



Press Release

Abivax 2018 Financial Results and Operations Update

ABX464 showed impressive safety and efficacy during induction treatment of Ulcerative Colitis (UC)

Magnitude and durability of efficacy further increased after 6 months treatment during open-label maintenance study

ABX464 advancing into Phase 2b trials in UC and Phase 2a for Crohn's disease and Rheumatoid Arthritis

ABX196 to file US IND for first clinical trial in patients with hepato-cellular carcinoma

Two RSV lead compounds from mRNA Discovery Platform advancing into pre-clinical development

Available funding, up to EUR 35 million, sustains operations for 12 months until Q1 2020

Abivax to focus on further building shareholder value

PARIS, March 14, 2019 - 7:00 AM (CET) – Abivax (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company harnessing the immune system to develop treatments for inflammatory diseases, autoimmune diseases and cancer, as well as a functional cure for HIV, today announced its 2018 yearly financial results, as of December 31, 2018, and provided an update on its current product pipeline progress. The financial statements for 2018, approved by the Company's Board of Directors on March 12, 2019, have been audited and the certification report is being prepared by the Company's external auditors.

*"2018 was a terrific year for Abivax both financially and clinically, highlighted by a safe cash position and transformative Phase 2a results in ulcerative colitis and HIV infection with our lead drug-candidate, ABX464. Last September, we reported impressive top-line Phase 2a safety and efficacy results of oral once daily ABX464 during 2 months of induction treatment of ulcerative colitis," said **Professor Hartmut Ehrlich, MD, Chief Executive Officer of Abivax**. "Earlier this week, we announced the exciting 6-months interim results of our maintenance study with ABX464 in ulcerative colitis, ABX-102, which showed an amplification of the beneficial effects and very good safety profile observed in patients during the induction study. The recent publication in Nature Scientific Reports on elucidation of ABX464's mechanism of action has further validated our decision to accelerate the development of this highly differentiated, oral, first-in-class therapeutic candidate in inflammatory diseases. Regulatory filings to authorize initiation of Phase 2b testing in UC have already been submitted in multiple countries."*

*"In addition, ABX464's unique mechanism of action, preclinical and clinical data suggest a broadly applicable anti-inflammatory effect, which has prompted the preparation of Phase 2a clinical trials of ABX464 in Crohn's disease and rheumatoid arthritis, to be initiated in the coming months. We are confident we can build strong shareholder value with these achievements," **Professor Ehrlich** continued. "Furthermore, an IND for our clinical trial with ABX196 in hepatocellular carcinoma patients will be submitted shortly to the US FDA. And finally, two lead compounds have been identified for the prophylaxis and/or treatment for patients with respiratory syncytial virus infection. Given this exciting R&D portfolio, the company is clearly prioritizing ABX464 in inflammatory indications, as well as ABX196, while other programs (e.g. Ebola) will be put on hold".*

Didier Blondel, Chief Financial Officer of Abivax, said: *“We are thrilled not only with the progress achieved by Abivax in 2018, but also with the prospects of our lead therapeutic-candidate, ABX464, and the company moving into 2019. Given ABX464’s novel mechanism of action, the impressive data together with the fact that it is administered orally once a day, we believe it has tremendous potential in multiple indications with important unmet medical need, representing large market opportunities. In our assessment, the current economic valuation of ABX464 (net present value, NPV) exceeds Abivax current market capitalization. We do not intend to raise additional capital via dilutive equity issuance in the near future.”*

2018 FINANCIAL HIGHLIGHTS

Items in the Income Statement <i>in millions of euros</i>	FY 2018	FY 2017	Variance
Total operating income	0.8	0.4	0.4
Total operating expenses	(19.9)	(14.5)	(5.4)
<i>of which Research and Development costs</i>	(15.9)	(10.8)	(5.1)
<i>of which administrative costs and overheads</i>	(4.0)	(3.7)	(0.3)
Operating result	(19.1)	(14.1)	(5.0)
Financial result	(0.5)	0.0	(0.5)
Ordinary result	(19.6)	(14.1)	(5.5)
Extraordinary result	0.0	0.2	(0.2)
Tax on income	3.8	2.7	1.1
Result for the period	(15.8)	(11.2)	(4.6)

