



InDex Pharmaceuticals enrolls first patient in the PK study with cobitolimod

December 8, 2021 – InDex Pharmaceuticals Holding AB (publ) today announced that the first patient has been enrolled in the clinical pharmacokinetic study (PK study) with cobitolimod. The purpose of the study is to evaluate the systemic uptake of cobitolimod in local treatment of colonic inflammation.

“Having recently treated the first patient in the pivotal phase III study CONCLUDE, I am very pleased to also announce that the first patient has been treated in the PK study with cobitolimod,” said Peter Zerhouni, CEO of InDex Pharmaceuticals. “With the PK study, we aim to confirm the limited systemic uptake of cobitolimod shown in previous preclinical and clinical studies. This likely contributes to cobitolimod’s excellent safety profile and 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 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 PK study is conducted in parallel with the global phase III study CONCLUDE with cobitolimod, which will include approximately 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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Publication

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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 Stockholm. 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.