InDex Pharmaceuticals will initiate patient recruitment for the Phase III study CONCLUDE after the summer

May 31, 2021 – InDex Pharmaceuticals Holding AB (publ) today announced that patient recruitment for the phase III study CONCLUDE is planned to initiate after the summer. The study will evaluate the efficacy and safety of the drug candidate cobitolimod for the treatment of moderate to severe left-sided ulcerative colitis.

"The Covid-19 pandemic continues to affect significantly healthcare systems and regulatory authorities around the world, but the pressure is now decreasing in many countries. We therefore plan to initiate patient recruitment for the phase III study with cobitolimod on a broad scale after the summer", says Peter Zerhouni, CEO of InDex Pharmaceuticals. "CONCLUDE is a global study that will be conducted at a several hundred clinics in over 30 countries, and we are pleased that a large number of clinics have expressed their desire to participate. To have many clinics recruit patients already from the outset is important for the cost-effectiveness of the study."

The process of applying for and obtaining approval from the relevant authorities in the participating countries is ongoing.

CONCLUDE is a randomised, double-blind, placebo-controlled, 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. 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. 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.

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Publication
This information is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (MAR). The information was submitted for publication through the agency of the contact person set out above at 19:15 CET on May 31, 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.