progress. The financial statements for the first half of 2022, approved by the Company's Board of Directors on September 14, 2022, have been audited and the certification report is being prepared by the Company's external auditors.

"The first half of 2022 has been very eventful for Abivax, as for many other listed companies within this unpredictable international context and its heavy implications on the stock markets. Nevertheless, we made significant progress in our development programs and achieved important milestones for our product candidate obefazimod. In April, we reported excellent results from the obefazimod phase 2b open-label maintenance study, including 217 patients who completed one year of once-daily oral treatment with 50mg obefazimod. These promising outcomes have very recently been recognized by the scientific community through a scientific article in the prestigious journal 'The Lancet Gastroenterology & Hepatology'. Abivax's current priority is the swift start and completion of the global phase 3 program in UC and, after the US IRB approval in August, we expect the first-patient-in for the end of September," **said Prof. Hartmut Ehrlich, M.D., CEO of Abivax.** *"Another important scientific validation of the anti-inflammatory potential of obefazimod was achieved in June by the publication of the phase 2a data of obefazimod in RA in the journal 'Annals of Rheumatic Diseases', and through a presentation of these results at the EULAR congress. This shows that our product has not only the potential to relieve UC-patients from symptoms and improve the quality of life in the long run, but that it could also have significant benefits for patients suffering from other chronic inflammatory diseases."*

Didier Blondel, CFO of Abivax, added: *"Our successful financing round of EUR 49.2M in September 2022 allows Abivax to further advance its priority clinical program of obefazimod in ulcerative colitis. The company's operations are fully funded until the end of Q1 2023 and we stay committed to completing this funding in due course through additional non-dilutive and dilutive financial resources in order to secure the full financing of our UC phase 3 program. Considering the currently very challenging financing environment, we are pleased that Abivax could attract new top-tier US biotech investors - TCGX, Venrock and Deep Track Capital - as well as our existing US and European biotech investors, for the capital increase and royalty certificates. As we have been able to do during the first half of 2022, we will make targeted use of these financial resources, mainly for the conduct and completion of our phase 3 clinical program in order to provide obefazimod as a long-lasting and effective treatment to patients in need and to maximize shareholder value."*

FIRST HALF 2022 FINANCIAL HIGHLIGHTS

Items in the Income Statement	**H1 2022**	**H1 2021**	**Change**
In millions of euros	*M€*	*M€*	*M€*
Total operating income	0.1	9.6	(9.6)
Total operating expenses	(18.7)	(26.5)	7.9
of which Research and Development costs	*(15.9)*	*(24.0)*	*8.1*
of which administrative costs and overheads	*(2.8)*	*(2.6)*	*(0.2)*
Operating result	**(18.6)**	**(16.9)**	**(1.7)**
Financial result	(2.1)	(1.3)	(0.8)
Ordinary result	**(20.7)**	**(18.2)**	**(2.5)**

Extraordinary result	(11.0)	0.1	(11.1)
Tax on income	2.2	1.6	0.6
Result for the period	**(29.6)**	**(16.5)**	**(13.0)**

Financial Items from the Balance Sheet	**30/06/2022**	**31/12/2021**	**Change**
in millions of euros	*M€*	*M€*	*M€*
Net financial position	**(22.9)**	**6.6**	**(29.5)**
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 flow	26.6	60.7	(34.1)
(of which financial debts)	(49.5)	(54.1)	4.6
Total Assets	**71.6**	**110.4**	**(38.7)**
Total Equity	**6.1**	**35.6**	**(29.5)**
of which equity capital	(0.8)	28.8	(29.5)
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 -18.6M as of June 30, 2022 (EUR -1.7M compared to EUR -16.9M as of June 30, 2021), with reduced R&D expenses in H1 2022 compared with H1 2021 (EUR +8.1M), balanced with reduced revenues in H1 2022 compared with H1 2021 (EUR -9.6M), when the company recorded a one-off grant from Bpifrance for Covid-19 program at EUR +9.6M.
- R&D expenses decreased to EUR -15.9M (a decrease of EUR +8.1M compared to EUR -24.0M as of June 30, 2021). In H1 2022, R&D expenses were mainly used for the progress of obefazimod development in inflammatory indications (89% of the total R&D expenses). H1 2022 was dedicated to preparatory work for the phase 3 program of obefazimod in UC, with an investment ramp up to be expected in H2 2022. In contrast, H1 2021 was recording full steam clinical development activities with the end of the phase 2b induction study with obefazimod in UC, as well as with several phase 1 clinical studies to support the overall preparation for the future filing.
- G&A expenses were almost flat at EUR -2.8M as of June 30, 2022 (15% of total operating costs) compared to EUR -2.6M (10%) as of June 30, 2021.
- Total number of employees at the end of June 2022 is 24.
- 2022 Research Tax Credit revenue amounts to EUR +2.2M as of June 30, 2022, compared with EUR +1.6M as of June 30, 2021.
- Finally, the company has recorded an Extraordinary Loss resulting from a EUR -11.0M impairment of the intangible assets relating to its immune enhancer technology platform, led by product candidate ABX196, following the decision to restrict its

development strategy to a partnering opportunity only.
- Net loss is amounting at EUR -29.6M as of June 30, 2022 (EUR -13.0M compared to EUR -16.5M as of June 30, 2021).
- Cash at the end of June 2022 was EUR +26.6M, compared to EUR +60.7M at the end of 2021.
- In September 2022, the Company has completed a EUR +49.2M fundraise with top-tier US and European investors, made of EUR +46.2M capital raise and EUR +2.9M royalty certificates. Following this financing, the Company is funded until the end of Q1 2023, taking into account the existing cash resources and the planned clinical development prioritization for obefazimod, focusing on the UC indication as a top priority.

