



## **ABIVAX First-Half 2019 Financial Results and Operations Update**

*Nine-month Phase 2a maintenance study confirmed further clinical improvements, with durability of efficacy and safety of ABX464 in ulcerative colitis patients*

*One-year Phase 2a maintenance results including endoscopy to be reported during UEG week (October 19-23, Barcelona, Spain)*

*ABX464 advanced into Phase 2b ulcerative colitis trial and Phase 2a rheumatoid arthritis trial*

*ABX196 to move into Phase 1/2 trial in hepatocellular carcinoma*

*€12m capital raised with Sofinnova in July 2019*

*Available funding sustains operations until end of Q2 2020*

**Paris, France, 19<sup>th</sup> September 2019 at 6:00 pm** – Abivax (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company harnessing the immune system to develop treatments for inflammatory diseases, autoimmune diseases, cancer and a functional cure for HIV, today announced its 2019 half-year financial results, as of June 30, 2019, and provided an update on its product pipeline progress. The financial statements for the first half of 2019, approved by the Company's Board of Directors on Sept. 17, 2019, have been audited and the certification report is being prepared by the Company's external auditors.

*"Abivax has made excellent progress in the first half of 2019, continuing to advance our products through clinical trials, combined with the successfully capital raise with Sofinnova Partners in July 2019, which extends our cash runway until the end of Q2 2020 and provides important validation of our science and strategy by a highly-respected life sciences investor," said **Prof. Dr. Hartmut J. Ehrlich, Chief Executive Officer of Abivax.** "We are accelerating development of ABX464, a highly differentiated oral, first-in-class therapeutic candidate, in a Phase 2b trial in ulcerative colitis. We have initiated a Phase 2a trial in rheumatoid arthritis, where ABX464's rapid and potent anti-inflammatory effects suggest it may have significant potential and are studying ABX196 in hepatocellular carcinoma in a Phase 1/2 study. Now with secured funding in place, we are very much looking forward to moving these promising and highly differentiated drug candidates through clinical development for the benefit of patients with these debilitating diseases."*

**Didier Blondel, Chief Financial Officer of Abivax, added:** *"Our strong cash position of €11.6m, together with Sofinnova's €12m investment, ensures sufficient funding to cover our working capital needs until the end of Q2 2020. With this backing, we are funding the important clinical trials with ABX464 and ABX196 through notable value inflection points, which will add further impetus to the company's*

development. In addition, the company is focusing on converting these successive positive scientific milestones into a major partnering for ABX464, allowing value creation for shareholders.”

## FIRST HALF 2019 FINANCIAL HIGHLIGHTS

Items in the Income Statement <i>in thousands of euros</i>	H1 2019 <i>k€</i>	H1 2018 <i>k€</i>	Change <i>k€</i>
Total operating income	40	492	(452)
Total operating expenses	(17 268)	(9 058)	(8 210)
<i>of which Research and Development costs</i>	14 981	7 061	7 919
<i>of which administrative costs and overheads</i>	2 288	1 996	291
<b>Operating result</b>	<b>(17 228)</b>	<b>(8 565)</b>	<b>(8 663)</b>
Financial result	(655)	27	(683)
<b>Ordinary result</b>	<b>(17 883)</b>	<b>(8 538)</b>	<b>(9 345)</b>
Extraordinary result	(47)	(59)	12
Tax on income	3 759	1 352	2 407
<b>Result for the period</b>	<b>(14 172)</b>	<b>(7 245)</b>	<b>(6 926)</b>

- H1 2019 results of -€14.2m (-€7.0m compared with -€7.2m as of June 30, 2018) mainly reflect the increasing investment in development of ABX464 in inflammatory indications (+€8.0m), as well as ABX196 clinical study preparation in hepatocellular carcinoma (+€0.8m), while toning down investment for ABX464 in HIV indication (-€1.3m).
- R&D expenses amounted to €15.0m, focused on ABX464 development costs (76%).
- G&A expenses were at €2.3m in H1 2019 (13% of total operating costs) compared to €2.0m (22%) in H1 2018.
- Revenues, which were comprised mainly of a Research Tax Credit, were at €3.8m in H1 2019, compared to €1.8m in H1 2018.
- Cash at the end of June 2019 was €11.6m, compared to €13.0m at the end of 2018.
- The Company has cashed in the €10m second tranche of Kreos Capital loan agreement during H1 2019, and has reported in July 2019 that they have completed a €12m capital raise with Sofinnova Partners, which is therefore adding to existing cash at the end of June 2019. The company is also planning to expand the remainder of its existing equity line funding with Kepler Cheuvreux (730 000 shares or 6.1 % of the current capital) by another 2 years until September 2021.
- Company is fully funded through Q2 2020, based on the assessment of planned R&D needs.
- Total headcount was 26 at the end of June 2019.

