Abivax's phase 1/2 clinical study results of ABX196 in liver cancer show good tolerability and promising signals of clinical benefit and were selected for presentation at the ASCO GI Cancers Symposium 2022

November 30, 2021

ABX196 is Abivax's second compound in clinical development after lead drug-candidate ABX464

ABX196 was well tolerated and demonstrated promising signals of clinical benefit in heavily pre-treated hepatocellular cancer patients

ABX196 phase 1/2 study results were selected for a presentation at the 2022 ASCO Gastrointestinal Cancers Symposium (ASCO GI Cancers Symposium)

Detailed data of the abstract submitted at the ASCO GI Cancers Symposium will be released as of January 18, 2022, in accordance with the official ASCO embargo policy

PARIS, France, November 30, 2021 – 6:00 pm (CEST) – 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 reports the good tolerability and promising signals of clinical benefit resulting from its clinical phase 1/2 study conducted with ABX196. In this study, heavily pre-treated hepatocellular cancer (HCC) patients were administered ABX196 in combination with checkpoint inhibitor nivolumab, including patients who were previously exposed to checkpoint inhibitor treatments. These results support the further clinical development of ABX196 in the HCC setting.

The Company further announces today that the dose escalation results of this phase 1/2 study with ABX196 have been selected for a presentation at the renowned ASCO Gastrointestinal Cancers Symposium, taking place on January 20-22, 2022, in San Francisco, CA, USA. The ASCO GI Cancers Symposium is one of the most important international conferences to present and discuss the latest, most innovative and promising research advances in the field of gastrointestinal cancer. It is organized every year by the American Society of Clinical Oncology (ASCO), the world's leading organization in cancer research.

Darren Sigal, M.D., Program Director of GI Oncology at Scripps MD Anderson Cancer Center in San Diego, physician with Scripps Clinic and principal investigator of the study said: *"We are excited to observe a good safety profile as well as signals of clinical benefit in liver cancer patients treated with a combination of ABX196 and the checkpoint inhibitor nivolumab. The selection of the results of this phase 1/2 trial for a poster presentation at the ASCO GI Cancers Symposium 2022 validates these first promising data generated in the dose escalation phase of the study. ABX196 is the first non-checkpoint inhibitor immune therapy to be evaluated in HCC, activating the iNKT cell, a key anti-cancer immune cell. We are very much looking forward to present and discuss these results with the world's leading oncology experts at the ASCO GI Cancers Symposium."*

According to the embargo policy of ASCO, the detailed clinical data and conclusions of the abstract will be published as of January 18, 2022. Abivax will make the clinical study results publicly available as soon as the embargo has been officially lifted.

A phase 1/2 study of ABX196 in combination with checkpoint inhibitor nivolumab in patients with previously treated hepatocellular carcinoma

The phase 1/2 clinical trial in hepatocellular carcinoma, the most common form of liver cancer, is conducted at two renowned cancer centers of excellence in the US, the Scripps MD Anderson Cancer Center in San Diego, CA, and the MD Anderson Cancer Center in Houston, TX. In this trial, ABX196, an invariant Natural Killer T cell (iNKT) agonist, is administered together with the checkpoint inhibitor nivolumab (Opdivo®, Bristol Myers Squibb) to evaluate safety and the potential beneficial effects of this combination therapy. Patients who were previously failing on checkpoint inhibitors were included into the study that consists of two phases: a dose escalation phase and a subsequent expansion phase.

Based on the first outcome, the Company is currently assessing next steps for the future clinical development of ABX196 in HCC, also considering the availability of the required financing or the opportunity of a licensing agreement.

About ABX196
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 a mouse model of HCC. Abivax holds exclusive rights to ABX196 from Scripps Research, the University of Chicago, and Brigham Young University.

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About Abivax (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. Follow us on Twitter @ABIVAX_.

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