



Press Release

## Abivax First-Half 2018 Financial Results and Operations Update

*ABX464 showed impressive safety and efficacy results and proof-of-concept in ulcerative colitis (UC) in phase 2a clinical trial*

*ABX464 proven to reduce HIV reservoirs in phase 2a clinical trials*

*ABX464 advancing into phase 2b trials in UC and HIV as well as phase IIa for Crohn's disease and rheumatoid arthritis*

*ABX196 to enter into Phase 1b/2a clinical trial for hepato-cellular carcinoma treatment*

*Additional preclinical product candidates advancing from ABIVAX mRNA discovery platform*

*Cash for operations through key milestones, until Q4 2019*

*Abivax to focus on potential partnering for ABX464: No capital raise planned at this stage*

**PARIS, Sept. 28<sup>th</sup>, 2018 at 6:30 a.m. CEST** – Abivax (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company harnessing the immune system to develop treatments for inflammatory/autoimmune diseases and cancer, as well as functional cure for HIV, today announced its 2018 half-year financial results, as of June 30, 2018, and provided an update on its product pipeline progress. The financial statements for the first half of 2018, approved by the Company's Board of Directors on Sept. 27, 2018, have been audited and the certification report is being prepared by the Company's external auditors.

*"The first half of 2018 has been terrific for Abivax, with excellent financial data and transformative Phase 2a results in ulcerative colitis and HIV infection with our lead drug-candidate, ABX464. Four weeks ago, we reported impressive top-line safety and efficacy Phase 2a results of oral once daily ABX464 in patients with ulcerative colitis," said Professor Hartmut Ehrlich, MD, Chief Executive Officer of Abivax. "Further elucidation of the mechanism of action of ABX464 has increased our confidence towards accelerating development of this highly differentiated first-in-class therapeutic candidate into Phase 2b trials for both UC and HIV. In addition, because its unique mechanism of action and the preclinical and clinical data we have gathered suggest a broad anti-inflammatory effect, we are now preparing the initiation of Phase 2a clinical trials of ABX464 in Crohn's disease and rheumatoid arthritis early next year. In addition, our phase 1/2 clinical trial with ABX196 in hepatocellular carcinoma is scheduled to start in the coming months, and several exciting new molecules are moving from discovery into preclinical testing for severe viral infections like respiratory syncytial virus, influenza and dengue fever. Of course, Abivax may prioritise some of these indications based on medical needs, market opportunities and upcoming additional data."*

**Didier Blondel, Chief Financial Officer of Abivax**, added: *"We are very excited about the prospects of ABX464 and the company. Given its mechanism of action, preclinical and clinical results and the fact that it is administered orally once a day, ABX464 is opening up to various potential indications with large unmet medical needs and broad market opportunities. Because of the scale of the development program justified by ABX464's potential, Abivax is pursuing a partnering strategy in order to leverage the resources and the*

industrial development infrastructure and competencies of a partner. In our assessment, ABX464's current economic valuation (net present value, NPV) already exceeds Abivax' current market capitalization: Therefore, and given Abivax's current market capitalization, we do not intend to raise dilutive equity in the near future."

## FIRST HALF 2018 FINANCIAL HIGHLIGHTS

Items in the Income Statement <i>in thousands of euros</i>	H1 2018	H1 2017	Change
Total operating income	492	4	488
Total operating expenses	(9 058)	(7 410)	(1 648)
<i>of which Research and Development costs</i>	(7 061)	(5 729)	(1 332)
<i>of which administrative costs and overheads</i>	(1 996)	(1 681)	(315)
<b>Operating result</b>	<b>(8 565)</b>	<b>(7 406)</b>	<b>(1 159)</b>
Financial result	27	33	(6)
<b>Ordinary result</b>	<b>(8 538)</b>	<b>(7 373)</b>	<b>(1 165)</b>
Extraordinary result	(59)	173	(232)
Tax on income	1352	1 651	(299)
<b>Result for the period</b>	<b>(7 245)</b>	<b>(5 549)</b>	<b>(1 696)</b>

- Operating loss €7.2m (+€1.7m compared with €5.5m as of June 30, 2017) mainly reflects the increasing investment in development of ABX464 in inflammatory and HIV clinical indications (+€1.5m), as well as the progressive scaling up of the mRNA splicing platform and library of small molecules (+€0.7m).
- Total headcount at the end of June 2018 was flat at 24.
- R&D expenses amounted to €7.1m, mainly due to ABX464 development costs (64%) and the mRNA splicing research platform investment (29%).
- G&A expenses were at €2.0m in H1 2018 (22% of total operating costs) compared to €1.7m (23%) in H1 2017.
- Revenues, which were comprised mainly of a Research Tax Credit, were at €2.0m in H1 2018, compared to €1.9m in H1 2017.
- The Company's cash utilization rate during H1 2018 was €1.6m per month.
- Cash at the end of June 2018 was €7.6m, compared to €17.0m at the end of 2017.
- Company is fully funded through Q4 2019, based on the assessment of planned R&D needs, and the €10m first tranche of Kreos Capital loan agreement in July 2018.

