



ABIVAX PRESENTS FIRST-HALF 2020 FINANCIAL RESULTS AND OPERATIONS UPDATE

- **ABX464 Phase 2a ulcerative colitis two-year maintenance study results confirm good safety profile and durable efficacy of 50 mg once-daily oral ABX464**
 - **77% (180/232) of patients randomized in ABX464 Phase 2b ulcerative colitis study, recruitment expected to be completed by the end of 2020**
- **ABX464 pivotal Phase 2b/3 trial for Crohn's disease planned with anticipated start of patient recruitment in Q1 2021**
- **ABX464 Phase 2b/3 Covid-19 study, ABX464 Phase 2a rheumatoid arthritis study and ABX196 Phase 1/2 hepatocellular carcinoma trial all making progress**
- **Cash for operations until beginning 2021, with major financing secured through non-dilutive funding from Bpifrance (EUR 36m) and a state-guaranteed loan from Société Générale (EUR 5m)**

PARIS, France, September 24, 2020 – 08:00 p.m. (CET) – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, today announces its 2020 half-year financial results, as of June 30, 2020, and provides an update on its pipeline progress. The financial statements for the first half of 2020, approved by the Company's Board of Directors on September 22, 2020, have been audited and the certification report is being prepared by the Company's external auditors.

Prof. Hartmut Ehrlich, M.D., CEO of Abivax said: *"Abivax has made tremendous progress in its ongoing clinical programs despite the Covid-19 pandemic, and the recruitment pace is now back on a pre-Covid-19 level. This is particularly important for Abivax's priority clinical program, the ABX464 Phase 2b trial in ulcerative colitis, conducted in 15 European countries as well as the US and Canada, with 77% of patients already randomized to date. We expect recruitment in this trial to be completed by the end of this year and to report top-line results in early Q2 2021. Given the fast enrollment, KOL and investigators' commitment, and high patient retention rate, we are confident that the outcome of this study will confirm the very promising two-year Phase 2a maintenance data that we announced at the beginning of September. Additionally, we were able to efficiently set up the miR-AGE trial to test the potentially beneficial triple effect of ABX464 for the treatment of high-risk Covid-19 patients. The trial is ongoing in six European countries and Brazil, and we expect to open centers in Mexico, Chile and Peru shortly. As always, our strategic decisions are driven by value generation for our shareholders as well as the ability to broadly and rapidly provide access to ABX464 for patients in need and partnering remains the Company's preferred scenario."*

Didier Blondel, CFO of Abivax, added: *"The past months have been particularly eventful for Abivax and opened up several new opportunities. Due to the unique properties of ABX464 which has both an antiviral and anti-inflammatory effects, we expanded our clinical pipeline to treat high-risk Covid-19 patients to prevent the development of life-threatening hyperinflammation and the resulting potentially fatal acute respiratory distress syndrome. We are grateful that the French government (Bpifrance and CGI) actively support the miR-AGE trial as well as the future development and required next steps for the potential commercialization of ABX464. The EUR 36 million in funding provided by Bpifrance was complemented by an additional EUR 5 million from Société Générale; taken together with our current cash resources, of EUR 12.1m as of June 30, 2020, we have sufficient funding for operations until early 2021. With the continued trust and financial support of our stakeholders and the French government, we are in a good position to select, in the near term, the most attractive opportunities for Abivax shareholders and patients in need of innovative Abivax products."*

FIRST HALF 2020 FINANCIAL HIGHLIGHTS

Items in the Income Statement	H1 2020	H1 2019	Change
<i>In millions of euros</i>	<i>M€</i>	<i>M€</i>	<i>M€</i>
Total operating income	1.6	0.0	1.6
Total operating expenses	(16.3)	(17.3)	1.0
<i>of which Research and Development costs</i>	(13.5)	(15.0)	1.5
<i>of which administrative costs and overheads</i>	(2.8)	(2.3)	(0.5)
Operating result	(14.6)	(17.2)	2.6
Financial result	(1.0)	(0.7)	(0.3)
Ordinary result	(15.6)	(17.9)	2.3
Extraordinary result	0.2	0.0	0.2
Tax on income	0.0	3.8	(3.8)
Result for the period	(15.4)	(14.2)	(1.3)

Financial Items from the Balance Sheet	30/06/2020	31/12/2019	Change
<i>in millions of euros</i>	<i>M€</i>	<i>M€</i>	<i>M€</i>
Net financial position	(12.4)	(11.0)	(1.5)
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	12.1	9.8	2.3
(of which financial debts)	(24.5)	(20.7)	(3.7)
Total Assets	49.8	51.7	(1.9)
Total Equity	9.4	18.6	(9.2)
of which equity capital	(3.6)	11.8	(15.4)
of which conditional advances	13.2	6.8	6.4

