



ABIVAX REPORTS 2021 FINANCIAL RESULTS AND OPERATIONS UPDATE

- Feedback received from the US and European regulatory agencies, both supporting the advancement ABX464 into a phase 3 clinical program in ulcerative colitis (UC), final preparations for the launch of the program are ongoing
- Primary endpoint met with excellent efficacy and safety results of once-daily oral ABX464 in a phase 2b induction study, confirmed by additional long-term data of phase 2a and 2b UC open-label maintenance trials
- Primary endpoint met in a phase 2a study in rheumatoid arthritis (RA) patients, good safety and short- as well as long-term efficacy of 50mg ABX464 once-daily oral administration confirmed by phase 2a induction and one-year maintenance results
- Promising results of the dose escalation phase of ABX196 phase 1/2 study in hepatocellular carcinoma (HCC) presented at ASCO GI Cancers Symposium
- Financing of EUR 85M secured in 2021 by the pricing of an oversubscribed capital increase of EUR 60M and convertible bonds of EUR 25M
 - Cash resources fund operations until the end of Q3 2022

PARIS, France, March 16, 2022 – 06:00 p.m. (CET) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company developing novel therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, today announces its 2021 annual financial results, as of December 31, 2021, and provides an update on the progress of its product pipeline. The financial statements for 2021, approved by the Company’s Board of Directors on March 14, 2022, have been audited and the certification report is being prepared by the Company’s external auditors.

“2021 was a year full of important progress for Abivax. We presented excellent efficacy results of the ABX464 phase 2b induction and our ongoing phase 2a and 2b maintenance trials in ulcerative colitis. Further, the induction and one-year maintenance results of the phase 2a trial of ABX464 in RA also showed promise for a durable efficacious treatment in this indication. Besides the efficacy data, the good safety and tolerability profile of ABX464 has been further strengthened and we now have a very solid safety database of over 1,000 subjects treated with ABX464 so far. In addition, the laboratory analysis results underpin the unique and innovative mechanism of action of ABX464, based on the upregulation of a single microRNA, miR-124, which has the capacity to durably dampen chronic inflammation,” **said Prof. Hartmut Ehrlich, M.D., CEO of Abivax.** *“Based on these results, the US and European regulators expressed their support in moving ABX464 into phase 3 clinical testing in UC and we are planning to enroll the first patient into this pivotal study in Q3 2022. It is our ambition to make ABX464 swiftly accessible to all UC patients in need of a safe and durably efficient therapeutic management option. With its novel mechanism of action, we are confident that ABX464 also has the potential to make a real difference in the treatment of additional, often very debilitating chronic inflammatory diseases.”*

Didier Blondel, CFO of Abivax, added: *“Our successful financing round of EUR 85M in 2021 allows Abivax to advance its priority clinical program of ABX464 in ulcerative colitis. Taking into account the initiation of the phase 3 studies, the company’s operations are fully funded until the end of Q3 2022. We have been and continuously are evaluating different options to extend our cash runway and fully finance the conduct of the pivotal phase 3 studies and the commercial launch of ABX464 for the treatment of ulcerative colitis, and potentially further indications. This evaluation includes discussions for potential collaboration with a pharmaceutical company, as well as potential non-dilutive and/or dilutive options which would be selected based on shareholder value.”*

2021 Financial Highlights

Items in the Income Statement	FY 2021	FY 2020	Change
<i>in millions of Euros</i>			
Total operating income	9.7	1.7	8.0
Total operating expenses	(52.2)	(39.7)	(12.6)
<i>of which Research and Development costs</i>	(47.2)	(34.5)	(12.7)
<i>of which administrative costs and overheads</i>	(5.0)	(5.1)	0.1
Operating result	(42.6)	(38.0)	(4.6)
Financial result	(3.1)	(2.3)	(0.8)
Ordinary result	(45.7)	(40.3)	(5.4)
Extraordinary result	0.1	0.2	(0.1)
Tax on income	4.2	2.6	1.6
Result for the period	(41.4)	(37.6)	(3.8)