<b>Financial Items from the Balance Sheet</b> in thousands of euros	<b>06/30/2018</b>	<b>12/31/2017</b>	<b>Change</b>
<b>Net financial position</b>	<b>7 579</b>	<b>16 862</b>	<b>(9 283)</b>
of which financial fixed assets*	5 000	15 000	(10 000)
of which fixed-term deposits (maturing in > 1 year)	0	0	0
of which fixed-term deposit (maturing in <1 year)	5 000	15 000	(10 000)
of which available cash flow	2 579	2 032	547
(of which financial debts)	0	(170)	170
<b>Total assets</b>	<b>46 045</b>	<b>53 815</b>	<b>(7 770)</b>
<b>Total equity</b>	<b>41 086</b>	<b>48 180</b>	<b>(7 094)</b>
of which equity capital	36 071	43 916	(7 215)
of which conditional advances	4 385	4 264	121

\* 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 early September, Abivax reported impressive top-line safety and efficacy data from its randomized, double-blind, placebo-controlled phase 2a clinical trial ABX464-101 in patients moderate to severe UC. In this clinical study, the efficacy of ABX464 on both clinical and endoscopic endpoints was already statistically significant different from placebo, which is indicative of a substantial therapeutic effect of the drug candidate. The onset of efficacy was rapid, with a 3.2 fold improvement in clinical remission rate and 4.5 fold in mucosal healing compared to placebo. The convenient once-a-day oral 50 mg regimen was safe and well tolerated in this chronic and severely debilitating disease. The clinically meaningful efficacy was judged by opinion leaders advising Abivax as indicative of a substantial therapeutic effect. With a first-in-class mechanism of action, i.e. an up-regulation of the anti-inflammatory microRNA miR124, ABX464 is ready to move into Phase 2b clinical trials, scheduled to start in Q1, 2019, as well as into phase 2a studies in Crohn's disease and rheumatoid arthritis at around the same time.

The inflammatory disease space represents an area of highly 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, based on 2017 pharmaceutical sales in this sector. In combination with 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 treated with anti-TNF monoclonal antibodies, including rheumatoid arthritis, represents over \$30 billion, a market and patient population that the Company expects will benefit from ABX464.

### ABX464 clinical development in HIV

In June of this year, Abivax communicated top-line data from ABX464-005, a phase 2a study in HIV infected patients that measured 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 and, therefore, Abivax will also advance the promising therapeutic candidate into phase 2b testing for HIV in H1 2019.

HIV still presents a significant burden to the quality of life of patients. Even with the availability of antiretrovirals, patients are still required to medicate daily for life, and risk the rebound of viral load with missed dosing because of the presence of the latent HIV reservoir. A functional cure for this disease is critical, and the market opportunity for such a functional cure capable of reducing the viral reservoir represents about \$22 billion.

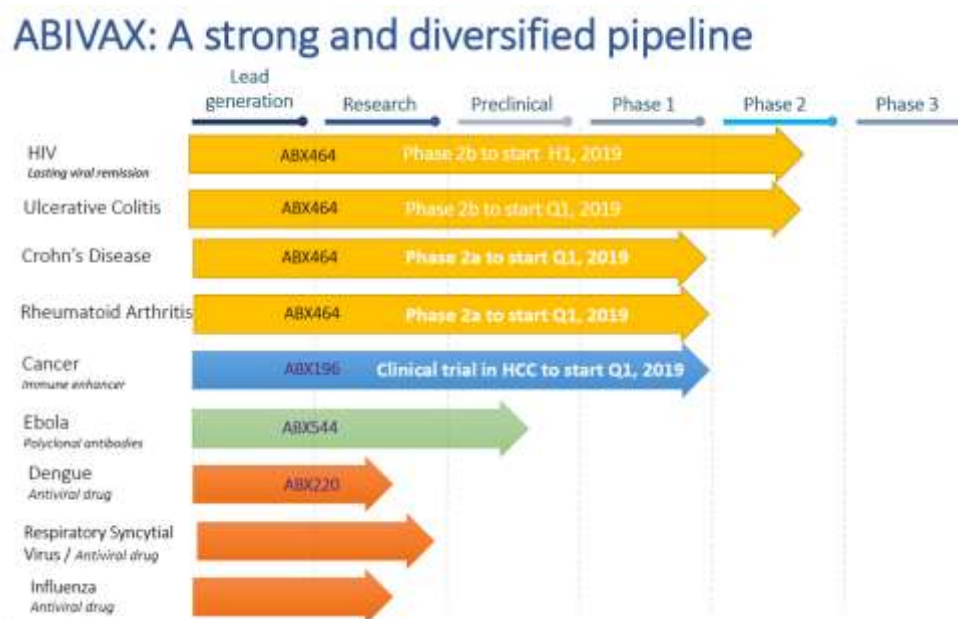
### ABX196 – a clinical stage immune enhancer for oncology based on iNKT regulation

ABX196 is a synthetic agonist (glycolipid) of iNKT (invariant Natural Killer T) cells, in a liposomal formulation, that is ready to begin Phase 1/2 clinical proof of concept studies. 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 successful Phase 1 clinical testing. Abivax is planning start a proof-of-concept clinical study in hepato-cellular cancer in Q1 2019. At the same time, Abivax is seeking an external partner for the development of this molecule the immune-oncology field, which is not a core focus for the company.

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

Abivax 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, lead molecules targeting RSV are in lead optimisation and will advance into preclinical proof of concept testing in H1 2019. Molecules for Dengue are currently in lead identification across the four subtypes of the virus and will advance into lead optimization in H2 2019. Molecules for influenza are currently in the hit optimization phase.

### Abivax Pipeline:



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

On July 25, 2018 Abivax completed an 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 tranche fully drawn in July 2018, extending cash runway (including phase 2b for UC and HIV, phase 2a for Crohn's disease and rheumatoid arthritis and phase 1/2 with ABX196 in hepatocellular carcinoma) until Q4 2019.

## FINANCIAL CALENDAR – UPCOMING EVENTS:

- During late October/early November, Abivax will hold a global investor webcast in association with a detailed R&D update

### 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 cure HIV and treat inflammatory bowel diseases, as well as 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](http://www.abivax.com/en). Follow us on Twitter @ABIVAX\_

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