- Operating loss €19.1m (- €5.0m compared to - €14.1m as of December 31, 2017) mainly reflects the increasing investments in R&D (+ €5,1m)
- Total number of employees at the end of December 2018 was steady at 25
- R&D expenses amounted to €15.9m, mainly due to the development of ABX464 in inflammatory indications (69%), as well as investments in the progressive scaling up of the mRNA splicing platform and library of small molecules (23%)
- G&A expenses were at €4.0m in 2018 (20% of total operating costs) compared to €3.7m (26%) in 2017
- Revenues, which were comprised mainly of a Research Tax Credit, were at €3.8m in 2018, compared to €2.7m in 2017
- The Company’s cash utilization rate during 2018 was €1.5m per month
- Cash at the end of 2018 was €13.0m, compared to €17.0m at the end of 2017
- Company is fully funded through Q1 2020, based on the following assumptions:
 - the assessment of planned R&D needs
 - the €10m second tranche of Kreos Capital, which has been amended in January 2019, with a drawing bound to the start of Ulcerative Colitis Phase 2b clinical trial before mid July 2019 (Tranche B). The €10m first tranche of Kreos Capital loan agreement was drawn in July 2018 (Tranche A)
 - the exercise of the remaining equity line with Kepler Cheuvreux for €7m (€9 share price assumption)

- the 2019 cash in resulting from 2018 Research Tax Credit and 2018 Bpifrance RNPVir milestone, which together are planned at €5m

Financial Items from the Balance Sheet in millions of euros	12/31/2018	12/31/2017	Variance
Net financial position	2.1	16.8	(14.7)
of which financial fixed assets*	5.0	15.0	(10.0)
of which fixed-term deposits (maturing in > 1 year)	0.0	0.0	0.0
of which fixed-term deposit (maturing in <1 year)	5.0	15.0	(10.0)
of which available cash flow	8.0	2.0	6.0
(of which financial debts)	(10.9)	(0.3)	(10.6)
Total assets	54.0	53.8	0.2
Total equity	34.7	48.2	(13.6)
of which equity capital	28.7	43.9	(15.2)
of which conditional advances	5.9	4.3	1.6

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

Operating Highlights: Portfolio Update

ABX464 in UC and other inflammatory diseases

In September of 2018, Abivax reported impressive top-line safety and efficacy data from its randomized, double-blind, placebo-controlled phase 2a clinical trial ABX464-101 in patients with moderate to severe UC. In this clinical trial, ABX464 induction treatment was conducted in 32 patients with moderate-to-severe UC, refractory to anti-TNF monoclonal antibodies or corticosteroids. The final data from this 2-month double-blind placebo controlled clinical study indicated that oral, once-daily 50mg ABX464 was safe, well-tolerated, and demonstrated statistically significant efficacy based on both clinical and endoscopic endpoints in this study. The proportion of subjects achieving clinical remission was greater in the ABX464 group than in the placebo group (35.0% vs. 11.1%, p=ns). The difference between ABX464 and placebo treated patients in colorectal mucosal healing was statistically significant (50% vs. 11%, p=0.034). Furthermore, the onset of the therapeutic effect of ABX464 was rapid, with a reduction of the partial Mayo Score (pMS)¹ between ABX464 and placebo being observed at the first assessment following treatment for two weeks, which became significant at eight weeks (-3.9 vs. -1.8, p=0.029; likelihood ratio CHI-square test). Similarly, the difference of the reduction of the total Mayo Score (tMS)² after eight weeks was statistically significant (-4.6 vs. -2.1, p=0.029). For additional details on the induction study results, please refer to a previous [press release](#).

