



## ABIVAX Completes €12 Million Capital Raise Entirely Subscribed by Sofinnova Partners at Market Price

July 11, 2019

- Abivax cash runway extended to end of Q2, 2020
- Sofinnova Partners strengthens and diversifies Abivax shareholder base
- Sofinnova Partners to join the Board of Directors
- Proceeds to be used for funding advanced stage clinical trials in inflammation and oncology

PARIS--(BUSINESS WIRE)--Regulatory News:

ABIVAX SA (the "Company" or "ABIVAX") (Paris:ABVX) (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, announced today the successful completion of a capital increase of 1,500,000 new ordinary shares with a nominal value of €0.01 per share (the "Transaction"), which has been entirely subscribed at market price by Sofinnova Crossover I, a fund managed by Sofinnova Partners ("Sofinnova").

"Sofinnova Partners is globally recognized as a leading specialist investor and their investment, combined with the continued support of our founding shareholder, Truffle Capital, not only validates our science and strategy but also extends our cash runway to the end of the second quarter of 2020," said Prof. Hartmut J. Ehrlich, MD, CEO 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 trials of ABX464 in ulcerative colitis, rheumatoid arthritis and Crohn's disease and one phase 1/2 trial of ABX196 in liver cancer."

"We are pleased to become investors in Abivax. We have followed Abivax's continuing progress and determined that its assets and management have the potential to create significant value for patients, corporate partners and Abivax shareholders," said Kinam Hong, MD, Partner at Sofinnova Partners. "We are particularly motivated by the strong anti-inflammatory properties and proof of concept demonstrated to date by ABX464 and its broad potential to address multiple diseases where patients are not adequately treated by existing therapies."

Philippe Pouletty, MD, Chairman of the Board of Abivax and CEO of Truffle Capital commented: "We are delighted to work with Sofinnova, which shares many of our values, to help further guide Abivax to clinical and corporate success."

Net proceeds of €12 million provide the Company with additional funding to implement its strategy, conduct its operations and reinforce its financial structure. In particular, funding will be primarily allocated to finance the next steps in the clinical development of its lead product, ABX464, including a Phase 2b study in ulcerative colitis and Phase 2a studies in rheumatoid arthritis and Crohn's disease. Secondly, the funds will also be used for next steps in the clinical development of ABX196 to treat hepatocellular cancer in the U.S.

In the framework of the Transaction, the Company agreed that Sofinnova, as a new major financial partner for Abivax, will present a candidate for appointment to the Company's Board of Directors ( *Conseil d'Administration* ) in replacement of Dr. Claude Bertrand, who resigned from his office as director of the Company.

### Key features of the Capital Increase

The New Shares were issued through a capital increase without shareholders' pre-emptive rights reserved to a specified category of investors under the provisions of Article L. 225-138 of the French Commercial Code (Code de commerce) and pursuant to the 14th resolution of the Annual General Shareholders' Meeting held on 7 June 2019. The Company explored various equity funding options prior to entering into the Transaction with Sofinnova, which best matched the Company's financing needs. The Company's intentions with regards to potential future partnerships remain unchanged.

The number of ordinary shares subscribed (the "New Shares") and the subscription price were decided by the Company's Chief Executive Officer (*Directeur Général*), in accordance with a sub-delegation granted by the Company's Board of Directors ( *Conseil d'Administration* ) on 9 July 2019.

Sofinnova subscribed to 1,500,000 New Shares with a par value of €0.01, at a price of €8.00 per New Share, including share premium, for a total subscribed amount of €12,000,000, representing approximately 12.7% of the share capital of the Company.

Payment and delivery of the New Shares is expected to occur on or about 15 July 2019.

The New Shares were issued with no discount to the closing price of the Company's shares on the regulated market of Euronext Paris as at 9 July 2019.

