Abivax presents first-half 2021 financial results and operations update

September 23, 2021

In May and September, Abivax reported excellent efficacy and safety results of once daily oral ABX464 in a phase 2b induction study in ulcerative colitis (UC) after 8 and 16 weeks of treatment, primary and key secondary endpoints were met

Abivax also communicated additional maintenance data of ABX464 phase 2a and 2b trials that confirmed long-term efficacy and safety of 50mg once daily oral ABX464 in UC patients

In June, Abivax announced that ABX464 met the primary endpoint in a phase 2a study in rheumatoid arthritis (RA) patients and demonstrated a good safety and tolerability profile with 50mg once daily oral administration

Abivax is currently evaluating the future clinical development prioritization for ABX464, focusing on the global phase 3 development in UC, to extend the Company's cash runway from Q2 2022 until the end of Q3 2022

Cash for operations strengthened in July with a financing of EUR 85M secured by the pricing of an oversubscribed capital increase of EUR 60M and convertible bonds of EUR 25M

On October 4, at UEG Week Virtual 2021, a late-breaking abstract on ABX464 phase 2b data in UC will be presented and Abivax will also be hosting a Live Industry Symposium at the conference

PARIS, France, September 23, 2021 – 6:00 pm (CEST) – 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 half-year financial results, as of June 30, 2021, and provides an update on its clinical development progress. The financial statements for the first half of 2021, approved by the Company's Board of Directors on September 21, 2021, have been audited and the certification report is being prepared by the Company's external auditors.

"2021 has been a particularly positive and eventful year for Abivax. We announced excellent phase 2b clinical top-line and subsequent full results for the treatment of ulcerative colitis patients as well as very promising data of the phase 2a study in rheumatoid arthritis, both conducted with our lead compound ABX464. It is particularly encouraging to see, that our one-year and three-year long-term data of the ongoing phase 2a and phase 2b open-label maintenance studies confirm the sustained efficacy as well as the continued good safety profile of ABX464 in UC patients. We are also pleased that our late breaking abstract on the UC phase 2b data has been selected for an oral presentation at this year's United European Gastroenterology conference. This is another external validation of the potential of ABX464 to become an efficient durable treatment for patients suffering from UC.", **said Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax.**

He continued: *"Additional laboratory analyses now also reinforce the novelty and differentiation factors of the mechanism of action of ABX464 with a statistically significant upregulation of miR-124, a specific, physiologic, anti-inflammatory microRNA, observed in rectal tissues of patients across all dose groups. With these very positive clinical results and laboratory data, Abivax engaged in advanced interactions with the relevant regulatory authorities to launch its priority phase 3 clinical program with ABX464 in ulcerative colitis as quickly as possible. There is an urgent need for long-term efficacious and safe new drugs in the field of inflammatory bowel diseases. The entire Abivax team and its scientific advisory board are committed to take ABX464 to the finish line and provide the many patients suffering from these very debilitating chronic diseases with a new, potent and well-tolerated therapeutic management option."*

Didier Blondel, CFO of Abivax, added: *"Abivax successfully secured EUR 85M major financing in July under attractive terms, with the pricing of an oversubscribed capital increase of EUR 60M and convertible bonds of EUR 25M. With our current and available cash resources, together with the planned outcome of the prioritization of our clinical development activities for ABX464, our operations are expected to be funded until the end of Q3 2022. We are now carefully evaluating the strategic possibilities for the Company. Our strategic priority remains a potential partnering with a large pharma or biotech company, under the premises that the full potential of ABX464 in inflammatory bowel diseases as well as in the entire chronic inflammatory field is taken into account. As an alternative strategic option, we are also looking into additional financing opportunities, notably in the US and in Europe, that would maximize shareholder value."*

FIRST HALF 2021 FINANCIAL HIGHLIGHTS

Items in the Income Statement	**H1 2021**	**H1 2020**	**Change**
In millions of euros	*M€*	*M€*	*M€*

