Abivax receives approval for ABX464 phase 1 study in Japanese subjects for subsequent inclusion of Japan into the global phase 3 program in ulcerative colitis

August 17, 2021

The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) approved a phase 1 clinical trial to confirm ABX464's pharmacokinetic profile in Japanese subjects

This phase 1 study is required to include Japan in Abivax's ABX464 global phase 3 program for the treatment of ulcerative colitis

As part of Abivax's ABX464 late-stage development plan, three additional phase 1 studies are being conducted in healthy volunteers, all progressing according to plan

Abivax plans to initiate its global phase 3 clinical program in UC by year end

Following the announcement of the ABX464 phase 2b top-line data in UC, the full results will be communicated during the first half of September

PARIS, France, August 17, 2021 – 6:00 p.m. (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, announces today that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) approved a phase 1 clinical trial to be conducted with ABX464 in healthy Japanese volunteers. This trial is required as part of the common clinical development plan to confirm the pharmacokinetic (PK) profile of ABX464 in Japanese subjects. Given positive results of this phase 1 study, Abivax will be able to include Japanese patients in its global phase 3 clinical development program of ABX464 for the treatment of ulcerative colitis.

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax said: *"The approval of our phase 1 study by the Japanese regulators is another important milestone as we are executing on our ABX464 global development strategy. Once the pharmacokinetics as well as safety and tolerability of ABX464 have been confirmed in the Japanese population, we will be able to subsequently expand our phase 3 clinical program to Japan. More and more people in industrialized countries are suffering from chronic inflammatory bowel diseases. Our objective is to make ABX464 broadly and globally available, including Japan where many patients are in need of new therapeutic options."*

A total of 48 healthy Japanese volunteers will be enrolled into the phase 1 study, consisting of one single administration and one multiple administration arm. The healthy volunteers will take either 25mg or 50mg of ABX464 orally and, in case of multiple administration, once daily over 28 days.

Treatment of the first subject is expected to occur end of September 2021. The enrollment is planned to be completed in February 2022 and the study results would then be available in Q2 2022.

Given the PK as well as safety and tolerability of ABX464 are confirmed in Japanese subjects, Abivax will without delay submit a regulatory approval request to PMDA to include Japanese patients suffering from UC into the Company's global phase 3 program.

In May 2021, Abivax announced its ABX464 phase 2b top-line data in UC, showing significant clinical efficacy in the overall patient population on primary and key secondary endpoints and a good safety profile of ABX464.

Additional phase 1 clinical studies to advance ABX464 late-stage clinical development

Besides the phase 1 study to be initiated in Japan, Abivax is also conducting three additional phase 1 studies with ABX464 in healthy volunteers, as part of the usual practice during late-stage clinical drug development. Enrollment of healthy volunteers has already been completed in the phase 1 "Thorough QT (TQT)" study as well as in the phase 1 "Drug-Drug Interaction (DDI)" study, with results expected to become available from Q3 2021 onwards. The phase 1 "Absorption, Distribution, Metabolism and Excretion (ADME)" study is progressing according to plan with 6 out of a total of 12 subjects enrolled. The studies will provide additional data required to support Abivax in seeking recommendations and agreement of the regulatory authorities for its late-stage clinical development program of ABX464 in chronic inflammatory bowel diseases and potentially other chronic inflammatory indications.

Epidemiology and market size in inflammatory bowel diseases

In 2020, there were an estimated 1.9M diagnosed cases of moderate to severe ulcerative colitis in G7 countries (US, France, Germany, Italy, Spain, UK and Japan) with app. 118K cases in Japan. For 2026, the moderate to severe UC cases in Japan are expected to grow to 120K.[1]

Full results of the ABX464 phase 2b clinical trial in UC

Following the announcement of the ABX464 phase 2b top-line results in UC in May this year, the availability of the full results has been delayed due to the late delivery of laboratory data. Abivax will communicate additional information on key clinical and laboratory indicators of this study during the first half of September.

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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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