



## Abivax to present at the J.P. Morgan 40th Annual Healthcare Conference

December 15, 2021

**Abivax's presentation at the virtual J.P. Morgan Healthcare Conference scheduled for Thursday, January 13, 2022, at 12:00-12:40 pm ET (9:00-9:40 am PST and 6:00-6:40 pm CET)**

**FDA end-of-phase-2 feedback received, raising no objections to proceeding ABX464 into pivotal phase 3 testing in ulcerative colitis (UC)**

**Abivax is focusing its operational activities on the ABX464 phase 3 program in UC**

**ABX464 long-term efficacy results provide a clear clinical differentiation from competing products**

**The currently accessible market for ABX464 in ulcerative colitis and Crohn's disease is close to USD 17B in the G7 countries and is expected to grow to USD 26.4B by 2026**

**PARIS, France, December 15, 2021 – 6:30 pm (CET) –** Abivax SA (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company developing novel therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, today announces that **Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, will present at the J.P. Morgan 40<sup>th</sup> Annual Healthcare Conference on Thursday, January 13, 2022 at 12:00-12:40 pm ET (9:00-9:40 am PST and 6:00-6:40 pm CET).**

The J.P. Morgan Annual Healthcare Conference is the largest healthcare investment symposium in the industry and will take place virtually from January 10 to 13, 2022.

**Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, said:** *"I am pleased to have the opportunity to present for the second consecutive year at the J.P. Morgan Healthcare Conference, the main forum for pharma partnering discussions globally. Abivax is very much looking forward to sharing the latest achievements as well as the plans for 2022 with the investors and the pharmaceutical community. We are convinced that the long-term maintenance data of ABX464 for the treatment of moderate to severe UC uniquely positions this oral drug candidate as transformative for the lives of the many patients who currently have only very limited treatment options for this chronic debilitating disease. The recently received FDA feedback, in the context of the end-of-phase-2 meeting, is of paramount importance as it allows Abivax to finalize the design of the ABX464 pivotal phase 3 program in ulcerative colitis. We are now looking forward to the EMA scientific advice, scheduled for the beginning of Q1 2022, and will then implement the agencies' recommendations to kick-off our global pivotal clinical studies."*

**Prof. William Sandborn, M.D., University of California San Diego School of Medicine, co-founder and Chief Medical Officer at Shoreline Biosciences, San Diego, CA and member of Abivax's clinical steering committee, added:** *"Based on the EoP2 responses from the FDA, I am looking forward to moving ABX464 into the pivotal phase 3 program, in order to rapidly bring this promising drug candidate to the many patients that will benefit from the safe and efficacious long-term treatment."*

Investors and other interested parties who will not participate in the JPM event are invited to access the live audio webcast of the presentation at [www.abivax.com/events](http://www.abivax.com/events). An archived version of the webcast will be available under the same link for a limited period of time.

The Abivax management team will be available for 1:1 meetings at the conference to be scheduled through the J.P. Morgan platform (registered participants only).

\*\*\*\*\*

During 2021, Abivax was able to compile an impressive clinical data package for ABX464, including the 3-years phase 2a maintenance study update as well as the phase 2b short- and long-term clinical results. As shown in the one-year read outs of the phase 2a and phase 2b maintenance studies, it is obvious that ABX464 is unique in inducing and maintaining clinical remission in more than half of the UC study patients, including severely ill patients who were previously refractory to treatments with biologics and/or JAK inhibitors.

Importantly, as shown in the phase 2a long-term extension study, these clinical remissions are stable during the second and third year of continuous daily treatment, which indicates a strong clinical differentiation of ABX464 from competing products.

These outstanding long-term results are consistent with the unique mechanism of action of ABX464, as the upregulation of miR-124, a single microRNA, induces a physiological brake to the inflammation by down-regulating the expression of several key pro-inflammatory cytokines.

As required for the treatment of a chronic disease like ulcerative colitis, ABX464 shows a good and persistent short-term as well as long-term safety profile.

### **Final preparations for start of ABX464 phase 3 global pivotal program in UC ongoing**

Following the FDA end-of-phase-2 meeting feedback, Abivax will now finalize the design of its global pivotal phase 3 study program of ABX464 in ulcerative colitis. The scientific advice of the European Medicines Agency (EMA) is scheduled for the beginning of Q1 2022 and both regulators' recommendations will be implemented prior to the start of the phase 3 program.

Abivax will again be working with IQVIA, a global premier CRO, to jointly set-up and conduct these studies across Europe, the US, Japan and other global geographies.

The first patient is expected to be included into the phase 3 study program in Q2 2022.

### **ABX464 potential market in inflammatory diseases**

The chronic inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. In 2020, there were an estimated 3.5M diagnosed cases of ulcerative colitis in G7 countries (US, France, Germany, Italy, Spain, UK and Japan). The total market opportunity for ABX464 in UC is USD 6.0B annually, based on 2020 pharmaceutical sales in the G7 countries, and will almost double to

USD 11.7B by 2026, i.e. the year ABX464 is expected to reach the market for UC.

For Crohn's disease, sales were USD 11.9B in 2020 and are estimated to grow to USD 14.7B by 2026. [1]

By 2026, the overall chronic inflammation market is estimated to exceed USD 110B.

\*\*\*\*\*

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

Abivax, a clinical stage biotechnology company, is developing novel therapies that modulate the physiological inflammation and immunological pathways to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax has two drug candidates in clinical development, ABX464 to treat severe chronic inflammatory diseases, and ABX196 to treat hepatocellular carcinoma. More information on the company is available at [www.abivax.com](http://www.abivax.com). Follow us on Twitter @ABIVAX\_.

#### **Contacts**

##### **Abivax Communications**

Regina Jehle  
[regina.jehle@abivax.com](mailto:regina.jehle@abivax.com)  
+33 6 24 50 69 63

##### **Investors LifeSci Advisors**

Ligia Vela-Reid  
[vela-reid@lifesciadvisors.com](mailto:vela-reid@lifesciadvisors.com)  
+44 7413 825310

##### **Press Relations & Investors Europe MC Services AG**

Anne Hennecke  
[anne.hennecke@mc-services.eu](mailto:anne.hennecke@mc-services.eu)  
+49 211 529 252 22

##### **Public Relations France Actifin**

Ghislaine Gasparetto  
[ggasparetto@actifin.fr](mailto:ggasparetto@actifin.fr)  
+33 6 21 10 49 24

##### **Public Relations France DGM Conseil**

Thomas Roborel de Climens  
[thomasdeclimens@dgm-conseil.fr](mailto:thomasdeclimens@dgm-conseil.fr)  
+33 6 14 50 15 84

##### **Public Relations USA Rooney Partners LLC**

Jeanene Timberlake  
[jtimberlake@rooneypartners.com](mailto:jtimberlake@rooneypartners.com)  
+1 646 770 8858

#### **DISCLAIMER**

*This press release contains forward-looking statements, forecasts and estimates (including patient recruitment) 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 d'Enregistrement Universel). Special consideration should be given to the potential hurdles of clinical and pharmaceutical development including further assessment by the company and regulatory agencies and ethics committees of preclinical, pharmacokinetic, carcinogenicity, toxicity, CMC, clinical data. 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.*