* Excluding items of the liquidity contract (liquidity and own shares) and deposits & guarantees

- Operating loss EUR -14.6m (EUR 2.6m compared to EUR -17.2m as of June 30, 2019) due to retained investments in R&D (EUR 1.5m).
- Total number of employees at the end of June 2020 steady at 26.
- R&D expenses decreased to EUR -13.5m (EUR 1.5m compared to EUR -15.0m as of June 30, 2019), mainly due to the consequences of the Covid-19 pandemic and the lockdown of the research laboratories. R&D funding was focused on the development of ABX464 in inflammatory indications (92% of the total R&D expenses).
- G&A expenses were at EUR 2.8m as of June 30, 2020 (17% of total operating costs) compared to EUR 2.3m (13%) as of June 30, 2019.
- Revenues of EUR 1.6m are relating to the grant component of the first milestone payment of Covid-19 Bpifrance funding agreement.
- 2020 Research Tax Credit should be limited, due to 2020 Covid-19 Bpifrance funding milestone payments, reducing the eligible R&D spending basis. Therefore, no revenue accrual has been recorded as of June 30, 2020 end, contrary to June 2019 (EUR 3.8m).
- Cash at the end of June 2020 was EUR 12.1m, compared to EUR 9.8m at the end of 2019.



- Company is currently funded until early 2021, based on the following assumptions:
 - the assessment of planned increasing R&D needs
 - the exercise of the remaining equity line with Kepler Cheuvreux for EUR 11m (EUR 20 Abivax share price assumption)
 - the 2020 cash in resulting from the second milestone payment of Covid-19 Bpifrance funding of EUR 7.9m before year-end

OPERATING HIGHLIGHTS: PORTFOLIO UPDATE

ABX464 in ulcerative colitis (UC)

After the promising results obtained during the Phase 2a 12-month-open-label extension study, Abivax recently [reported excellent two-year efficacy and safety data for ABX464 ulcerative colitis Phase 2a maintenance study](#). These results once again confirmed the good safety profile and durable efficacy of 50 mg once-daily oral ABX464 in patients with moderate-to-severe UC after the second year of treatment, with 69% of patients in clinical remission and 94% benefiting from a clinical response. Furthermore, readings of the endoscopies were performed centrally by independent reviewers and median fecal calprotectin, the key biological marker of UC disease activity, remained at 31.6 µg/g (normal levels are below 50 µg/g).

For the currently ongoing UC Phase 2b trial, ABX464-103, patient enrollment is ongoing and on track in all 15 European countries, as well as in Canada and the US where patients have been included into the study. 77% (180/232) of patients have been randomized to date and recruitment is anticipated to be completed by the end of 2020. Top-line results of the two-month induction study are expected for Q2 2021. Abivax is currently preparing all required steps to advance ABX464 for the treatment of moderate-to-severe UC into a Phase 3 clinical program.

With its persistent good clinical safety and tolerability profile along with its durable superior efficacy, Abivax is very confident that ABX464 can become a potent chronic therapy option to address the high unmet medical need in UC and potentially additional inflammatory diseases.

ABX464 in Crohn's disease (CD)

Abivax decided to follow the latest recommendations of its leading KOLs and is now planning to go straight into a pivotal Phase 2b/3 trial in CD. Due to the pathophysiological and clinical similarities of CD and UC, Abivax is keen to investigate if the pivotal study in CD will demonstrate strong efficacy and favorable safety as already reported in UC. The clinical study in CD is expected to start patient recruitment beginning of 2021.

ABX464 in Covid-19 – miR-AGE trial

In May, Abivax announced the launch of a randomized, double-blind, placebo-controlled Phase 2b/3 trial of ABX464 in 1,034 Covid-19 elderly or high-risk patients (miR-AGE trial - ABX464-401). In June, the miR-AGE trial was selected by the French Government as one of six research projects to find a therapeutic solution to treat Covid-19 patients. These projects are financed with a total of EUR 78m by the French state, of which Abivax receives 36m EUR in non-dilutive funding for the conduct of the trial as well as for manufacturing scale-up and additional development costs related to other ABX464 studies for the potential filing of Marketing Authorization Applications (MAAs).

The miR-AGE trial is currently ongoing in France, Italy, Spain, Germany, Belgium and the UK as well as in Brazil. Patient recruitment in Mexico is imminent, as are regulatory approvals to initiate the study in Peru and Chile. Abivax will perform an interim analysis after the treatment of 300 patients and, subject to the evolution of the pandemic, plans to complete recruitment in Q4 2020.