Financial Items from the Balance Sheet	31/12/2021	31/12/2020	Change
<i>in millions of Euros</i>			
Net Financial Position	6.6	(4.7)	11.3
of which financial fixed assets*	0	0	0
of which fixed-term deposits (maturing in > 1 year)	0	0	0
of which fixed-term deposits (maturing in < 1 year)	0	0	0
of which available cash	60.7	29.3	31.4
of which financial debts	(54.1)	(34.0)	(20.1)
Total Assets	110.4	71.3	39.1
Total Equity	35.6	17.9	17.7
of which equity capital	28.8	4.7	24.1
of which conditional advances	6.8	13.2	(6.4)
* Excluding items of the liquidity contract (liquidity and own shares) and deposits & guarantees			

- Operating loss EUR -42.6M (EUR -4.6M compared to EUR -38M as of December 31, 2020) mainly reflects the increasing investments in R&D (EUR +12.7M), which is partly balanced by the one-off income resulting from Bpifrance grants relating to the full completion of the ABX464 Covid-19 program (EUR +8.0M)
- Total number of employees at the end of December 2021 was steady at 26
- R&D expenses amounted to EUR -47.2M, mainly due to increasing funding needs of the development of ABX464 in inflammatory indications (97% of the total R&D expenses)
- G&A expenses stayed stable at EUR -5.0M in 2021 (9.5% of total operating costs) compared to 2020 at EUR -5.1M
- Revenues comprised EUR +13.9M in 2021, including EUR +9.7M resulting from Bpifrance ABX464 Covid-19 funding (EUR +1.6M in 2020) as well as EUR +4.2M R&D tax credit in 2021 (EUR +2.6M in 2020)
- Cash at the end of 2021 was EUR +60.7M, compared to EUR +29.3M at the end of 2020
- The company's cash utilization rate during 2021 was EUR -5.5M per month (EUR -4.4 M in 2020), whereas it has successfully completed a fund raising in July 2021 (EUR +85M gross amount, EUR +81.5 net amount after deduction of transaction fees), composed of EUR +60M equity raise combined with EUR +25.0 convertible bonds



- The Company is currently funded until the end of Q3 2022, based on the following assumptions:
 - Assessment of planned R&D needs in 2022, notably taking into account the start of the ABX464 UC phase 3 program in Q3 2022
 - 2022 opening cash
 - Exercise of the remaining equity line with Kepler Cheuvreux, corresponding to the issuance of a maximum of 300,000 new shares
 - 2022 cash in resulting from the reimbursement of the 2021 Research Tax Credit

Operating Highlights: Portfolio Update

ABX464 phase 2b induction study in ulcerative colitis (UC)

In May and September 2021, Abivax announced the top-line and subsequent full results of its ABX464 randomized, placebo-controlled phase 2b trial in moderate to severe ulcerative colitis following **8 weeks** and 16 weeks of induction treatment. The data confirm the potency of once-daily oral ABX464 to maintain and to further improve clinical remission¹ rates over time, across all tested dose levels (25mg, 50mg and 100mg). This is true for both, the entire population as well as in the subset of patients who were previously refractory to biologic treatments and/or JAK inhibitors.

Additional analyses also confirm the novel mechanism of action of ABX464, which fundamentally differentiates this first-in-class small molecule from any other drug or drug-candidate in the inflammatory field. It is based on the upregulation of a single physiological microRNA (miR-124), a potent down-regulator of key pro-inflammatory cytokines and chemokines, thereby “putting a brake” on inflammation.² A highly statistically significant upregulation of miR-124 could be detected in rectal tissue in all patients treated for 8 weeks with ABX464, compared to baseline. This observation underpins the potential of ABX464 to become a safe short- and long-term efficient treatment option in UC and potentially additional inflammatory indications.

254 patients with moderate to severe active ulcerative colitis were enrolled into the phase 2b clinical study and dosed within three once-daily oral ABX464 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 ABX464 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).

ABX464 phase 2a and 2b maintenance studies in ulcerative colitis

The durable safety and excellent efficacy results of the phase 2a and 2b induction studies were confirmed by [additional maintenance data](#), released in October 2021.

15 out of the 22 patients who were initially enrolled into the phase 2a maintenance study completed the third year of treatment with 50mg once-daily oral ABX464 as of June 29, 2021. Among the 13 patients who had centrally read endoscopies at the completion of year 3, 11 patients (85%) were still in clinical remission, of which 7 patients (54%) had an endoscopic remission (endoscopic subscore=0) and 11 patients had an endoscopic remission or improvement (endoscopic subscore=0 or 1).

