



InDex Pharmaceuticals enters agreement with Parexel Biotech for phase III clinical study of cobitolimod for ulcerative colitis

March 30, 2021 - InDex Pharmaceuticals Holding AB (publ) today announced that the company has entered an agreement for services with global clinical research organization (CRO) Parexel Biotech for the phase III study CONCLUDE. The study will evaluate the efficacy and safety of the drug candidate cobitolimod for the treatment of moderate to severe left-sided ulcerative colitis.

“We are excited to advance cobitolimod into phase III, which is the final stage of development before application for market approval. After the successful collaboration in our recent phase IIb study CONDUCT, we are very pleased to collaborate once again with Parexel Biotech as our clinical development partner”, says Peter Zerhouni, CEO of InDex Pharmaceuticals. “Parexel Biotech is a leading global CRO with considerable experience managing phase III studies in inflammatory bowel disease, which will ensure an efficient execution of the study.”

CONCLUDE is a randomised, double-blind, placebo-controlled, global phase III study to evaluate cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis. The induction study will include approximately 400 patients, and the primary endpoint will be clinical remission at week 6. 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.

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. This higher dose has the potential to provide an even better efficacy than what was observed in the phase IIb study.

“We are pleased to partner with InDex Pharmaceuticals on the phase III clinical trial CONCLUDE to evaluate a potential new therapy for patients with moderate to severe ulcerative colitis,” said Jim Anthony, Senior Vice President and Global Head, Parexel Biotech. “Our collaboration with InDex Pharmaceuticals demonstrates our commitment to designing innovative solutions that draw from our global clinical experience and therapeutic expertise to fulfill unmet medical needs on behalf of patients worldwide.”

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Publication

The information was submitted for publication through the agency of the contact person set out above at 8:00 CET on March 30, 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 were recently 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.