



## ABIVAX First-Half 2017 Financial Results and Update

September 20, 2017

**Exciting development progress for lead HIV drug candidate ABX464**

**ABX464 to enter clinical trials in expanded indications**

**Cash for operations through key milestones until end Q3 2018**

### 2017 FIRST HALF HIGHLIGHTS

- **H1 2017 net loss of €5.5m versus €8.3 in H1 2016**
- **€16.4m in cash as of June 30, 2017, funding operations until end of Q3 2018**
- **First-ever clinical reduction in HIV reservoirs observed in Phase 2a clinical trial of ABX464**
- **Initiated additional Phase 2a study of ABX464's effects on HIV reservoirs in gut tissue and blood**
- **Planned new Phase 2a trial with ABX464 in ulcerative colitis received first regulatory approval by French Authorities**
- **Positive preclinical results with ABX196 in cancer animal models**
- **Antiviral platform scale-up generated multiple hits on targets to treat RSV, Influenza and Dengue**
- **Long-term strategic agreements signed with CNRS and Evotec**
- **Received Bpifrance milestone of €2.1m for RNP-Vir program**

PARIS, Sept. 20<sup>th</sup>, 2017 at 6:30p.m. CEST – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to eliminate viral diseases, today announced its 2017 half-year financial results, as of June 30, 2017, and provides an update on its progress during the first half of 2017. The financial statements for the first half of 2017, approved by the company's board of directors on Sept. 18, 2017, have been audited and the certification report is being prepared by the Company's external auditors.

*"We are very pleased with ABIVAX's progress in the first half 2017,"* said Professor Hartmut J. Ehrlich, M.D., chief executive officer of ABIVAX. *"ABX464, our most advanced product candidate, which could become a key component for achieving a sustained viral remission or functional cure in patients with HIV, demonstrated positive Phase 2a results with the first-ever treatment-induced reduction in HIV reservoirs. We are eager to report data from the ongoing additional study with ABX464 in HIV patients, which are expected during the first week of October (Cohort 1) and in Q2 2018 (Cohort 2)."*

*"Separately, in Q4 2017 we will begin enrolling the first clinical proof-of-concept study of ABX464 in ulcerative colitis patients in order to explore the anti-inflammatory properties of this exciting drug-candidate in patients with ulcerative colitis,"* continued Professor Ehrlich. *"Our antiviral platform continues to show significant progress in identifying novel drug candidates against additional viruses, with positive hits on RSV, influenza and Dengue viruses. Finally, our immune enhancer candidate, ABX196, has shown positive preclinical data in animal models of hepatocellular carcinoma and bladder cancer."*

### FIRST HALF 2017 OPERATING HIGHLIGHTS

#### ABX464 clinical development progress in HIV and discovery of potential new indications

- **First ever treatment induced reduction in HIV reservoirs ABX464-004Phase IIa trial**

In the ABX464-004 trial, 30 HIV patients received either ABX464 or matching placebo in addition to their current antiretroviral treatment over 28 days. The viral load at the start of the study was well controlled with boosted darunavir. After the 28-day treatment period, a reduction in viral DNA copies in peripheral blood mononuclear cells (PBMCs) was observed in 8/15 treated and evaluable patients and no responders were observed in the placebo group. Safety was the primary endpoint in the trial and ABX464 was well tolerated and there were no severe adverse events in the treatment group.

- **A second Phase IIa (ABX464-005) study exploring the effect of ABX464 on the HIV reservoirs in gut tissue and PBMCs was initiated in March 2017, with top-line data expected during the first week of October**

ABX464-005 is a 28-day (1. Cohort) and 84-day (2. Cohort) compartmental pharmacokinetics (PK) study where HIV infected patients are being treated with ABX464 in addition to their antiretroviral treatment. Rectal biopsies are being collected at different intervals, allowing the quantification of HIV-DNA and the level of inflammation in the reservoirs over time. This study, being conducted at the Germans Trias i Pujol University Hospital Badalona (Barcelona, Spain), will further evaluate the long-term HIV-DNA reduction in immune cells and the anti-inflammatory effects observed in preclinical models with ABX464. Top-line data from the one-month treatment cohort are expected in the first week of October, and from the three-month treatment cohort in Q2 2018.

- **ABX464 will initiate clinical (ABX464-101) testing in a new indication, ulcerative colitis**

ABIVAX researchers published in Nature Scientific Reports that ABX464 has anti-inflammatory effects in preclinical models<sup>[1]</sup>. As a result, the company has planned ABX464-101, a Phase 2a proof-of-concept study aimed at evaluating the safety and efficacy of ABX464 in 30 patients with moderate to severe active ulcerative colitis who have failed or are intolerant to immunomodulators, anti-TNF $\alpha$ , vedolizumab and/or corticosteroids. Patients will be randomized to receive either ABX464 50mg or placebo given once daily for eight weeks. Exploratory objectives include assessing the clinical remission and healing of the ulcerative colitis lesions as well as the level of inflammation around the intestine. This clinical study will be conducted in seven European countries: France, Belgium, Germany, Poland, Hungary, Czech Republic and Spain. Regulatory and ethics committee approvals are being sought in all these countries. France already has granted regulatory approval.

- **ABX196 – 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 has successfully completed a Phase 1 clinical trial in volunteers. Preclinical development of ABX196 has shown its capacity to turn tumors that are non-responsive to checkpoint inhibitors into responsive tumors. ABIVAX does not intend to play a role in the immune-oncology field, and is therefore seeking an external partner to develop this molecule. However, ABIVAX is determined to bring ABX196 into a proof-of-concept clinical study in hepatocellular cancer to increase the value of the asset. This product is largely derived from technology and exclusive patent rights transferred to ABIVAX from the Scripps Research Institute (La Jolla, CA), the University of Chicago (Chicago, IL) and the Brigham Young University (Salt Lake City, UT).

