



## Abivax 2019 Financial Results and Operations Update

- **ABX464 Phase 2a ulcerative colitis maintenance study showed excellent long-term efficacy and continued safety**
- **ABX464 Phase 2b ulcerative colitis study progressing well in 15 European countries and Canada with patient enrollment on target**
- **FDA granted ABX464 IND, U.S. patient enrollment in Phase 2b ulcerative colitis trial expected for Q2 2020**
  - **ABX464 Phase 2a rheumatoid arthritis study progressing according to plan**
  - **First patient recently treated with ABX196 in U.S. Phase 1/2 clinical hepatocellular carcinoma trial**
- **Cash for operations until end of Q2 2020**

**PARIS, France March 16, 2020 – 07:00 p.m. (CET)** – Abivax SA (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 announced its 2019 yearly financial results, as of December 31, 2019, and provided an update on progress in its product pipeline. The financial statements for 2019, approved by the Company’s Board of Directors on March 10, 2020, have been audited and the certification report is being prepared by the Company’s external auditors.

**Prof. Hartmut Ehrlich, M.D., Chief Executive Officer of Abivax said:** *“Abivax achieved several exciting clinical and regulatory milestones in 2019 and early 2020, making it a very successful year where we delivered on our long-term development strategy. With the transformative potential of the efficacy results of ABX464 in ulcerative colitis, our lead product candidate made significant clinical progress and is now in mid-stage clinical testing in Europe and Canada, with patient recruitment allowed in the U.S. after a recently granted IND from the FDA. Importantly, we also expanded our clinical pipeline with ABX196 for liver cancer, which is currently in clinical testing in the U.S. At present, we are working to create value and the best outcome for our shareholders by accelerating our ongoing development programs and expanding our funding resources. Partnering continues to be our preferred scenario.”*

**Didier Blondel, Chief Financial Officer of Abivax, added:** *“Even before the recent decline of the stock price due to Covid-19, we believe that the valuation of Abivax did not reflect the potential blockbuster sales and profitability of ABX464. This treatment is expected to be useful across various inflammatory disease indications and simultaneously targets important markets with high unmet medical needs. Our available cash position, including EUR 9.8m at the end of 2019, provides funding for operations through Q2 2020. Thanks to the financing completed so far and to the continued support of our investors, we are in a robust position to weigh our strategic options in order to further optimize shareholder value.”*

With regards to the current Covid-19 developments, Abivax is taking necessary measures to limit the impacts on the ongoing clinical study programs and to ensure that patients continue to have access to the study medication. Abivax is closely monitoring the situation and will communicate significant potential changes appropriately.

## 2019 Financial Highlights

Items in the Income Statement <i>in millions of Euros</i>	FY 2019	FY 2018	Change
Total operating income	0.0	0.8	(0.8)
Total operating expenses	(33.3)	(19.9)	(13.4)
<i>of which Research and Development costs</i>	(29.0)	(15.9)	(13.1)
<i>of which administrative costs and overheads</i>	(4.3)	(4.0)	(0.3)
<b>Operating result</b>	<b>(33.3)</b>	<b>(19.1)</b>	<b>(14.2)</b>
Financial result	(1.7)	(0.5)	(1.2)
<b>Ordinary result</b>	<b>(35.0)</b>	<b>(19.6)</b>	<b>(15.4)</b>
Extraordinary result	0.1	0.0	0.1
Tax on income	4.2	3.8	0.4
<b>Result for the period</b>	<b>(30.6)</b>	<b>(15.8)</b>	<b>(14.8)</b>

Financial Items from the Balance Sheet <i>in millions of Euros</i>	31/12/2019	31/12/2018	Change
<b>Net financial position</b>	<b>(11.0)</b>	<b>2.1</b>	<b>(13.1)</b>
of which financial fixed assets*	0.0	5.0	(5.0)
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	5.0	(5.0)
of which available cash flow	9.8	8.0	1.8
(of which financial debts)	(20.7)	(10.9)	(9.8)
<b>Total Assets</b>	<b>51.7</b>	<b>54.0</b>	<b>(2.3)</b>
<b>Total Equity</b>	<b>18.6</b>	<b>34.7</b>	<b>(16.1)</b>
of which equity capital	11.8	28.7	(17.0)
of which conditional advances	6.8	5.9	0.9

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

- Operating loss EUR -33.3m (EUR -14.2m compared to EUR -19.1m as of December 31, 2018) mainly reflects the increasing investments in R&D (EUR 13.1m)
- Total number of employees at the end of December 2019 was steady at 26
- R&D expenses amounted to EUR 29m, mainly due to increasing funding needs of the development of ABX464 in inflammatory indications (81% of the total R&D expenses), as well as investments in the progressive scaling up of the mRNA splicing platform and library of small molecules (12%)
- G&A expenses were at EUR 4.3m in 2019 (13% of total operating costs) compared to EUR 4m (20%) in 2018
- Revenues, which were comprised mainly of a Research Tax Credit, were at EUR 4.2m in 2019, compared to EUR 3.8m in 2018
- The company's cash utilization rate during 2019 was EUR 2.7m per month; Abivax has drawn a EUR 10m second tranche of the Kreos loan agreement in May 2019, and has achieved a



EUR12m capital raise with Sofinnova in July 2019, which were allowing a limited EUR -3.2m decrease in cash position during 2019; cash at the end of 2019 was EUR 9.8m, compared to EUR 13.0m at the end of 2018

- Company is funded through Q2 2020, based on the following assumptions:
  - the assessment of planned R&D needs
  - the exercise of the remaining equity line with Kepler Cheuvreux for EUR 7m (EUR 12 Abivax share price assumption)
  - the 2020 cash in resulting from 2019 Research Tax Credit at EUR 4m

## Operating Highlights: Portfolio Update

### ABX464 in ulcerative colitis (UC)

After the promising results obtained in the Phase 2a induction study, Abivax presented data from the subsequent [12-month open-label extension study](#). The observations confirmed the preliminary positive results on safety and tolerability of ABX464 along with a first evidence of its excellent long-term efficacy. Furthermore, the data showed that ABX464 maintained the overexpression of miR-124 (a critical factor of immunity and inflammation modulated by ABX464) during the 12-month study period.

