InDex Pharmaceuticals receives FDA clearance to start the phase III study CONCLUDE with cobitolimod

August 24, 2021 – InDex Pharmaceuticals Holding AB (publ) today announced that the U.S. Food and Drug Administration (FDA) has given clearance to start the phase III clinical study CONCLUDE in the United States. The study will evaluate the efficacy and safety of the first-in-class TLR9 agonist cobitolimod for the treatment of moderate to severe left-sided ulcerative colitis.

"The United States is the largest pharmaceutical market in the world, and to receive clearance from the FDA to start the phase III study CONCLUDE with cobitolimod is an important milestone for InDex," said Peter Zerhouni, CEO of InDex Pharmaceuticals.

CONCLUDE is a global phase III study that will be conducted at several hundred clinics in over 30 countries. The process of applying for and obtaining approval from the relevant authorities in the participating countries is ongoing. It is a randomised, double-blind, placebo-controlled, clinical study to evaluate cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis.

The induction study will include approximately 440 patients, and the primary endpoint will be clinical remission at week 6. Apart from the dosing 250 mg x 2, which was the highest dose and the one that showed the best efficacy in the phase IIb study CONDUCT, the phase III study will also evaluate a higher dose, 500 mg x 2, in an adaptive study design. Patients responding to cobitolimod in the induction study will be eligible to continue in a one-year maintenance study, where they will be treated with either cobitolimod or placebo.

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Publication
This information is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (MAR). The information was submitted for publication through the agency of the contact person set out above at 09:18 CET on August 24, 2021.

Cobitolimod in brief
Cobitolimod is a first-in-class Toll-like receptor 9 (TLR9) agonist that can provide an anti-inflammatory effect locally in the large intestine, which may induce mucosal healing and relief of the clinical symptoms in ulcerative colitis. Cobitolimod met the primary endpoint in the phase IIb study CONDUCT and demonstrated an outstanding combination of efficacy and safety. The results have been published in the reputable medical journal, The Lancet Gastroenterology & Hepatology. Data from four previous completed placebo-controlled clinical trials support the efficacy and safety demonstrated in the CONDUCT study.

InDex Pharmaceuticals in brief
InDex is a pharmaceutical development company focusing on immunological diseases where there is a high unmet medical need for new treatment options. The company's lead asset is the drug candidate cobitolimod, which is in late stage clinical development for the treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based ImmunoModulatory Sequences (DIMS), with the potential to be used in the treatment of various immunological diseases.

InDex is based in Stockholm, Sweden. The company's shares (ticker INDEX) are traded on Nasdaq First North Growth Market. Redeye AB with email address certifiedadviser@redeye.se and phone number +46 8 121 576 90 is the company's Certified Adviser. For more information, please visit www.indexpharma.com.