As of the settlement and delivery date, which is expected to occur on 15 July 2019, the New Shares will be fungible with the Company's existing shares and are entitled to current dividend rights. The New Shares will be listed on Euronext Paris under ISIN FR0012333284 on 15 July 2019.

The issuance of the New Shares will have the following impact on the allocation of the share capital and the voting rights of the Company:

Shareholders	Before Transaction					After Transaction				
	Number of shares	% capital (non-diluted)	% capital (fully diluted)	% voting rights (non-diluted)	% voting rights (fully diluted)	Number of shares	% capital (non-diluted)	% capital (fully diluted)	% voting rights (non-diluted)	% voting rights (fully diluted)
Truffle Capital	5,393,493	52.42%	40.72%	66.23%	55.49%	5,393,493	45.75%	36.58%	60.31%	51.27%
Management and board of Directors	692,971	6.74%	16.50%	4.58%	12.02%	692,971	5.88%	14.82%	4.17%	11.11%
Kreos	0	0.00%	4.91%	0.00%	3.57%	0	0.00%	4.41%	0.00%	3.29%

Other (1)	412,436	4.01%	9.26%	4.39%	8.14%	412,436	3.50%	8.32%	3.99%	7.52%
Free float	3,790,039	36.84%	28.61%	24.81%	20.79%	3,790,039	32.15%	25.70%	22.59%	19.21%
Sofinnova	-	-	-	-	-	1,500,000	12.72%	10.17%	8.94%	7.60%
<b>Total</b>	<b>10,288,939</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>11,788,939</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

(1) This category includes former board members and employees, historical shareholders, Kepler Cheuvreux and treasury shares.

For illustration purposes, a shareholder, who held 1% of the Company's share capital prior to the Transaction, will hold 0.87% of the Company's share capital upon completion of the Transaction (or 0.70% on a fully diluted basis).

As a result of the Transaction, Sofinnova will cross the 10% of the share capital threshold. In accordance with applicable regulations, Sofinnova will issue a declaration on its intentions and on the threshold crossing.

#### Financial update

The Company confirms that, in its view, following the issuance of the New Shares and taking into account (i) the €10 million raised by the Company as a result of the draw of the second tranche of the Kreos financing which took place on 31 May 2019, and (ii) other financial sources available to the Company such as the equity line with Kepler Cheuvreux, the Company will have the financial resources required to cover its net working capital needs over the next 12 months.

The Company has no immediate intention to draw on the Kepler Cheuvreux equity line. Since the beginning of this agreement in September 2017, out of 970,000 shares available, Kepler Cheuvreux exercised 200,000 shares (2.0% of the current total shares of Abivax) until June 2019.

The primary terms and conditions of the Kreos financing were set forth in the press release issued by the Company, dated 25 July 2018. The second tranche of the Kreos financing is composed of 8 million straight bonds with a nominal value of 1 euro each and 2 million of convertible bonds with a nominal value of 1 euro each. The conversion price for the convertible bonds is €10.70 corresponding to the potential issuance of 186,916 new shares.

As part of the second tranche, ABIVAX has also issued warrants to Kreos Capital, giving it the right to subscribe up to €800,000 into new shares of ABIVAX at a nominal value of €0.01 and a subscription price identical to the conversion price of the convertible bonds for the second tranche.

The Kreos financing is an unsubordinated and first rank debt financing and is secured by pledges over ABIVAX's tangible and intangible assets, including all the Company's intellectual property rights over its drug candidates.

#### About ABX464

ABX464 was shown to target the cap binding complex (CBC), which is a novel mechanism of action for anti-inflammatory drugs. By binding to the CBC, ABX464 reinforces the biological functions of this complex in cellular RNA biogenesis including splicing. ABX464 enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory miR-124, which acts by downregulating proinflammatory cyto- and chemokines like TNF- $\alpha$ , Il-6 and MCP-1, thereby putting a brake on inflammation. A seven- to ten-fold increase of miR124 was observed in peripheral blood mononuclear cells (PBMCs), and in colorectal biopsies of UC patients treated with ABX464.