OPERATING HIGHLIGHTS: PORTFOLIO UPDATE

Obefazimod global pivotal phase 3 clinical program in ulcerative colitis (UC)

1,200 moderate to severe UC patients across 36 countries will take part in the pivotal phase 3 program which consists of two induction studies and a single subsequent maintenance study (ABTECT-1 and ABTECT-2 induction trials - ABX464-105 and ABX464-106 - and ABTECT maintenance trial - ABX464-107). These three pivotal studies are all randomized, double-blind and placebo controlled, using independent, blinded review of the video-taped endoscopies. The primary efficacy endpoint assessed at week 8 (induction) and at week 44 (maintenance) will be clinical remission according to the modified Mayo Score, as required by FDA.[1]

In consultation with international regulators, including FDA and EMA, obefazimod 25mg and 50mg will be investigated in phase 3 for the treatment of UC in advanced therapies (AT) naïve and in AT-failure patients[2] to support the future submission of marketing authorizations.

Abivax is working with IQVIA, a global premier CRO, to jointly set-up and conduct these studies across 36 countries in Europe, the Americas, Japan and other global geographies.

Currently, more than 430 study sites, out of the targeted 600 sites, have already been qualified to take part in the phase 3 trials.

In August, Abivax received approval from the central US Institutional Review Board (IRB) for the protocols of the phase 3 induction studies. This allows the initiation of enrollment of patients into the two phase 3 induction studies in UC in the US. A first patient is anticipated to be included at the end of September 2022.

Obefazimod phase 2b clinical induction and maintenance studies in UC

In April 2022, Abivax reported excellent results from its phase 2b open-label maintenance study, including the full set of 217 patients who completed one year of once-daily oral treatment with 50mg obefazimod or who dropped out of the study. These data emphasize obefazimod's capacity to maintain and further improve patient-outcomes over time, as well as its continued favorable safety and tolerability.

97.7% (217/222) of all patients who completed the phase 2b induction study, irrespective of treatments or treatment outcome during the induction phase, enrolled in the open-label maintenance study to evaluate the long-term safety and efficacy profile of obefazimod for up to two years.

Among the 217 patients who completed the first year of 50mg once-daily oral dosing with obefazimod, 52 had entered the maintenance study already in clinical remission. 38 (73.1%) out of these 52 patients stayed in clinical remission during this first year of maintenance treatment. It is remarkable that 82/165 (49.7%) patients who were not in clinical remission at the end of induction achieved a *de novo* clinical remission during the first year of maintenance.

Furthermore, the clinical remission rate for patients who did not show at least a clinical response at the end of the induction phase was 42.7% (full analysis set) after 48 weeks of treatment, demonstrating that long-term administration of obefazimod provided substantial clinical benefits also for these patients.

33/217 (15.2%) of patients dropped out during the first 48 weeks of the phase 2b maintenance study. Worsening of UC was the primary cause of premature study discontinuation (10 patients - 30%). These patients were all considered as treatment failures in the full analysis set.

During the induction and the maintenance phases of the phase 2b study, obefazimod continued to show a good safety and tolerability profile, confirming the data already generated in over 1,000 patients and volunteers treated with obefazimod so far.[3]

254 patients with moderate to severe active ulcerative colitis were enrolled into the phase 2b clinical study and dosed within three once-daily oral obefazimod treatment groups (25mg, 50mg and 100mg) or placebo. 50% of these patients had inadequate response, loss of response, or intolerance to biologics and/or JAK inhibitor treatments while the other 50% were refractory to conventional treatments. Endoscopies were read centrally and blinded by independent reviewers. The baseline disease characteristics were well balanced across all obefazimod dose groups and the placebo group. Enrolled patients suffered from longstanding UC with an overall mean disease duration of 8.05 years and 71.4% of the patients showed a severe disease profile (baseline modified Mayo Score of 7 to 9 points).

Obefazimod phase 2b study publication in The Lancet Gastroenterology & Hepatology

In September, Abivax published a scientific article in the peer-reviewed journal "The Lancet Gastroenterology & Hepatology", the world-leading gastroenterology and hepatology research journal.[4] 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*". ***[5]***

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.[6]

Obefazimod phase 2a induction and maintenance studies in rheumatoid arthritis (RA)

In June 2022, the safety and efficacy study results of the obefazimod phase 2a study in RA patients were published in the renowned and peer-reviewed journal "Annals of the Rheumatic Diseases (ARD)" [7] and presented at the Annual European Congress of Rheumatology, EULAR 2022.

