InDex Pharmaceuticals enrols first patient in the phase III study CONCLUDE with cobitolimod in ulcerative colitis

November 24, 2021 – InDex Pharmaceuticals Holding AB (publ) today announced that the first patient has been enrolled in the pivotal phase III study CONCLUDE. The study will evaluate the efficacy and safety of the first-in-class TLR9 agonist cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis.

"I am thrilled to announce the enrolment of the first patient in the pivotal CONCLUDE study, which is an important milestone in bringing cobitolimod to the market for patients suffering from this debilitating disease," said Peter Zerhouni, CEO of InDex Pharmaceuticals. "The phase III program will form the basis for marketing approval of cobitolimod in moderate to severe ulcerative colitis, where great importance is put on patient safety, as current treatment options are associated with serious side effects. Given cobitolimod's outstanding combination of efficacy and safety, the annual global peak sales at a successful commercialisation are estimated to have the potential to reach more than USD 1 billion."

"The medical community has long recognised the enduring unmet need for safer and effective treatment options for patients with moderate to severe ulcerative colitis," said Professor Raja Atreya of the University of Erlangen-Nürnberg in Germany and principal investigator of the CONCLUDE study. "With its novel mechanism of action, and competitive efficacy and excellent safety profile shown in the clinical studies to date, I believe that cobitolimod holds great potential as an attractive treatment alternative for these patients. I look forward to contributing as principal investigator in this important study."

The study will include approximately 440 patients and be conducted at several hundred clinics in over 30 countries including Europe, the Americas and the Asia-Pacific region. Professor William Sandborn at the University of California San Diego and Professor Walter Reinisch at the Medical University of Vienna respectively are the Medical Advisors in the study.

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Publication
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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.

About ulcerative colitis
Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. Today approximately 2 million people in Europe and the US suffer from ulcerative colitis. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, abdominal pain, fever, weight loss and anemia. Moreover, patients have a significantly elevated risk of developing colon cancer. Despite the currently available drugs, many patients with ulcerative colitis still suffer from severe symptoms.

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.