

InDex Pharmaceuticals to exhibit at Digestive Disease Week

May 12, 2022 – InDex Pharmaceuticals Holding AB (publ) today announced that the company will be exhibiting at the Digestive Disease Week (DDW) May 21-24, 2022 in San Diego. DDW is the world's premier meeting for healthcare professionals, researchers and industry in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery.

InDex Pharmaceuticals will be located at booth #1413 in the exhibition hall, San Diego Convention Centre. InDex's team members will be present on site to provide information about cobitolimod and the ongoing phase III clinical study CONCLUDE, evaluating the Toll-like receptor 9 agonist cobitolimod as a novel treatment for moderate to severe left-sided ulcerative colitis. The study will include approximately 440 patients and be conducted at several hundred clinics in over 30 countries in Europe, the Americas and the Asia-Pacific region.

"DDW is an important industry and professional event, and we look forward to meeting healthcare professionals and other stakeholders with an interest in inflammatory bowel disease to discuss our lead drug candidate cobitolimod and the phase III study CONCLUDE," said Johan Giléus, acting CEO of InDex Pharmaceuticals. "With cobitolimod we aim to develop a novel, effective and safe treatment to improve the lives of patients suffering from this debilitating disease."

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Publication

The information was submitted for publication through the agency of the contact person set out above at 11:00 CET on May 12, 2022.

About the CONCLUDE study

CONCLUDE is a randomised, double-blind, placebo-controlled, clinical phase III study to evaluate cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis with an inadequate response or failure to tolerate conventional therapy, biological therapy or JAK inhibitors. The study has been designed in consultation with both the US and European regulatory authorities, the FDA and EMA respectively. The induction study will include approximately 440 patients, and the primary endpoint will be clinical remission at week 6, which is the same primary endpoint as used in the successful phase IIb study CONDUCT. Apart from the dosing 250 mg given at baseline and week 3, which was the highest dose and the one that showed the best efficacy in the phase IIb study, the phase III study will also evaluate a higher dose, 500 mg, 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 once every three weeks.

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 is being evaluated in the phase III study CONCLUDE as a novel treatment of moderate to severe 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 being evaluated in the phase III study CONCLUDE as a novel 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.