**Press Release**

# 2017 Full-Year Results and Progress Report

## *Reinforced cash position finances operations through key clinical milestones to mid-2019*

## *Phase IIb clinical programs for ABX464 in HIV and IBD patients expected to be initiated around end of 2018*

## HIGHLIGHTS of 2017

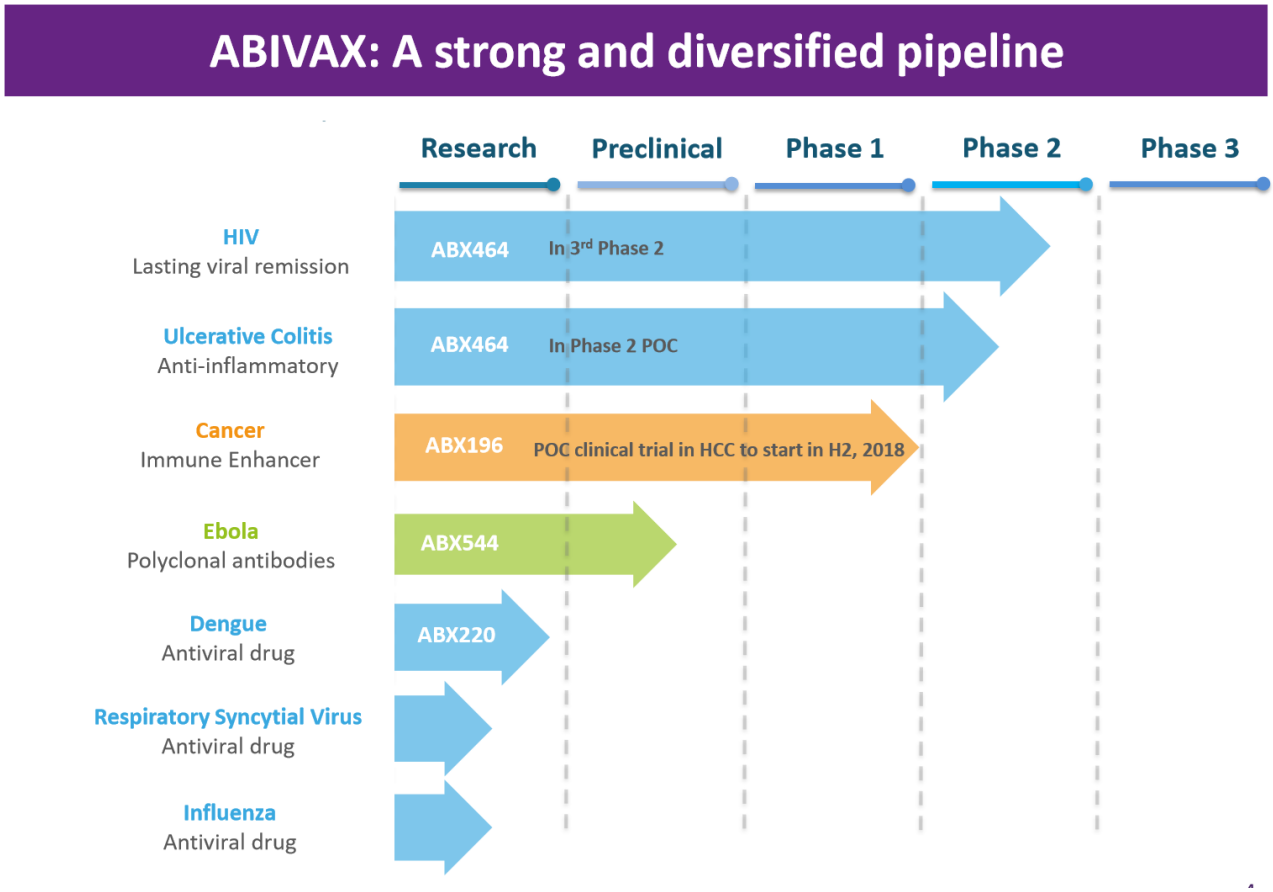
- **HIV: first ever reduction of HIV reservoir in patients' blood observed in two independent ABX464 Phase IIa trials**
- **Ulcerative colitis: phase IIa proof-of-concept clinical trial on track with over half (16/30) of the patients recruited and the first patient already enrolled in the one year open-label extension study**
- **ABX464's novel mechanism of action further elucidated**
- **Cancer: promising ABX196 preclinical results showing the immune enhancer's effects in hepatocellular cancer (HCC)**
- **Antivirals (RSV, influenza, Dengue): ABIVAX's proprietary antiviral discovery platform yielded promising new compounds targeting Respiratory Syncytial Virus (RSV), influenza and all serotypes of Dengue**
- **Total cash employed for operations was €12m and net cash consumption, after Bpifrance funding and research tax credit, was €6m in 2017, resulting in a €17m cash position as of December 31, 2017**