#### ABX464 in Ulcerative Colitis

Following the exciting results of the Phase 2a proof-of-concept study in ulcerative colitis, Abivax is launching a randomized, double-blind, placebo-controlled, dose-ranging Phase 2b trial ([link to ClinicalTrials.gov](http://link.to/ClinicalTrials.gov)) in 232 UC patients that will have four arms: three escalating doses of once-daily oral ABX464 (25 mg/day, 50 mg/day and 100 mg/day) and placebo. The study will be conducted in up to 150 study sites in more than 17 countries under the leadership of its steering committee (Prof. Severine Vermeire, M.D., Ph.D., Prof. Herbert Tilg, M.D. Ph.D., Prof. Xavier Hebuterne, M.D., Ph.D., and Prof. William Sandborn, M.D.), and includes an eight week induction phase followed by an open-label maintenance study with ABX464. The primary endpoint is reduction in modified Mayo Score at 8 weeks, and secondary endpoints will include clinical remission, endoscopic improvement and biomarker fecal calprotectin. Full regulatory and ethics approvals have already been granted in several European countries and in Canada, with first patient enrollment expected in late July/early August of this year and top-level results expected around the end of 2020.

#### ABX464 in Rheumatoid Arthritis

Abivax is also launching a phase 2a proof-of-concept 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 Rheumatoid Arthritis (RA) who had an inadequate response to MTX and/or to one or more anti-tumor necrosis factor alpha (TNF $\alpha$ ) biologicals. This is a randomized, double-blind, placebo-controlled, multicenter study in sixty patients with moderate to severe active RA, who will be assigned to receive 50mg ABX464, 100mg ABX464 or placebo during the twelve-week treatment phase. The primary endpoint of the study will be safety and tolerability. Secondary endpoints will be indicators of efficacy including the change from baseline in the individual components of the American College of Rheumatology (ACR), the proportion of patients achieving ACR20 response and change from baseline in Disease Activity Scores (DAS) in 28 joints. For further details, please click [here](http://link.to/ClinicalTrials.gov). The first patient is expected to be enrolled in late July/early August of 2019 and top-level results expected during summertime 2020.

#### ABX464 in Crohn's Disease

Abivax is also preparing an international phase 2a clinical study of ABX464 in 30 patients with Crohn's disease ([link to ClinicalTrials.gov](http://link.to/ClinicalTrials.gov)). This study is scheduled to start enrolling patients around the end of this year.

#### ABX464 in other Inflammatory Diseases

The inflammatory disease space represents an area of high 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 patients globally, representing a potential market opportunity of up to \$5.5 billion annually, based on 2017 pharmaceutical sales in this sector. For IBD (UC and Crohn's disease), pharmaceutical sales during this same period are estimated to have reached \$15 billion<sup>1</sup>. The market potential for the full range of inflammatory conditions (including neuro-inflammatory diseases) is currently estimated to be in excess of \$70 billion, a market and patient population that the Company believes could benefit from ABX464. Therefore, Abivax is currently conducting preclinical proof-of-concept studies in multiple sclerosis, Parkinson's disease, Psoriasis, NASH and pulmonary arterial hypertension.

<sup>1</sup> Source: Global Data

#### ABX464 in HIV

The results of the ABX464-004 and ABX464-005 studies, showing that ABX464 reduced HIV-viral reservoirs in the blood as well as in rectal tissue, make it a promising therapeutic candidate for a phase 2b study. However, given the complexity of the US and European regulatory processes to develop an HIV cure, in view of the opportunities Abivax has in the inflammatory space, the company decided to conduct the next steps of development of ABX464 in HIV through investigator-initiated clinical studies with third party and/or public funding. The first such study is scheduled to

be initiated by the end of 2019.