Total operating income	9.6	1.6	8.0
Total operating expenses	(26.5)	(16.3)	(10.3)
of which Research and Development costs	(24.0)	(13.5)	(10.5)
of which administrative costs and overheads	(2.6)	(2.8)	0.2
Operating result	(16.9)	(14.6)	(2.3)
Financial result	(1.3)	(1.0)	(0.4)
Ordinary result	(18.2)	(15.6)	(2.7)
Extraordinary result	0.1	0.2	(0.1)
Tax on income	1.6	0.0	1.6
Result for the period	(16.5)	(15.4)	(1.1)

Financial Items from the Balance Sheet	**30/06/2021**	**31/12/2020**	**Change**
in millions of euros	*M€*	*M€*	*M€*
Net financial position	(27.5)	(4.7)	(22.8)
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	4.3	29.3	(25.0)
(of which financial debts)	(31.8)	(34.0)	2.2
Total Assets	55.1	71.3	(16.2)
Total Equity	2.4	17.9	(15.5)
of which equity capital	(4.5)	4.7	(9.1)

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 -16.9M (EUR -2.3M compared to EUR -14.6M as of June 30, 2020) due to increased investments in R&D (EUR 10.5M), partly balanced by grants received from Bpifrance (EUR 9.6M).
- Revenues of EUR 9.6M are relating to ABX464 Covid-19 funding by Bpifrance which have entirely become grants after the announcement of the failure of miR-AGE clinical study in March 2021.
- R&D expenses increased to EUR 24M (an increase of EUR 10.5M compared to EUR 13.5M as of June 30, 2020), mainly due to overall strong progress of ABX464 development costs in inflammatory indications (94% of the total R&D expenses).
- G&A expenses were at EUR 2.6M as of June 30, 2021 (10% of total operating costs) compared to EUR 2.8M (17%) as of June 30, 2020.
- Total number of employees at the end of June 2021 is 29.
- 2021 Research Tax Credit revenue amounts to EUR 1.6M as of June 30, 2021.
- Cash at the end of June 2021 was EUR 4.3M, compared to EUR 29.3M at the end of 2020, before taking into account the EUR 85M financing realized in July 2021.
- The Company is currently funded until Q2 2022 and is expecting to extend the funding until the end of Q3 2022, taking into account the existing cash resources and the planned clinical development prioritization for ABX464, focusing on the UC indication as a top priority.

OPERATING HIGHLIGHTS: PORTFOLIO UPDATE

ABX464 phase 2b clinical induction study in ulcerative colitis

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 remission[1] rates over time, across all tested dose levels (25mg, 50mg and 100mg). The sustained and improved effects after 16 weeks of treatment could also be observed for the reduction of the modified Mayo Score[2], the endoscopic improvement[3], the presence of clinical response[4] as well as for the reduction in fecal calprotectin in patients treated with ABX464. 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.

Consistent with the other clinical studies, ABX464 was found to be safe and well tolerated at all dose levels during the 8-week and 16-week induction period. Within the ABX464 phase 2b induction study, the most frequently reported adverse events were mild and transient (i.e. headache, nausea, gastrointestinal pain) and manageable with or without over-the-counter medication.

Additional laboratory 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. [5] 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. In the phase 2b clinical study, 254 patients with moderate to severe active ulcerative colitis were enrolled into the trial and dosed with 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 inhibitors 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 median duration of 5.45 years and 71.4% of the patients showed a severe disease profile (baseline modified Mayo Score of 7 to 9 points).

ABX464 phase 2b clinical maintenance study in ulcerative colitis

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 into the subsequent open-label maintenance study to evaluate the long-term safety and efficacy profile of ABX464 for up to two years. Preliminary results of the open label maintenance study in the first 51 patients after 48 weeks of once-daily treatment with 50mg ABX464 are in line with the **previously observed outcomes in the phase 2a study**, with 53% (ITT[6]) in clinical remission and 59% (ITT) with endoscopic improvement at 48 weeks (centrally read endoscopies).