**Paris, March 16, 2018 at 8:30am CET** – ABIVAX (Euronext Paris: FR0012333284 – ABVX), an innovative biotechnology company targeting the immune system to develop treatments for viral and inflammatory diseases, and cancer, today announced its 2017 full year financial results, as of December 31st, and provided an update on its progress, as well as its outlook for 2018. The audited financial statements for 2017 were approved by the Company's Board of Directors on March 15, 2018. The certification report is being prepared by the Company's external auditors.

*"2017 was an exciting year for ABIVAX, witnessing strong progress both in the development of our portfolio as well as from a financial perspective*," said **Professor Hartmut Ehrlich, M.D., Chief Executive Officer of ABIVAX**. *"ABX464, the company's most advanced therapeutic candidate, has shown in two separate clinical trials that it reduces the HIV viral reservoir by up to 50% after only one month of treatment. These data clearly validate ABX464 as a key component of a potential functional cure in HIV patients. Top-line data after longer-term 3-month treatment are expected in mid-2018 and, at around the same time, we anticipate filing the requests for regulatory authorizations in U.S. and Europe to start phase IIb testing of ABX464 in HIV patients. These data and plans forward substantiate the commitment of ABIVAX to improve the life of people with HIV."*

**Dr. Ehrlich** continued: "*Also, we are making excellent progress with our phase IIa POC clinical trial of ABX464 in patients with ulcerative colitis, which is halfway enrolled and expected to deliver top-line data during the second half of 2018, with initiation of phase IIb IBD testing scheduled for around the end of 2018.*"

*"Finally, we secured additional financing extending our financial resources for at least one additional year, enabling us to fund all planned activities until mid-2019,"* added Dr. Ehrlich.




## 2017 OPERATING HIGHLIGHTS

### Strategic business focus: Leverage proprietary technologies to discover and develop new therapeutic candidates targeting the human immune system

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

- **"Antiviral,"** based on technologies jointly developed with the National Center for Scientific Research (CNRS) in Montpellier, France, and the Curie Institute in Orsay, France. This platform has generated a highly targeted chemical library of more than 1200 compounds that block viral replication due to

completely new modes of action, i.e. the modulation of mRNA biogenesis. The relevance of this platform is exemplified by ABX464, which to date has been administered to more than 170 subjects and has been shown to be safe and well tolerated, with heretofore unobserved activity in reducing the HIV viral reservoirs in patients, as well as viral load.

In addition to ABX464, this platform has generated various molecules targeting other viruses, such as RSV, influenza and all four serotypes of the Dengue virus. ABIVAX is developing these novel molecules, which are currently in hit-to-lead stage, in collaboration with EVOTEC, a global leading contract research organization, with the goal to start lead optimization for the first molecule (an antiviral against RSV) by the end of this year.

- **"Immune enhancer,"** based on an intellectual property licensed from the Scripps Research Institute (La Jolla, CA, 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. Following encouraging results of the lead immune enhancer compound ABX196 in preclinical testing in several cancer models, as well as Phase I clinical testing in human volunteers, ABIVAX is now preparing for a POC phase I/II clinical trial in HCC, which is expected to start around year-end 2018.

- **"Polyclonal antibodies,"** which leads to the generation of neutralizing antibodies for the prevention and treatment of Ebola virus infections. ABX544 is currently in preclinical development, and ABIVAX will review the next steps depending on results of ongoing studies.

## Pipeline update

- **ABX464, a potential key element for a functional HIV cure**

During the past two decades, antiretroviral treatments have turned HIV from a lethal into a chronic disease, at least in developed countries. Currently, there are approximately 37 million people living with HIV, resulting in global sales of pharmaceutical products for HIV of $24 billion in 2017. However, none of the products on the market are able to act on the viral reservoir from infected individuals, and new treatments are needed to achieve a (functional) cure.

Clinical development of ABX464: Following two phases I studies conducted on healthy subjects, a first phase IIa study on 66 subjects infected with HIV-1 provided initial evidence of the antiviral activity of ABX464 in humans, while confirming its good tolerability.