Financial Items from the Balance Sheet <i>in thousands of euros</i>	30/06/2019 <i>k€</i>	31/12/2018 <i>k€</i>	Change <i>k€</i>
<b>Net financial position</b>	<b>(10 244)</b>	<b>2 102</b>	<b>(12 346)</b>
of which financial fixed assets*	0	5 000	(5 000)
of which fixed-term deposits (maturing in > 1 year)	0	0	0
of which fixed-term deposits (maturing in < 1 year)	0	5 000	(5 000)
of which available cash flow	11 556	8 002	3 554
(of which financial debts)	(21 800)	(10 900)	(10 900)
<b>Total Assets</b>	<b>54 598</b>	<b>54 048</b>	<b>550</b>
<b>Total Equity</b>	<b>20 913</b>	<b>34 655</b>	<b>(13 742)</b>
of which equity capital	14 977	28 744	(13 767)
of which conditional advances	5 936	5 910	26

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



## Operating Highlights: Portfolio Update

### ABX464 in ulcerative colitis (UC) and other inflammatory diseases

In August 2019, the first patient was enrolled in the multinational Phase 2b clinical trial of ABX464 with once a day, convenient oral dosing, for the treatment of moderate to severe active UC. In total, the clinical trial will be conducted in more than 15 countries globally. Twelve countries involved have already approved the study. The objectives of this trial are to confirm that ABX464's novel mechanism of action will result in potent and durable anti-inflammatory responses in a much larger patient population, and to define the optimal dose for subsequent Phase 3 testing. Top-line data after 2 months of induction treatment are expected around the end of 2020.

In August 2019 as well, the first patient was dosed in study ABX464-301, a Phase 2a clinical trial of ABX464 to treat moderate to severe active rheumatoid arthritis (RA). The trial has been fully approved in four countries (France, Poland, Czech Republic, and Hungary). ABX464-301 is a Phase 2a study 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. Top-line data, after 3 months of induction treatment, are expected during the summer of 2020.

### ABX196 in hepatocellular carcinoma (HCC)

Last June, U.S. FDA has accepted an investigational new drug (IND) application for ABX196, which has shown potent efficacy in HCC animal models. The open IND allows Abivax to test ABX196 in combination with nivolumab (Opdivo<sup>®</sup>, Bristol Myers Squibb), a checkpoint inhibitor, in a first Phase 1/2 clinical trial to treat patients with HCC. The initial dose escalation phase of the study will be conducted at 2 internationally renowned U.S. cancer centers of excellence (the Scripps Clinic in San Diego, California & the MD Anderson Cancer Center in Houston, Texas). Top-line results from the dose-escalation part are expected during summer 2020.

### Other programs

#### ABX464 in HIV

The results of the Phase 2a studies ABX464-004 and ABX464-005, showing that ABX464 reduced HIV-viral reservoirs in the blood as well as in the rectal tissue, make it a promising therapeutic candidate for a Phase 2b study. Abivax plans to advance ABX464 into Phase 2 studies for HIV subject to third party funding.

#### ABX544 in Ebola

With a vaccine for this indication currently under regulatory review and a change of the macroeconomic landscape in public funding; Abivax has decided to terminate this programme.

#### Respiratory syncytial virus



This program is progressing well and Abivax expects to have a potential drug candidate to enter into pre-clinical development in early 2020.