The decision to expand Abivax's clinical pipeline with a Covid-19 indication was based on the potentially beneficial triple effect of ABX464 for the treatment of elderly and high-risk patients, including: 1) antiviral effect to inhibit SARS-CoV-2 replication, demonstrated in an *in vitro* stringent human pulmonary epithelium model; 2) anti-inflammatory effect to prevent hyper-inflammation, shown in a Phase 2a clinical trial in UC patients with



once-daily oral administration of ABX464; and 3) tissue repair properties that might limit longer-term pulmonary damage as observed for the healing of inflammatory lesions in UC patients. With its unique molecular mechanism of action, and convenient oral dosing, ABX464 has the potential to prevent and treat cytokine storm and hyper-inflammation, which lead to acute respiratory distress syndrome (ARDS) and death of Covid-19 patients.

Other clinical programs:

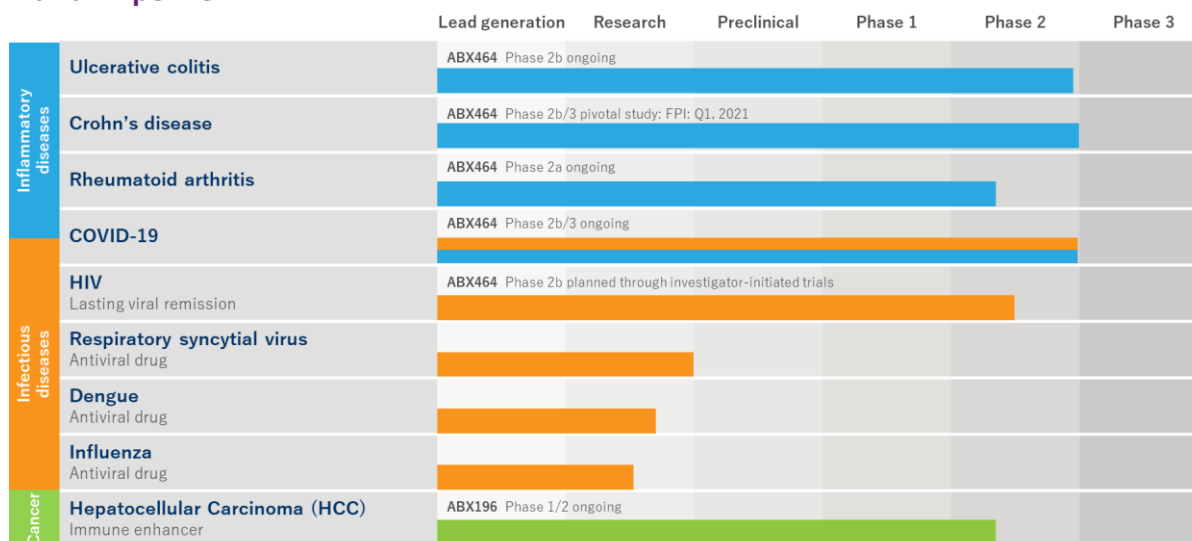
ABX464 in rheumatoid arthritis (RA)

The ongoing [ABX464-301 Phase 2a study](#) is designed to evaluate the safety, tolerability and preliminary efficacy of two oral dose-levels of ABX464 administered daily, in combination with methotrexate (MTX), in patients with moderate-to-severe active RA who had an inadequate response to MTX and/or to one or more anti-tumor necrosis factor alpha (TNF α) biological therapeutics. The trial is ongoing in 24 study centers across Europe and the completion of enrollment of 60 patients is expected for the end of this year.

ABX196 in hepatocellular carcinoma (HCC)

In the Phase 1/2 clinical trial ongoing at the Scripps MD Anderson Cancer Center in San Diego and the MD Anderson Cancer Center in Houston, HCC patients are treated with ABX196 in combination with the checkpoint inhibitor nivolumab (Opdivo[®], Bristol Myers Squibb). Up to 46 patients will be included into this clinical study that consists of two phases, a dose escalation phase and an expansion phase. Top-line data from the dose escalation phase are expected at the end of this year.

Abivax Pipeline



Financial Calendar 2020

- **Wednesday September 30, 2020:** Publication and release of 2020 Half Year Report

About Abivax (www.abivax.com)

Abivax, a clinical stage biotechnology company, is mobilizing the body’s natural immune machinery to treat patients with autoimmune diseases, viral infections, and cancer. Abivax is listed on Euronext compartment C (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

Chris Maggos

chris@lifesciadvisors.com

+41 79 367 6254

Public Relations France

DGM Conseil

Thomas Roborel de Climens

thomasdeclimens@dgm-conseil.fr

+33 6 14 50 15 84

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

Marion Janic

mjanic@rooneyco.com

+1 212 223 4017

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