At the end of the completed 2-month induction study in 32 patients, 22 of these (15 previously treated with ABX464 and 7 who had received placebo) opted to enroll in the 12-month open-label maintenance study, ABX464-102. At month six, 19 of the 22 patients were still in the study, receiving a once-daily, oral capsule

¹ The partial Mayo Score is composed of stool frequency, rectal bleedings and the physician's global assessment of disease severity

² The total Mayo Score is composed of the 3 parameters listed above, plus mucosal appearance at endoscopy

of 50mg ABX464. The 6-month interim analysis showed that ABX464 continued to have a good safety profile when administered chronically. The efficacy data as assessed by partial Mayo Score (pMS)³ show that 12 of 13 patients (92%) who were originally in the active group during the induction phase are still improving during the maintenance study with an overall mean reduction of 76% versus baseline during their total of 8 months treatment with ABX464, including a 36% decrease of pMS during the maintenance phase. The 6 patients who entered the maintenance study after placebo during the 2 months induction phase showed a mean decrease of 68% in pMS during their 6 months of treatment with ABX464.

Importantly, the reduction in pMS was correlated with a major reduction of fecal calprotectin, the most widely used biomarker in UC. During the maintenance study at month 6, fecal calprotectin was reduced by an overall of 98% versus baseline in patients on ABX464 during induction (68% after 2 months induction and 30% during maintenance), and by 91% in former placebo patients. Importantly, the mean fecal calprotectin levels in the 2 groups decreased to 86 and 54 ug/g respectively, and thus very close to normal values, which are in the range of up to 50 ug/g for individuals with no IBD, between 50 and 200 ug/g for borderline cases, and above 200 ug/g for patients with Inflammatory Bowel Disease (IBD).

The inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. It is estimated that nearly 1 million patients with ulcerative colitis live in the US, 650,000 in Europe, and over 2.7 million globally, representing a potential market opportunity of up to \$5.5 billion annually, based on 2017 pharmaceutical sales in this sector. For IBD (UC and Crohn's disease), pharmaceutical sales during this same period are estimated to have reached \$15 billion. The market potential for the full range of inflammatory conditions (including neuro-inflammatory diseases) is currently estimated to be in excess of \$70 billion, a market and patient population that the Company believes could benefit from ABX464.

ABX464 clinical development in HIV

In June of 2018, Abivax communicated top-line data from ABX464-005, a Phase 2a study in HIV infected patients that evaluated whether ABX464 could reduce the HIV reservoir in blood and in rectal tissue of these fully suppressed HIV patients. ABX464-005 showed that ABX464 reduced HIV-viral reservoirs in the blood as well as in rectal tissue. Abivax currently plans to advance this promising therapeutic candidate into Phase 2 testing for HIV (reduction of viral reservoir and inflammation) based on access to third party funding.