Among the subset of 101 patients of the phase 2b maintenance study for whom one-year maintenance data was available by the cut-off date of September 15, 2021, 28 had entered the maintenance study already in clinical remission: 23/28 (82.1%) of these patients stayed in clinical remission and only 5/28 patients (17.9%) lost clinical remission during this first year of maintenance. Importantly, 36/73 patients (49.3%) who were not in clinical remission at the end of induction achieved a *de novo* clinical remission during the first year of maintenance.

¹ Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1.

² J. Tazi et al.: [Specific and selective induction of miR-124 in immune cells by the quinoline ABX464: a transformative therapy for inflammatory diseases](#), Drug Discovery Today, Volume 26, Issue 4, April 2021, Pages 1030-1039



Remarkably, the clinical remission rate for patients who did not show at least a clinical response³ at the end of the induction phase was 55.9% (PP) and 50% (ITT) after 48 weeks of treatment, demonstrating that long-term administration of ABX464 provided substantial clinical benefits also for these patients.

During the induction and the maintenance phases of the phase 2a and 2b studies, ABX464 continued to show a good safety and tolerability profile, confirming the data already generated in over 1,000 patients and volunteers treated with ABX464 so far.

The full phase 2b clinical data set after one year of continued once-daily treatment with 50mg ABX464 in UC will become available in the course of Q2 2022.

ABX464 phase 1 clinical studies

Abivax conducts four phase 1 studies with ABX464 in healthy volunteers, as part of the usual practice during late-stage clinical drug development.

The patient enrollment has been completed in all studies and the data analysis is progressing according to plan.

The currently available preliminary results are all supportive in advancing ABX464 into the pivotal phase 3 program.

ABX464 global pivotal phase 3 clinical program in ulcerative colitis

In December 2021 and January 2022 respectively, the US regulatory agency (FDA) as well as the European Medicines Agency (EMA) expressed their support in moving ABX464 into a pivotal phase 3 program in moderate to severe UC. The agencies raised no concerns regarding clinical safety, non-clinical safety, or CMC.

Both the FDA and EMA agreed with Abivax that progressing 25mg and 50mg (as the highest dose) into phase 3 testing is appropriate for both induction and the subsequent maintenance studies in UC. The agencies were supportive of Abivax's intention to drop the 100mg dose, as no additional therapeutic benefit could be observed with this higher dose.

Abivax is working with IQVIA, a global premier CRO, to jointly set-up and conduct these studies across Europe, the US, Japan and other global geographies. Given the current developments, Abivax decided that Ukraine, Russia and Belarus cannot be part of the ABX464 global phase 3 study program in UC.

In the context of the current situation in Ukraine, Russia and Belarus and in order to ensure the robustness of the list of countries and study sites which will be part of the phase 3 program, the enrollment of the first patient is now planned for Q3 2022. This change is not expected to have an impact on the overall timelines of study completion.

Potential impact of military crisis in Ukraine on Abivax's clinical study program

The ABX464 phase 2b maintenance study in moderate to severe UC patients is the only clinical study currently conducted by Abivax on Ukrainian territory. The evaluation after 12 months of treatment has already been conducted for all Ukrainian patients enrolled and the availability of the phase 2b one-year maintenance results in Q1 2022 will thus not be impacted by the current situation.

Jointly with its CRO IQVIA, Abivax puts great efforts into ensuring the follow-up on the patients who are not able to present themselves in the study centers. This is done by means of the remote monitoring system that has been established and successfully applied during the Covid-19 pandemic.

Abivax ABX464 abstract presentation and Industry Symposia

Abivax's late-breaking abstract on the ABX464 phase 2b clinical data in UC was accepted as an oral presentation for the UEG Week Virtual conference and presented in October 2021 by Prof. Séverine Vermeire, M.D., Ph.D, the principal investigator of the study.

In addition, Abivax hosted an industry symposium at the [UEG Week Virtual in October 2021](#) as well as at the [Congress of ECCO in February 2022](#) on "ABX464, a novel anti-inflammatory drug-candidate for the treatment of

³ Clinical response (per Modified Mayo Score) is defined as a decrease from baseline in the Modified Mayo Score ≥ 2 points and $\geq 30\%$ from baseline, plus a decrease in RBS ≥ 1 or an absolute RBS ≤ 1 .



ulcerative colitis". At both events, the presentations were given by the internationally renowned key opinion leaders Prof. Bruce Sands, M.D., M.S. and Prof. William Sandborn, M.D.