### **ABX196 in Liver Cancer**

US FDA recently accepted an investigational new drug (IND) application for ABX196, which showed potent efficacy in HCC animal models. ABX196 is a synthetic glycolipid agonist of invariant Natural Killer T cells (iNKT) in a liposomal formulation. A phase 1 clinical trial conducted by Abivax in healthy volunteers has been completed and demonstrated safety and tolerability as well as potent activation of iNKT cells. Preclinical studies have demonstrated the potential of ABX196 for cancer therapy: ABX196, both alone and in combination with a checkpoint inhibitor, showed a statistically highly significant therapeutic effect in reducing tumor growth as measured by MRI and increasing survival in mice with HCC. Abivax holds exclusive rights to ABX196 from Scripps Research, the University of Chicago, and Brigham Young University. The open IND allows Abivax to test ABX196 in combination with nivolumab (Opdivo®, 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 the Scripps MD Anderson Cancer Center in San Diego, CA, USA; additional leading cancer centers in the US will be involved in the subsequent expansion phase of the study. The first patient is expected to be enrolled in August of 2019 and top-level results of the first study phase (escalation phase) during summertime 2020.

### **Information disclosed to the public**

The 2018 registration document (*document de référence*) of the Company, filed with the French *Autorité des Marchés Financiers* ("AMF") on April 29, 2019 is available free of charge on the Company's website ([www.abivax.com](http://www.abivax.com)). Attention is drawn to the risk factors related to the Company and its activities presented in chapter 4 of its registration document.

An update of the Company's corporate presentation, dated June 2019, with a presentation of the Company's activities, including the progress of preclinical and clinical programs, is available on the Company's website.

This press release does not constitute a prospectus within the meaning of the Prospectus Directive nor a public offering.

Dechert LLP acted as legal advisor to Abivax on this transaction.

### **Webcast Presentation**

Abivax senior management will host a webcast and teleconference on **July 15th, 2019 at 14 :00 CEST/ 8 am ET (NYC time)**, to discuss the completion by ABIVAX of the €12 million capital raise entirely subscribed by Sofinnova Partners at market price.

Attendees can participate by weblink (<https://edge.media-server.com/mmc/p/zoxix92m>) or connect by phone using the following coordinates:

Telephone conference

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### **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. 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\_

### **About Sofinnova Partners**

Sofinnova Partners is a leading European venture capital firm specialized in Life Sciences. Based in Paris, France, the firm brings together a team of professionals from all over Europe, the U.S. and China. The firm focuses on paradigm shifting technologies alongside visionary entrepreneurs. Sofinnova Partners invests across the Life Sciences value chain as a lead or cornerstone investor, from very early stage opportunities to late stage/public companies. It has backed nearly 500 companies over more than 45 years, creating market leaders around the globe. Today, Sofinnova Partners has over €2 billion under management. For more information, please visit: [www.sofinnovapartners.com](http://www.sofinnovapartners.com).

### **Important Notice**

*This document and the information contained herein do not constitute either an offer to sell or purchase, or the solicitation of an offer to sell or purchase, securities of the Company.*

*This announcement does not, and shall not, in any circumstances, constitute a public offering nor an invitation to the public in connection with any offer. 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.*

*This announcement is an advertisement and not a prospectus within the meaning of the Prospectus Directive (as defined below), as implemented in each member State of the European Economic Area.*

*The Transaction does not constitute a public offering in France as defined in Article L.411-1 of the French Monetary and financial code and Article 2(1)(d) of the Prospectus Directive.*

*With respect to the Member States of the European Economic Area (including France) ("Member States"), no action has been undertaken or will be undertaken to make an offer to the public of the securities referred to herein requiring a publication of a prospectus in any Member State.*

*For the purposes of the provision above, the expression "offer to the public" in relation to any shares of the Company in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State. The expression "Prospectus Directive" means Directive 2003/71/EC, as amended, and includes any relevant implementing measure in the Member State.*

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