ABX196 – a clinical stage immune enhancer for oncology based on iNKT regulation

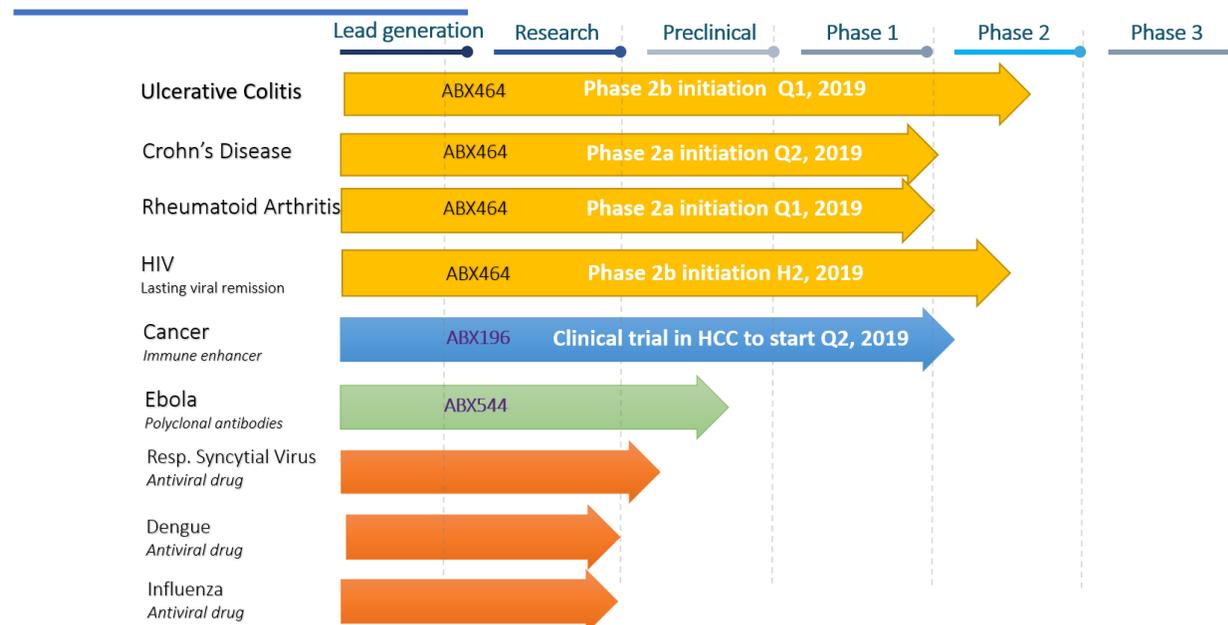
ABX196 is a synthetic agonist (glycolipid) of iNKT (invariant Natural Killer T) cells, in a liposomal formulation. Preclinical development of ABX196 has shown its capacity to turn tumors that are non-responsive to checkpoint inhibitors into responsive tumors and the molecule previously underwent Phase 1 clinical testing as a potential adjuvant in healthy volunteers. Abivax is planning to start a proof-of-concept clinical study in hepato-cellular cancer in Q2 2019 in the US.

Novel antiviral molecules with potential to treat RSV, Influenza and Dengue discovered

Abivax's screenings of its targeted library of small antiviral molecules have generated positive hits with potential for Respiratory Syncytial Viral (RSV), Influenza and Dengue indications. As part of its long-term collaboration with EVOTEC, two lead molecules targeting RSV have been identified and are in the lead optimisation phase. They will advance into pre-clinical proof of concept testing in H2 2019. Molecules for Influenza and Dengue are currently in the lead identification phase.

Abivax Pipeline:

Abivax: A strong and diversified pipeline



Kreos Capital up to €20m debt financing agreement in July 2018

On July 25, 2018, Abivax completed up to €20m debt financing agreement with Kreos Capital. This financing comprises two tranches of €10m each (€8m straight bonds and €2m convertible bonds), with the first €10m tranche fully drawn in July 2018 (Tranche A), and the second €10m tranche amended in January 2019 with a drawing bound to the start of Ulcerative Colitis Phase 2b clinical trial before mid July 2019 (Tranche B).

FINANCIAL CALENDAR

- **Tuesday April 30, 2019** : Publication and Release of the 2018 Annual Financial Report
- **Friday June 7, 2019** : Annual Shareholders Meeting
- **Thursday September 19, 2019** : Publication of Financial Statements as of June 30, 2019
- **Friday September 27, 2019** : Publication and Release of 2019 Half Year Report

UPCOMING EVENTS:

- **BIO Europe SPRING** – March 25 -27, 2019
- **Digestive Disease Week (DDW)** – May 18-21, 2019

WEBCAST PRESENTATION

Abivax senior management will host a webcast and teleconference Thursday, March 14 at 2:00 pm CET (Paris time) / 9am ET (NYC time), to discuss 2018 financial results, clinical results, and address questions.

Attendees can participate by weblink (<https://edge.media-server.com/m6/p/neya9py8>) or connect by phone using the following coordinates:

Telephone conference

Dial in details, Participants:

Confirmation Code: **8987717**

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About Abivax (www.abivax.com)

Abivax is mobilizing the body's natural immune machinery to treat patients with inflammatory/autoimmune diseases, viral diseases and cancer. A clinical-stage company, Abivax leverages its anti-inflammatory/antiviral and immune enhancing platforms to optimize candidates to treat inflammatory diseases, HIV and liver cancer. Abivax is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). More information on the company is available at www.abivax.com/en.

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