The publication and EULAR presentation cover the excellent top-line results of the induction phase of its phase 2a clinical study 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.

The primary endpoint of this study, safety and tolerability, was met with 50mg obefazimod once-daily, demonstrating a good safety and tolerability profile in the overall patient population during the 12-week induction phase.

Although the sample size of this study was not powered to show efficacy, the 50mg group already showed statistically significant differences for the key secondary endpoint ACR20[8] compared to placebo at week 12 in the per protocol population.

Following the induction study results, in March 2022, Abivax reported its phase 2a maintenance results in RA after the first year of treatment. Out of the 40 patients who enrolled into the obefazimod maintenance study, 23 patients have completed the first year of treatment and all achieved at least an ACR20, with 19 and 12 patients even achieving ACR50 and ACR70 respectively.

The long-term safety profile of 50mg obefazimod once daily administered in association with methotrexate showed to be favorable and 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. As Abivax is at present focusing on the phase 3 program in UC, the initiation of next steps for the further clinical development in RA depends on the availability of the necessary resources and funding.

"Obefazimod" registered as INN for ABX464

In June, Abivax announced that "obefazimod" was confirmed as international nonproprietary name (INN) for drug-candidate ABX464. Obefazimod has officially been registered and published at the WHO as well as the USAN (United States Adopted Names).

ABX196 phase 1/2 clinical study in hepatocellular carcinoma (HCC)

The phase 1/2 clinical trial in HCC is 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 (HCC) 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 clinical study consists of two phases, a dose escalation phase, and a subsequent expansion phase.

10 patients were enrolled in the dose escalation phase and dosed with 0.1µg, 0.2µg, or 0.4µg ABX196 in combination with nivolumab. A clinical benefit was observed in 5 patients, including 1 patient with a partial response and 4 patients with stable disease. Median progression-free survival for all patients was 113.5 days (49-450 days) and at 276 days (172-450 days) for those showing a clinical benefit.

ABX196 in combination with nivolumab was well tolerated without any dose limiting toxicities or treatment related serious adverse events.

The results of the dose escalation phase were presented at the ASCO GI Cancers Symposium in January 2022.

These results support the further clinical development of ABX196 in the HCC setting and, as a priority, Abivax is assessing potential partnering options.

FURTHER ANNOUNCEMENTS

Abivax change in governance

In August, Abivax announced a transition in the governance of its Board of Directors. Dr. Philippe Pouletty, MD, founder of Abivax and Chairman of the Board of Directors since the inception of the company in 2013, has notified the Board of his decision to resign from his Chairmanship. Until the appointment of a new permanent independent Chairperson, Mrs. Corinna zur Bonsen-Thomas, a current independent Board Member, is taking the role of interim Chairperson of Abivax.

*****

About Abivax (www.abivax.com)

Abivax, a phase 3 clinical stage biotechnology company, is developing novel therapies that modulate the body's natural immune machinery to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax, founded by Truffle Capital, is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax has two drug candidates in clinical development, obefazimod (ABX464) to treat severe inflammatory diseases, and ABX196 to treat hepatocellular carcinoma. More information on the company is available at www.abivax.com. Follow us on Twitter @ABIVAX_.

Contacts

Abivax
Communications
Regina Jehle
regina.jehle@abivax.com
+33 6 24 50 69 63

Investors
LifeSci Advisors
Ligia Vela-Reid
lvela-reid@lifesciadvisors.com
+44 7413 825310

Press Relations & Investors Europe
MC Services AG
Anne Hennecke
anne.hennecke@mc-services.eu
+49 211 529 252 22

Public Relations France
Actifin
Ghislaine Gasparetto
ggasparetto@actifin.fr
+33 6 21 10 49 24

Public Relations France
Primatice
Thomas Roborel de Climens
thomasdeclimens@primatice.com
+33 6 78 12 97 95

Public Relations USA
Rooney Partners LLC
Jeanene Timberlake
jtimberlake@rooneypartners.com
+1 646 770 8858

DISCLAIMER

This press release contains forward-looking statements, forecasts and estimates (including patient recruitment) with respect to certain of the Company's programs. Although Abivax' 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 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, 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 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) which 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, in particular in France. 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 judgement. 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.

[1] Modified Mayo Score refers to stool frequency, rectal bleeding and endoscopy sub score.

[2] Advanced therapies include biologics (TNF inhibitors, anti-integrins, anti-IL-23), and/or S1P receptor modulators, and/or JAK inhibitors.

[3] S. Vermeire et al.: Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial, Gastroenterology, March 2021.

[4] "The Lancet Gastroenterology & Hepatology" has an Impact Factor of 45 (2021 Journal Citation Reports ®, Clarivate 2022).

[5] 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.

[6] 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).

[7] 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.

[8] 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, health assessment questionnaire.