#### 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 RSV, Influenza and Dengue indications. The Company recently signed long-term agreements with CNRS and Evotec, allowing access to unparalleled scientific expertise and resources for ABIVAX to scale up its antiviral platform. Development of ABX311 (Chikungunya) has been de-prioritized due to decreased viral epidemics.

#### Bpifrance milestone payment of €2.1 million for RNP-Vir program received in September

The milestone-based funding allows ABIVAX to increase the throughput and further optimize its antiviral discovery platform. The first milestone payment of €2.1 million was received in early September.

Under the program, called "Projets de R&D Structurants Pour la Compétitivité" (PSPC) of the "Invest in the Future Program" (PIA), ABIVAX is leading a consortium, including the CNRS and qualified contract research organizations (CROs), with the goal to identify molecules against additional viruses with high medical need. The total funding provided by Bpifrance is €10.3 million, of which €8.4 million are a mix of loans and subsidies for ABIVAX and €1.9 million for the CNRS. This program is supervised by the General Commissariat of Investment (Commissariat Général de l'Investissement) and operated by Bpifrance.

#### FIRST HALF 2017 FINANCIAL HIGHLIGHTS

Items in the Income Statement <i>in thousands of euros</i>	H1 2017	H1 2016	Change
Total operating income	4	137	(134)
Total operating expenses	(7 410)	(10 755)	3 345
<i>of which Research and Development costs</i>	(5 729)	(9 205)	3 476
<i>of which administrative costs and overheads</i>	(1 681)	(1 550)	(131)
Operating result	(7 406)	(10 617)	3 211
Financial result	33	(229)	262
<b>Ordinary result</b>	<b>(7 373)</b>	<b>(10 846)</b>	<b>3 473</b>
Extraordinary result	173	486	(313)
Tax on income	1 651	2 086	(435)
<b>Result for the period</b>	<b>(5 549)</b>	<b>(8 274)</b>	<b>2 725</b>

- Operating loss €5.5m (compared with €8.3m as of June 30, 2016) reflects the stringent monitoring of costs, including putting ABX203 development on hold since H2 2016.
- Total headcount at the end of June 2017 was flat at 24.
- R&D expenses amounted to €5.7m, mainly due to ABX464 development (50%) and the antiviral platform investment (30%).
- G&A expenses were flat at €1.7m in H1 2017 compared to €1.6m in H1 2016.
- Revenues, which were comprised mainly of a Research Tax Credit, decreased to €1.9m in H1 2017, compared to €2.5m in H1 2016.
- The Company's cash utilization rate during H1 2017 was €1.1m per month.
- Cash at the end of June 2017 was €16.4m, compared to €23.0m at the end of 2016.
- Company is fully funded through Q3 2018, based on the assessment of planned R&D needs.

<b>Financial Items from the Balance Sheet</b>	<b>30/06/2017</b>	<b>31/12/2016</b>	<b>Change</b>
in thousands of euros			
Net financial position	16 114	22 732	(6 617)
of which financial fixed assets*			
of which fixed-term deposits (maturing in > 1 year)	0	10 000	(10 000)
of which marketable securities	6	6	0
of which cash instruments	15 087	5 044	10 043
of which available cash flow	1 276	7 937	(6 661)
(of which financial debts)	(255)	(255)	0
Total assets	55 189	60 597	(5 408)
<b>Total equity</b>	<b>51 169</b>	<b>56 718</b>	<b>(5 549)</b>
of which equity capital	48 961	54 510	(5 549)
of which conditional advances	2 208	2 208	0

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

### **Strategic business focus of ABIVAX: Leveraging multiple R&D technologies to facilitate new products from its three immune-virology platforms**

ABIVAX develops antivirals and immunotherapies that originate from three proprietary technological platforms:

- “Antiviral,” based on technologies jointly developed with CNRS (Montpellier, France) and Institut Curie (Orsay, France). This platform has generated a chemical library of more than one thousand compounds that block viral replication due to a completely new mode of action, i.e. the inhibition of mRNA biogenesis. In addition to ABX464, which inhibits HIV replication, this platform has generated various molecules targeting other viruses, such as ABX202 to treat Dengue virus, which is currently in lead optimization.
- “Immune enhancer,” based on intellectual property licensed from The Scripps Research Institute (La Jolla, United States). It focuses on invariant natural killer T cells (or iNKT) agonists, which have been shown to stimulate both humoral and cellular immune responses and may have clinical applications in both infectious diseases and oncology. Positive preclinical results in animal models for several cancers, including Hepato-Cellular Carcinoma (HCC) and bladder cancer, with the immune enhancer ABX196 demonstrate its capacity to turn tumors that are non-responsive to checkpoint inhibitors into responsive tumors. ABIVAX does not intend to play a role in the immune-oncology field, and is therefore seeking external partners in order to out-license this molecule.
- “Polyclonal antibodies,” which may lead to the generation of neutralizing antibodies for the prevention and treatment of Ebola virus infections. ABX544 is in preclinical development, with data expected Q4 2017.

### **FINANCIAL CALENDAR – UPCOMING EVENTS:**

- **September 29<sup>th</sup>**: 2017 first half year financial report published on [www.abivax.com](http://www.abivax.com)

[1]<https://www.nature.com/articles/s41598-017-04071-3>