A second phase IIa study (ABX464-004) was initiated in June 2016 in Spain, Belgium and France, to explore the effect of ABX464 on the viral reservoir (i.e. the immune cells with integrated viral DNA where the virus is "hiding' during antiretroviral treatment) when used in association with other antivirals. A total of 30 patients were enrolled and treated with ABX464 or placebo for 28 days in addition to boosted Darunavir, which is an established treatment of HIV. The results of this study showed a 25% to 50% reduction in 8 out of 15 evaluable ABX464 treated patients, with no reduction in the placebo group. These results were presented at 9$^{th}$ IAS Conference on HIV Science in Paris, France on 23-26 July, 2017 and at the 16$^{th}$ European AIDS Conference (EACS) in Milan, Italy on 25-27 October 2017.

In March of 2017, ABIVAX launched a compartmental pharmacokinetics (PK) clinical study (ABX464-005). In this study, HIV infected patients received in cohort 1 ABX464 for 28 days (completed) and for 84 days in cohort 2 (ongoing) in addition to their regular antiretroviral treatment. Also, in cohort 2, rectal biopsies are being collected in addition to blood at different intervals, allowing the quantification of viral reservoir and level of inflammation in intestinal tissue. This study, conducted at the *Germans Trias i Pujol* University Hospital Badalona (Barcelona, Spain), will provide a better understanding of the reservoir reduction in blood as well as in the gut, which is considered to contain the largest HIV reservoir in the body.

Results from the first cohort (28 days of treatment) fully confirmed the results from the previous study: a reduction (up to 50%) of the HIV reservoir in the blood was seen in 8 out of 9 patients ($p<0.001$). These results were presented at 8th International Workshop on HIV Persistence During Therapy in Miami, FL., December 12-15,2017. Top-line results of the ongoing second cohort are expected for mid-2018.

The results of these ABX464-004 and -005 studies will guide the Company in designing the phase IIb study, which is expected to begin around the end of 2018.

- **ABX464, a molecule with strong anti-inflammatory effect leading to a potential indication in inflammatory bowel disease (ulcerative colitis)**

Ulcerative colitis is a debilitating inflammatory bowel disease in adults and children, with limited therapeutic management options for many patients. There is an estimated number of close to 1 million patients with ulcerative colitis in the United States, and global pharmaceutical sales for this disease are estimated to be around 5,7 billion US$ in 2017.

Clinical development of ABX464 in ulcerative colitis: In November of 2017, ABIVAX launched a double-blind, placebo-controlled, phase IIa POC clinical study in patients with moderate to severe ulcerative colitis. The rationale for this study was derived from new preclinical data generated with ABX464, which demonstrate a strong anti-inflammatory effect of the compound. In macrophages, this effect was shown to be mediated by a 50-fold increase of the expression of IL-22, a cytokine known as a potent suppressor of inflammatory processes, and in PBMC a ten-fold increase in miR124, a micro-RNA with potent anti-inflammatory properties.

Inflammation is a cornerstone of the pathologies observed, not only in HIV, but also in a number of other diseases, such IBD, including ulcerative colitis and Crohn's disease. When evaluated in a mouse model of IBD, ABX464 demonstrated a long-lasting effect in preventing the typical symptoms of inflammatory colitis, including histological changes[1].

In the ongoing clinical study, 30 patients are randomized 2:1 to receive ABX464 or placebo, respectively. The study employs state-of-the art technologies for monitoring potential treatment effects including numerical recording of the colonoscopies with centralized reading. Sixteen of the 30 patients are already recruited and the trial is on track for top-line results to be reported during H2 of 2018. Finally, first approvals have been received for an open-label one-year maintenance study, and the first patient is already receiving ABX464 as part of this protocol.

[1] K Chebli et al., The Anti-HIV Candidate ABX464 Dampens Intestinal Inflammation by Triggering Il-22 Production in Activated Macrophages. Nature Scientific Reports 2017, DOI:10.1038/s41598-017-04071-3

- **ABX464 mechanism of action**

Significant progress was made in 2017 in characterizing ABX464; new data elucidating this therapeutic candidate's unique mechanism of action are being analyzed and prepared for scientific communication at peer reviewed international scientific conferences.

## Novel antiviral molecules with potential for RSV, influenza, and dengue treatments have been discovered

ABIVAX completed screening its targeted library of small molecules to discover and develop antiviral therapeutic candidates against RSV, influenza and all 4 serotypes of dengue. These molecules are currently in the hit-to-lead phase of drug development, and the RSV compound is expected to proceed to lead optimization by the end of 2018.