ABX464 in rheumatoid arthritis (RA)

In June, Abivax communicated excellent [top-line results of the induction phase of its phase 2a clinical study](#) of ABX464 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 TNF α inhibitors participated in the study.

The primary endpoint of this study, safety and tolerability, was met with 50mg ABX464 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 ACR20⁴ compared to placebo at week 12 in the per protocol population.

Recently, Abivax reported its [phase 2a maintenance results in RA](#) after the first year of treatment. Out of the 40 patients who enrolled into the ABX464 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 ABX464 once daily administered in association with methotrexate showed to be favorable and consistent with previous observations.

The phase 2a data clearly support moving ABX464 into a subsequent phase 2b trial for the treatment of RA. As Abivax is at present focusing on the launch of 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.

ABX464 in Crohn's disease (CD)

Due to the pathophysiological and clinical similarities of CD and UC, Abivax is planning a pivotal phase 2b study in CD with the objective to demonstrate a similar strong efficacy and favorable safety as already reported in the phase 2a and phase 2b studies in UC.

With the development focus of ABX464 being on UC, the initiation of the clinical trial in CD depends on the availability of the necessary resources and funding.

ABX464 market potential in inflammatory diseases

The inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. In 2021, there were an estimated 3.6M diagnosed cases of ulcerative colitis in G7 countries (US, France, Germany, Italy, Spain, UK and Japan). The total market opportunity for ABX464 is USD 6.2B annually, based on 2021 pharmaceutical sales estimates for ulcerative colitis in these countries. For inflammatory bowel diseases (ulcerative colitis and Crohn's disease), sales were USD 19.2B in 2021 and are estimated to grow to USD 25B by 2026.⁵

For rheumatoid arthritis, there were an estimated 3.8M diagnosed cases in G7 countries in 2021. The total market size in RA is USD 22.3B annually, based on 2021 pharmaceutical sales estimates for rheumatoid arthritis in these countries and is expected to stay at this level in the years to come.⁶

The currently accessible market for ABX464 in IBD and RA is estimated to grow to approximately USD 50B by 2026. The overall chronic inflammation market is estimated to exceed USD 110B at that time.

⁴ 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.

⁵ Source: Informa for Biologics, JAK inhibitors and S1P

⁶ Source: Informa for Biologics and JAK inhibitors



Stopping of ABX464 in Covid-19 – miR-AGE trial

On March 5, 2021, Abivax [announced it would be stopping the phase 2b/3 Covid-19 study](#) (miR-AGE trial - ABX464-401) due to lack of efficacy. However, the safety data generated in these Covid-19 infected high-risk patients, are important as they showed no imbalance in safety and tolerability between the 335 patients on ABX464 vs. the 170 placebo patients.

The remaining funding from Bpifrance has been fully received by the Company in 2021.

ABX196 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 Abivax is currently evaluating the design of a follow-on study of ABX196 in HCC and, in parallel, assessing potential partnering options.

Financial Calendar 2022

- **Friday April 29, 2022:** Publication of the 2021 annual financial report
- **Thursday June 9, 2022:** Annual Shareholders Meeting
- **Thursday September 15, 2022:** Publication of financial statements as of June 30, 2022
- **Friday September 30, 2022:** Publication of 2022 half year financial report

About Abivax (www.abivax.com)

Abivax, a 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 is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax has two drug candidates in clinical development, 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

Public Relations France

Actifin

Ghislaine Gasparetto

ggasparetto@actifin.fr

+33 6 21 10 49 24

Investors

LifeSci Advisors

Ligia Vela-Reid

lvela-reid@lifesciadvisors.com

+44 7413 825310

Public Relations France

Primatice

Thomas Roborel de Climens

thomasdeclimens@primatice.com

+33 6 78 12 97 95

Press Relations & Investors Europe

MC Services AG

Anne Hennecke

anne.hennecke@mc-services.eu

+49 211 529 252 22

Public Relations USA

Rooney Partners LLC

Jeanene Timberlake

jtimberlake@rooneypartners.com

+1 646 770 8858

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