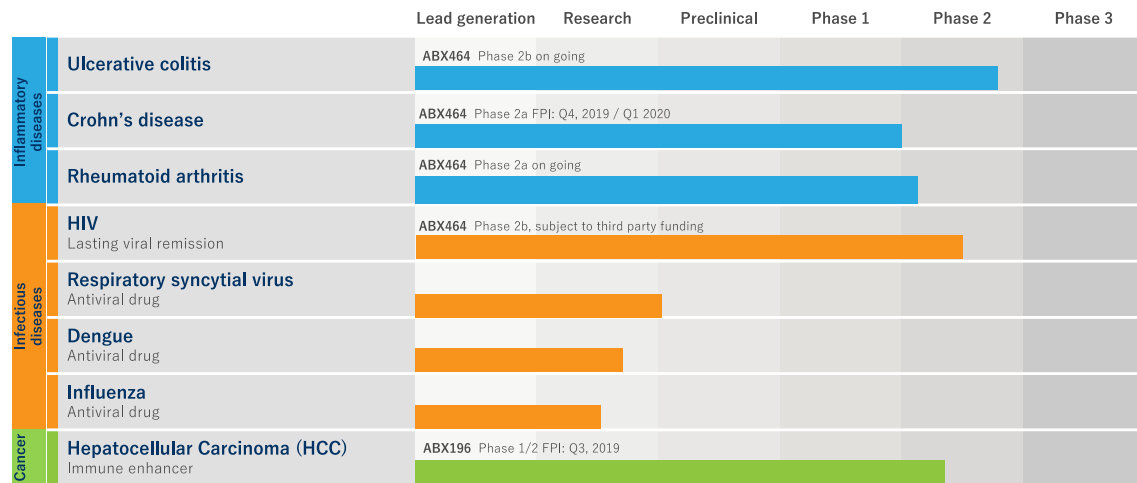
### Sofinnova Partners investment

Abivax successfully completed a capital increase of 1,500,000 new ordinary shares with a nominal value of €0.01 per share (12.7% of the current capital), which was entirely subscribed at market price by Sofinnova Crossover I, a fund managed by Sofinnova Partners, globally recognized as a leading specialist investor. The investment, combined with the continued support of Abivax’s founding shareholder, Truffle Capital (45.8% of the current capital), validates the science and strategy and extends the cash runway to the end of the second quarter of 2020. Dr. Kinam Hong, Partner at Sofinnova has been appointed to the Board of Directors of Abivax.

Abivax now has sufficient time and resources to leverage maximum value in ongoing partnering discussions for ABX464, while also providing funding to achieve important value-creating milestones in three Phase 2 programs for ABX464 in UC, RA and Crohn’s disease and the Phase 1/2 program for ABX196 in hepatocellular carcinoma.

### Abivax pipeline

#### Abivax: A strong and diversified pipeline



### Financial Calendar – Upcoming events

October 19-23, 2019: Planned presentation of 12-month maintenance data (including endoscopy) for ABX464-102 in UC during the annual United European Gastroenterology Week in Barcelona, Spain. In addition, the Company will host a one-hour breakfast symposium (Chairman: Prof. William Sandborn, M.D., University of California, San Diego) on ABX464 during the conference.



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

ABIVAX is mobilizing the body's natural immune machinery to treat patients with viral infections, autoimmune diseases and cancer. A clinical-stage company, ABIVAX leverages its antiviral and immune enhancing platforms to optimize candidates to treat ulcerative colitis and other inflammatory diseases, viral diseases and liver cancer (hepatocellular carcinoma). ABIVAX is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). More information on the company is available at [www.abivax.com/en](http://www.abivax.com/en). Follow us on Twitter @ABIVAX\_

## Contacts

### Abivax

#### Communication

Pierre Courteille

[Pierre.Courteille@abivax.com](mailto:Pierre.Courteille@abivax.com)

+33 6 85 34 24 04

### Press Relations USA

#### Rooney Partners LLC

Marion Janic

[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)

+1 212 223 4017

### Investors

#### LifeSci Advisors

Chris Maggos

[chris@lifesciadvisors.com](mailto:chris@lifesciadvisors.com)

+41 79 367 6254

### Press Relations France

#### Actifin

Ghislaine Gasparetto

[ggasparetto@actifin.fr](mailto:ggasparetto@actifin.fr)

+33 1 56 88 11 22

### Press Relations and Investors

#### Europe

#### MC Services AG

Anne Hennecke

[anne.hennecke@mc-services.eu](mailto:anne.hennecke@mc-services.eu)

+49 211 529 252 22

## DISCLAIMER

This press release contains forward-looking statements, forecasts and estimates with respect to certain of the Company's programs. Although the Company believes that its forward-looking statements, forecasts and estimates are based on assumptions and assessments of known and unknown risks, uncertainties and other factors that have been deemed reasonable, such forward-looking statements, forecasts and estimates are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated in such forward-looking statements, forecasts and estimates. A description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the French Autorité des Marchés Financiers pursuant to its legal obligations including its registration document (Document de Référence). Furthermore, these forward-looking statements, forecasts and estimates are only as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. ABIVAX disclaims any obligation to update these forward-looking statements, forecasts or estimates to reflect any subsequent changes that the Company becomes aware of, except as required by law.

This press release is for information purposes only, and the information contained herein does not constitute either an offer to sell, or the solicitation of an offer to purchase or subscribe securities of the Company in any jurisdiction, in particular in France. Similarly, it does not give and should not be treated as giving investment advice. It has no connection with the investment objectives, financial situation or specific needs of any recipient. It should not be regarded by recipients as a substitute for exercise of their own judgement. All opinions expressed herein are subject to change without notice.



The distribution of this document may be restricted by law in certain jurisdictions. Persons into whose possession this document comes are required to inform themselves about and to observe any such restrictions.