Abivax phase 1/2 clinical study results of ABX196 in liver cancer to be presented on Jan. 21 at ASCO GI Cancers Symposium 2022

January 19, 2022

ABX196 phase 1/2 study results for the treatment of hepatocellular carcinoma (HCC) were selected for a presentation at the ASCO Gastrointestinal Cancers Symposium 2022

ABX196 at a maximum dose of 0.4µg was very well tolerated in combination with checkpoint inhibitor nivolumab

10 heavily pre-treated patients were included in the dose escalation phase of which 5 (50%) experienced a clinical benefit during the treatment period

The results support the further clinical development of ABX196 in HCC

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

PARIS, France, January 19, 2022 – 8:00 am (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, announces today the detailed results of the dose escalation phase of its clinical phase 1/2 study conducted with ABX196 for the treatment of hepatocellular carcinoma (HCC), to be presented at the ASCO GI Cancers Symposium on January 20-22, 2022. 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 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: *"I am looking forward to presenting the encouraging results on the safety profile and clinical benefit of ABX196 as part of this phase 1/2 study at the ASCO GI Cancers Symposium 2022. Within the dose escalation phase, 10 heavily pre-treated HCC patients were administered ABX196 in combination with nivolumab with 50% experiencing a clinical benefit, including one patient with a partial response and four patients with stable disease during the treatment period. It is remarkable that four of these patients were previously exposed to a checkpoint inhibitor and benefited when rechallenged with a checkpoint inhibitor in combination with ABX196."*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, added: *"The positive results of the dose escalation phase are very good news for Abivax, showing ABX196's capacity to broaden and potentiate the efficacy of checkpoint inhibitors for the treatment of HCC. The selection of our clinical data for a presentation at ASCO GI Cancers Symposium confirms the potential benefit of our second clinical compound for liver cancer patients who were previously failing on checkpoint inhibitor treatments. Based on these encouraging results, we are reviewing the design of the follow-on study and the initiation of potential partnering discussions. HCC remains a major medical need, with 86,900 newly diagnosed cases in the G7 countries in 2020, and an overall five-year survival rate below 20%.[1]"*

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 first line therapy, including checkpoint inhibitors, were enrolled into the study that consists of two phases: a dose escalation phase and a subsequent expansion phase.

Within the dose escalation phase of the study, 10 patients were enrolled and dosed with 0.1µg, 0.2µg, or 0.4µg ABX196 in combination with nivolumab. Key objectives were to assess safety, maximum tolerated dose as well as signs of clinical benefit.

The median age of the patients was 66 years, and 9/10 patients were previously treated with an immune checkpoint inhibitor, including 7 patients treated with prior nivolumab. In total, 76 adverse events were reported, including diarrhea (6), malaise/fatigue (6), AST/ALT increase (6), and one injection site reaction. The maximally administered dose was at 0.4µg.

A clinical benefit was observed in 5 patients, including 1 patient with a partial response and 4 patients with stable disease. Median progression-free survival for all patients was 113.5 days (49-450 days) and at 276 days (172-450 days) for those showing a clinical benefit.

ABX196 in combination with nivolumab was well tolerated without any dose limiting toxicities or treatment related serious adverse events. In this small but heavily pre-treated HCC patient population, the combination treatment showed promising signals of clinical benefit, including patients previously treated with checkpoint inhibitors.

Based on the first outcome, Abivax is currently evaluating the design of a follow-on study of ABX196 in HCC and, in parallel, assessing potential partnering options.

About ABX196

ABX196 is a synthetic glycolipid agonist of invariant Natural Killer T cells (iNKT) in a liposomal formulation administered intramuscularly. 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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[1] Source: Informa, with G7 countries incl. the US, France, Germany Italy, Spain, UK and Japan