Press Release

Abivax and Scripps Research announce FDA Approval to Initiate a Phase 1/2 Clinical Trial with ABX196 in Patients with Hepatocellular Carcinoma

ABX196, an iNKT (invariant Natural Killer T cell) agonist, to be tested in combination with checkpoint inhibitor nivolumab to treat hepatocellular carcinoma (HCC, liver cancer)

Clinical trial to be initiated this summer at Scripps MD Anderson Cancer Center (San Diego, CA)

Following its front-runner ABX464 for inflammatory diseases, ABX196 is Abivax' second compound in clinical development

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PARIS, May 13, 2019, 8:00 a.m. (CEST) and La Jolla, CA– Abivax (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, with their collaborator, Scripps Research, that the U.S. Food and Drug Administration (FDA) has accepted an investigational new drug (IND) application for ABX196, which showed potent efficacy in HCC animal models. 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 this summer.

"*We are thrilled to have been given the green light by FDA for our US study.*" said **Prof. Hartmut J. Ehrlich, M.D., Chief Executive Officer of Abivax,** and he continued: *"This open IND allows Abivax, in collaboration with leading key opinion leaders at internationally renowned U.S. cancer centers of excellence, to explore the clinical potential of our iNKT agonist ABX196 to broaden and potentiate the activity of the checkpoint inhibitor nivolumab. Based on its unique mechanism of action and exciting preclinical data in several cancer models, we believe ABX196 is a promising immunotherapeutic product candidate for patients with liver cancer that may also have potential in other cancers."*

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 a 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.

"Despite the recent introduction of checkpoint inhibitors, hepatocellular carcinoma continues to be a substantial therapeutic challenge, as only about 20% of the treated patients show a response to these new drugs" said **Dr. Darren Sigal, M.D., Program Director of GI Oncology at Scripps Clinic and Scripps MD**

Anderson Cancer Center in San Diego, CA and principal investigator of the study. "*While checkpoint inhibitors block a 'do not attack me' signal on cancer cells, ABX196 activates iNKT cells, a subpopulation of lymphocytes that is critical for mounting an effective immune response. The synergy between these two molecules carries substantial promise for improved outcomes for patients with this deadly cancer."*

Checkpoint inhibitors like nivolumab are a leading class of therapeutic monoclonal antibodies that block certain endogenous proteins (PD-1/PDL-1) made by immune cells, such as T cells, as well as some cancer cells. These proteins effectively hijack the immune system, causing it to keep immune responses in check and preventing T cells from killing cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells much more efficiently. In some cancers, treatment with checkpoint inhibitors has been highly efficacious. However, due to the tumor micro-environment in other cancers, such as HCC, checkpoint inhibitors can have difficulties exerting their effects. ABX196 is intended as a drug that will potentiate the efficacy of checkpoint inhibitors by activating iNKT cells to kill tumor cells.

HCC is the most common form (75-90%) of primary liver cancer in adults. It typically occurs in the setting of chronic liver inflammation and/or cirrhosis, and is closely linked to chronic viral infection such as hepatitis B or C, exposure to toxins such as alcohol, and to certain diseases such as non-alcoholic steato-hepatitis (NASH). The incidence of and deaths related to HCC are increasing in the United States and globally due to hepatitis B and C virus infections, as well as NASH. Prevalence data from 2018 show a total of 79,000 cases of HCC in the US and G5 Europe (Germany, France, Italy, Spain and UK), with 67,000 new cases, and a total of 260,000 cases in China with 338,000 new cases. Globally, there were 841,000 new cases of liver cancer (ranks 6th of all reported cancers) and 782,000 fatalities (ranks 4th) in 2018. Currently, the American Cancer Society reports five year survival rates in the US of 31% for localized HCC, 11 % for regional, and 2% for distant or metastatic, indicating a clear unmet medical need for improved therapies for HCC. Pharmaceutical sales in HCC (US, G5 Europe and Japan) were $ 616 M in 2018, up 20% from 2017 ($ 513 M)[1].

"*The translation of basic research discoveries to the clinic is the greatest achievement we can hope for as clinician scientists."* said **Prof. Luc Teyton, M.D., Ph.D. from Scripps Research and member of Abivax' Scientific Advisory Board.** *"The use of ABX196 in the context of immunotherapy has been shown to be beneficial in multiple animal models of cancer, but the results with hepatocellular carcinoma are spectacular. We are looking forward to impact the disease in patients, especially given the limitations of current therapies."*

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 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. Follow us on LinkedIn and Twitter @ABIVAX_

About Scripps Research

Scripps Research is a leading nonprofit biomedical research institute whose faculty and graduate students have made major advances in basic science and significant contributions to the development of new medicines. Scripps Research has a top ten ranked graduate program (US News and World Report) and is ranked #1 in the world for scientific innovation by the leading science journal Nature. The unique structure of Scripps Research merges foundational studies in biology, chemistry and computer science with translational science to produce the next generation of drugs and advances in digital and precision medicine. Scientists in the institute's five academic research departments work hand-

[1] Source: Global data

in-hand with researchers at Calibr, its drug discovery division. Scripps Research' mission is to train the next generation of scientific leaders, expand the frontiers of human knowledge, and accelerate the development of new medicines to improve lives around the planet.

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