In this maintenance study, ABX464 continues to show a good safety and tolerability profile.

Additional phase 2b maintenance results including the first 101 patients who completed 48 weeks of daily treatment with ABX464 will be made public in the late-breaking abstract presentation on October 4, given by Prof. Séverine Vermeire, principal investigator of the study, at the UEG Week Virtual 2021.

ABX464 phase 2a study in ulcerative colitis: Update on ongoing maintenance trial

Abivax recently reported the 3-year efficacy data from its ongoing phase 2a maintenance study in UC. 15 out of the 22 patients who were initially enrolled into the phase 2a maintenance study in 2018, now completed the third year of treatment with 50mg once daily oral ABX464.

Among the 13 patients who underwent centrally read endoscopies at the completion of year 3, 11 patients (85%) were still in clinical remission, among which 7 patients (54%) had an endoscopic remission (endoscopic subscore=0) and 11 patients had an endoscopic improvement (endoscopic subscore=0 or 1).

The long-term safety profile of chronic ABX464 administration continues to be very favorable.[7]

Launch of ABX464 global phase 3 clinical development program in ulcerative colitis

For the launch of its global phase 3 clinical program with ABX464 in UC, Abivax plans to engage in the mandatory consultations with the relevant regulatory authorities. The End-of-Phase-2 meeting with the US regulatory agency (FDA) is expected to occur in Q4 2021. Subject to a positive feedback from the FDA, expected for the end of the year, and the subsequent scientific advice from the European Medical Agency (EMA), planned for Q1 2022, Abivax is planning to start the recruitment and inclusion of the first patients without delay.

ABX464 phase 2a clinical study 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 TNFα 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 ACR20[8] compared to placebo at week 12 in the per protocol population. The ACR20is the key primary efficacy endpoint required by the FDA for licensure of new drugs in rheumatoid arthritis.

Following the positive results of the phase 2a trial, entering into the next stage of clinical testing in RA will depend on the outcome of Abivax's clinical development prioritization.

ABX464 in Crohn's disease (CD)

Due to the pathophysiological and clinical similarities of CD and UC, Abivax is planning to initiate 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.

However, the initiation of the clinical trial in CD will depend on the outcome of Abivax's clinical development prioritization.

ABX464 phase 1 clinical studies

Abivax is currently conducting four phase 1 studies with ABX464 in healthy volunteers, as part of the usual practice during late-stage clinical drug development. All studies are progressing according to plan. With respect to the phase 1 study conducted in healthy Japanese volunteers, for which Abivax announced the authorization of the Japanese regulatory authorities in August, dosing of the first subject is scheduled for September 28.

The four studies will provide additional data required to support Abivax in seeking approval from the regulatory authorities for its late-stage clinical development program of ABX464, starting with UC.

ABX464 potential market in inflammatory diseases

The inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. In 2020, there were an estimated 3.5M diagnosed cases of ulcerative colitis in G7 countries (US, France, Germany, Italy, Spain, UK and Japan). The total market opportunity for ABX464 is USD 6.0B annually, based on 2020 pharmaceutical sales estimates for ulcerative colitis in these countries. For inflammatory bowel diseases (ulcerative colitis and Crohn's disease), sales were USD 17.9B in 2020 and are estimated to grow to USD 25.0B by 2025, i.e. the year ABX464 is expected to reach the market for ulcerative colitis.

For rheumatoid arthritis, there were an estimated 3.8M diagnosed cases in G7 countries in 2020. The total market size in RA is USD 20.4B annually, based on 2020 pharmaceutical sales estimates for rheumatoid arthritis in these countries, estimated to grow to USD 22.9B by 2025. [9]

The currently accessible market for ABX464 in IBD and RA is estimated to grow to USD 48B by 2025. The overall chronic inflammation market is estimated to exceed USD 110B at that time.