- **ABX311 put on hold**

During 2017, the development of ABX311 (Chikungunya) was paused, as epidemic outbreaks of Chikungunya have not been observed for several years.

- **ABX196 immune enhancer being prepared for POC clinical trial in HCC**

Previously, ABX196 was shown to trigger an immune response and was well tolerated in phase I clinical testing in healthy volunteers. Preclinical results of ABX196 have shown its capacity to turn tumors that are non-responsive to checkpoint inhibitors into responsive tumors in the B16 mouse melanoma model and, more recently, showed reduction of tumor growth and increased survival in a mouse model of HCC.

ABIVAX is preparing a phase I/II POC clinical study of ABX196 in patients with HCC, scheduled to begin around the end of 2018.

## Governance and strengthening of the Board of Directors and Scientific Advisory Board

In May 2017 and in January 2018, respectively, ABIVAX strengthened and diversified its board of directors with the appointments of Ms. Corinna zur Bonsen-Thomas, a German lawyer, who has chaired the Baxter AG supervisory board in Vienna, Austria for more than a decade, and Prof. Carol Brosgart, M.D., an American physician with extensive experience in patient care, pharmaceutical development (e.g. Gilead) and public health work (e.g. US-CDC) in infectious diseases, especially in the areas of HIV and hepatitis B and C. Ms. zur Bonsen-Thomas chairs the audit committee of the board of directors.

Furthermore, in September of 2017, ABIVAX named Prof. Christian Brechot, M.D., Ph.D., an infectious disease specialist of worldwide renown and past President of the Institute Pasteur in Paris as member of its Scientific Advisory Board.

## Financing of €8.4 million from the "Invest in the Future Program" (PIA), operated by Bpifrance, to strengthen ABIVAX's proprietary antiviral platform

In 2017, ABIVAX signed an agreement with Bpifrance, awarding a financing of €8.4 million from the competitive funding called "Projets de R&D Structurants Pour la Compétitivité" (PSPC) of the "Invest in the Future Program" (PIA). This program is supervised by the General Commissariat of Investment (Commissariat Général de l'Investissement) and operated by Bpifrance.

Under this new program, ABIVAX is driving a consortium, including the CNRS and EVOTEC, a global leading contract research organization. A total budget of €18.8 million has been approved for the project over a period of five years. 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. ABIVAX received a first milestone of €2.1 million in September 2017.

The milestone-based funding allows ABIVAX to accelerate its development timelines and further optimize its antiviral discovery platform, with a goal to identify molecules against other viruses with high medical need, like the respiratory syncytial virus, dengue and the influenza virus.

# 2017 FINANCIAL HIGHLIGHTS

| **Items in the Income Statement**<br>*in thousands of euros* | **2017 FY**<br>*k€* | **2016 FY**<br>*k€* | **Change**<br>*k€* |
|---|---|---|---|
| Total operating income | 357 | 151 | 206 |
| Total operating expenses | (14,507) | (18,387) | 3,880 |
| *of which Research and Development costs* | *(10,846)* | *(15,459)* | *4,613* |
| *of which administrative costs and overheads* | *(3,661)* | *(2,928)* | *(733)* |
| **Operating result** | **(14,150)** | **(18,236)** | **4,086** |
| Financial result | 77 | 258 | (181) |
| **Ordinary result** | **(14,073)** | **(17,978)** | **3,905** |
| Extraordinary result | 159 | 152 | 7 |
| Tax on income | 2,692 | 3,519 | 827 |
| **Result for the period** | **(11,223)** | **(14,308)** | **3,085** |

The operating loss was -€14.1m in 2017, significantly less than the -€18.2m loss in 2016.

This reflects the stringent monitoring of costs and resources by the Company, as well as the development freeze of ABX203 at end of 2016. The ABX203 phase III clinical study had generated nearly €5m in costs in 2016, which were not replicated in 2017.

ABIVAX had 24 employees (excluding consultants) at the end of December 2017, which is on a par with 2016.

In 2017, R&D expenses were €10.8m, primarily driven by a focused investment in our lead compound ABX464 in the amount of €6.2m (57%). The remaining development and research costs were €2.6m (25%) and €2.0m (18%), respectively.

The net result amounts to -€11.2m in 2017 compared to -€14.3m in 2016.