Based on the encouraging results from the Phase 2a induction and maintenance trials, Abivax initiated a Phase 2b study, ABX464-103, in UC and enrolled the first patient in August 2019. The company is also conducting another open-label maintenance study, ABX464-104, in patients who complete ABX464-103 trial to confirm the long-term safety and efficacy profile of ABX464. The Phase 2b induction study in UC is currently conducted in 232 patients in 126 study centers in 15 European countries, Canada and more recently in the U.S., after an [IND was granted by the FDA in January 2020](#). Top line results from this trial are expected in Q4 2020.

At present, more than 210 patients have been treated with ABX464, including UC patients who, to date, have been on continuous daily dosing for up to two years. Compared to currently available therapy options in UC, ABX464 shows a very good clinical safety and tolerability profile along with evidence of superior long-term efficacy.

### 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 $\alpha$ ) biological therapeutics. The primary endpoint of the study will be safety and tolerability and the trial is being conducted in 24 study centers across Europe including Belgium, Czech Republic, France, Hungary and Poland with up to 60 patients. Top-line data, after 3 months of induction treatment, are expected during the summer of 2020.

Patients who complete the ABX464-301 trial have the possibility to roll over into a Phase 2a open-label study, ABX464-302, aiming at the evaluation of the one-year safety and efficacy of ABX464 as a maintenance therapy in RA.

### ABX464 in Crohn's disease (CD)

Due to the clinical similarities of CD and UC, and the predictability of the DSS model for both diseases, several key opinion leaders (KOLs) are confident that ABX464 will also show beneficial effects in



patients suffering from CD. Along with the good safety data and promising efficacy results obtained for ABX464 in UC, the company has been encouraged to directly enter a Phase 2b trial for the treatment of CD. Abivax is currently planning for a start of the enrollment of patients in the second half of 2020.

#### **ABX464 market potential in inflammatory diseases**

The inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. According to recent statistics, there were an estimated 1.7m diagnosed cases with UC in the U.S., G5 Europe (France, Germany, Italy, Spain, Great Britain) and Japan in 2019 with about half of the patients suffering from the moderate-to-severe form. This represents a potential market opportunity of up to USD 5.8bn annually, based on 2019 pharmaceutical sales estimates in these countries for UC only. For IBD (UC and CD), these sales have reached about USD 17.2bn in 2019. There were approximately 4.3m diagnosed cases in RA in U.S., G5 Europe and Japan in 2019, representing a market potential of about USD 25bn.

The market potential for the full range of inflammatory conditions (including neuro-inflammatory diseases) is currently estimated to be in excess of USD 80bn, a market and patient population that the Company believes could benefit from ABX464.<sup>1</sup>

#### **ABX196 in hepatocellular carcinoma (HCC)**

Abivax is currently running a [U.S. Phase 1/2 clinical trial](#) in which HCC patients are treated with ABX196 in combination with the checkpoint inhibitor nivolumab (Opdivo®, Bristol Myers Squibb). This trial is conducted in collaboration with two cancer centers of excellence, the Scripps MD Anderson Cancer Center in San Diego and the MD Anderson Cancer Center in Houston, and the first patient has recently been treated with ABX196 in combination with nivolumab. Up to 46 patients will be included into this clinical study that consists of 2 phases, a dose escalation phase and an expansion phase. We expect to have first data from the dose escalation phase at the end of this year. This data will provide information about the dose level which shows efficacy and is, at the same time, well tolerated by the patients.

#### **ABX464 clinical development in HIV**

In HIV, Abivax is continuing its clinical development plan with ABX464 through potential investigator-initiated trials, conducted independently at clinical research institutes, with Abivax to provide the test medication for these studies.

#### **Novel antiviral molecules in the infectious disease space**

Abivax's screening of its targeted library of small antiviral molecules has generated positive hits with potential for Respiratory Syncytial Virus (RSV), Influenza and Dengue. As part of its long-term collaboration with Evotec, a lead compound targeting RSV was identified and recently entered pre-clinical development.

In addition, Abivax expects to test several of its antiviral compounds against COVID-19.

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<sup>1</sup> Source: GlobalData



## Abivax Pipeline



## Financial Calendar 2020

- **Thursday April 30, 2020:** Publication and release of the 2019 Annual Financial Report
- **Friday June 5, 2020:** Annual Shareholders Meeting
- **Thursday September 24, 2020:** Publication of Financial Statements as of June 30, 2020
- **Wednesday September 30, 2020:** Publication and release of 2020 Half Year Report

## Upcoming Events

- **May 2 - 5, 2020:** Digestive Disease Week - Chicago, U.S.

## About Abivax ([www.abivax.com](http://www.abivax.com))

Abivax is mobilizing the body's natural immune machinery to treat patients with autoimmune diseases, viral infections, and cancer. Abivax is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). More information on the company is available at [www.abivax.com](http://www.abivax.com). Follow us on Twitter @ABIVAX\_.

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