Prioritization of clinical study programs

Abivax today will further reinforce its focus regarding the launch and conduct of its future clinical trial programs. In order to efficiently allocate and manage the Company's financial and human resources, the Abivax management and board of directors decided to evaluate the clinical development prioritization for ABX464. The decision, expected in Q4 2021, will be based on market opportunities, market access, product differentiation, clinical development costs, timelines, the probability of success in the US, Europe and Asia and maximizing shareholder value.

ABX196 in hepatocellular carcinoma (HCC)

The phase 1/2 clinical trial in HCC is ongoing at the Scripps MD Anderson Cancer Center in San Diego and the MD Anderson Cancer Center in Houston. In this proof-of-concept study, patients who are failing on checkpoint inhibitors are treated with ABX196 in combination with nivolumab (Opdivo®, Bristol Myers Squibb). The clinical study consists of two phases, a dose escalation phase, and a subsequent expansion phase.

Currently, the data consolidation of dose escalation phase for which the last patient has been enrolled in June this year, is underway.

Given a positive outcome of the analysis, the Company will decide on next steps, depending on the availability of the required financing or the opportunity of a licensing agreement.

Stopping of ABX464 clinical study in Covid-19 and Bpifrance financing

In March 2021, Abivax **announced it would be stopping the phase 2b/3 Covid-19 study** (miR-AGE trial - ABX464-401) due to lack of efficacy. This decision followed the recommendation of the Data Safety and Monitoring Board (DSMB), based on an interim analysis evaluating data of 305 high-risk Covid-19 patients after they completed the 28-days study period.

Exit conditions of the Bpifrance agreement relating to the funding of this program are being finalized. In total, Abivax and its academic partner CHU Nice are expecting to benefit from a total funding of EUR 22M (EUR 11M in grants for each partner), which would properly cover the dedicated expenses relating to this program.

UPCOMING EVENTS

UEG Week Virtual 2021 – Abivax late-breaking abstract presentation and live symposium

Abivax's late-breaking abstract on its ABX464 phase 2b clinical data in UC has been accepted for this year's UEG Week Virtual and will be presented by Prof. Séverine Vermeire, M.D., Ph.D, the principal investigator of the study, on Monday, October 4, 2021, between 10:30-11:30 am CEST (4:30-5:30 am EST).

In addition, Abivax will be hosting an **Industry Symposium at the UEG Week Virtual 2021** on Monday, October 4, 2021 at 1:00-2:00 pm CEST (7:00-8:00 am EST) on "ABX464, a novel anti-inflammatory drug-candidate for the treatment of ulcerative colitis". Presentations on the continued need for novel drugs in IBD and the potential of ABX464 to address them will be given by the internationally renowned key opinion leaders Prof. Bruce Sands, M.D., M.S. and Prof. William Sandborn, M.D. In addition, Didier Scherrer, Ph.D., Vice-President R&D at Abivax, will provide more details on the novel and unique mechanism of action of ABX464.

UEG Week Virtual subscribers can follow the live symposium and view the subsequently provided on-demand replay under the following link: **https://virtualweek.ueg.eu/symposium/is-10**

FURTHER ANNOUNCEMENTS

Jean-Marc Steens, M.D., has decided to end his career at Abivax

After more than five years as Chief Medical Officer at Abivax, Jean-Marc Steens, M.D., has decided to end his career at Abivax. Abivax would like to thank him for his contribution and wishes him all the best in his future endeavors. Sophie Biguenet, M.D., has joined Abivax as Chief Medical Officer.

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About Abivax (www.abivax.com)

Abivax, a clinical stage biotechnology company, is developing novel therapies that modulate the physiological inflammation and immunological pathways 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 chronic inflammatory diseases, and ABX196 to treat hepatocellular carcinoma. More information on the company is available at www.abivax.com. Follow us on Twitter @ABIVAX_.

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

[3] Endoscopic improvement is defined as endoscopic subscore ≤1.

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

[5] 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

[6] Intent-to-treat patient population

[7] 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

[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.

[9] Source: Informa