Beyond a strict monitoring of spending planning throughout 2017, the Company has also benefited from the cash received from the 2016 Research Tax Credit, as well as of the first milestone payment of the 2017 awarded Bpifrance funding program. Combined these amount to nearly €6m and were paid during the second half of 2017.

The net cash used in 2017 was €6m, the cash in hand of the Company by the end of 2017 was €17m, compared to €23m at the end of 2016.

In September 2017, the Company signed an agreement with Kepler Cheuvreux, for an equity line allowing them to exercise ABIVAX shares of up to 10% of the capital of the Company (max. 970000 new shares). By the end of 2017, 60000 shares have been issued as a result of that program and have brought an additional €0.6m in cash to the Company. Based on the current share price of €9, the Company has a potential cash reserve of €7.6m from this program.

Based on the assessment of planned R&D needs, the current cash position and the remaining value of the equity line, the Company is fully funded until mid-2019.

| **Financial Items from the Balance Sheet**<br>*in thousands of euros* | **12/31/17**<br>*k€* | **12/31/16**<br>*k€* | **Change**<br>*k€* |
|---|---|---|---|
| **Net financial position** | **16,862** | **22,732** | **(5,870)** |
| of which financial fixed assets* | 15,000 | 15,000 | - |
| of which fixed-term deposits (maturing in > 1 year) | - | 10,000 | (10,000) |
| of which fixed-term deposits (maturing in < 1 year) | 15,000 | 5,000 | 10,000 |
| of which available cash flow | 2,032 | 7,987 | (5,955) |
| (of which financial debts) | (170) | (255) | 85 |
| **Total assets** | **53,815** | **60,597** | **(6,782)** |
| **Total Equity** | **48,180** | **56,718** | **(8,538)** |
| of which equity capital | 43,916 | 54,510 | (10,594) |
| of which conditional advances | 4,264 | 2,208 | 2,056 |

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

The assets of the Company at the end of 2017 included goodwill, classified in Intangible Fixed Assets, and resulting from the previous mergers of Wittycell (which contributed the adjuvant platform and the iNK anti-viral agonist adjuvant ABX196) and Splicos (which contributed the antiviral platform and the small molecule ABX464). This goodwill is amounting to €32m since the creation of the company, as of year-end 2014. Due to significant progress in the developments of ABX464 and ABX196, the Company has opted not to proceed to any write-off and the value of those intangible assets remained unchanged in 2017.

## PERSPECTIVES 2018

In 2018, the Company anticipates achieving the following major milestones:

**Antiviral platform:**

- Releasing top-line data from the second cohort of the ABX464-005, mid 2018
- Filing an IND with the FDA for ABX464 in HIV in H1 of 2018
- FSI in phase IIb study for ABX464 in HIV around year end 2018
- Releasing top-line data from Phase II POC study in ulcerative colitis in H2 2018
- Initiating a phase IIb clinical study of ABX464 in ulcerative colitis around year end 2018
- Starting lead optimization for RSV molecule towards the end of H2, 2018

**Immune enhancer platform:**

- Filing an IND with the FDA for ABX196 in mid-2018
- Initiating a phase I/II POC clinical trial with ABX196 in HCC in H2 2018

## FINANCIAL CALENDAR – UPCOMING EVENTS 2018:

- **June 15:** Annual General shareholders' meeting
- **September 19**: 2018 first half year results
- **September 28**: 2018 first half year financial report published on www.abivax.com

## WEBCAST PRESENTATION

ABIVAX's senior management will host a webcast presentation on March 16, 2018 at 3:00 pm CET (Paris time), to discuss FY 2017 results and to provide an update of current activities. Attendees can log on using the following telephone information (Participant, local):

| Location | Phone |
|---|---|
| Austria, Vienna | +43 (0)1 928 1466 |
| Belgium, Brussels | +32 (0)2 400 6926 |
| France, Paris | +33 (0)1 76 77 22 57 |
| Germany, Frankfurt | +49 (0)69 2222 2018 |
| Ireland, Dublin | +353 (0)1 2465621 |
| Italy, Milan | +39 02 3600 9838 |
| Netherlands, Amsterdam | +31 (0)20 703 8261 |
| Spain, Madrid | +34 91 419 2524 |
| Sweden, Stockholm | +46 (0)8 5065 3942 |
| Switzerland, Geneva | +41 (0)22 567 5750 |
| United Kingdom, Local | +44 (0)330 336 9411 |
| United States, Brooklyn | +1 646-828-8193 |

### About ABIVAX (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 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. Follow us on Twitter @ABIVAX_

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