InDex Pharmaceuticals conducts PK study with cobitolimod

August 19, 2021 – InDex Pharmaceuticals Holding AB (publ) today announced that the company will conduct a clinical pharmacokinetic study (PK study) with cobitolimod in Sweden. The Swedish Medical Products Agency has given approval to start the study.

The purpose of the study is to evaluate the systemic uptake of cobitolimod in local treatment of colonic inflammation. The study will include at least 6 patients with moderate to severe ulcerative colitis treated with doses of 500 mg of cobitolimod administered rectally. First the uptake of cobitolimod will be measured in patients with active disease, and then a second time in those of the patients that respond to the treatment.

"The data from the PK study with cobitolimod will support future regulatory applications for market approval," said Peter Zerhouni, CEO of InDex Pharmaceuticals. "Previous preclinical and clinical studies have shown that the systemic uptake of cobitolimod is very limited, which likely contributes to the excellent safety profile. This is a significant advantage compared to the current systemically administered drugs for ulcerative colitis that can cause severe off-target effects."

The PK study will be conducted in parallel with the global clinical phase III study CONCLUDE with cobitolimod, which will include 440 patients and be conducted at several hundred clinics in over 30 countries. CONCLUDE 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.

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The information was submitted for publication through the agency of the contact person set out above at 08:00 CET on August 19, 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.