The Lancet Gastroenterology and Hepatology publishes InDex Pharmaceuticals' results of the phase IIb study with cobitolimod

October 6, 2020 – InDex Pharmaceuticals Holding AB (publ) today announced that the results of the CONDUCT study have been published in the high-impact medical journal *The Lancet Gastroenterology and Hepatology*. CONDUCT was a phase IIb dose optimisation study, evaluating the first-in-class TLR9 agonist cobitolimod for the treatment of moderate to severe ulcerative colitis. The study met the primary endpoint and cobitolimod demonstrated an outstanding combination of efficacy and safety.

"We are delighted that the CONDUCT study results have been published in a prestigious journal, which is one of the highest ranked journals within the field of gastroenterology", says Peter Zerhouni, CEO of InDex Pharmaceuticals. "This is an additional important confirmation of the successful results of the CONDUCT study in ulcerative colitis, which is a disease with a significant need for new treatment options as many patients do not respond to or suffer severe side effects from current treatments."

CONDUCT was a randomised and placebo-controlled clinical study that included 213 patients with left-sided moderate to severe active ulcerative colitis not responding to conventional therapy. The study was conducted at 91 sites in 12 different European countries. The patients were divided into four treatment arms receiving cobitolimod and one arm receiving placebo. The study met the primary endpoint with 21.4% of the patients in clinical remission at week 6 in the highest dose group receiving 250mg x 2 of cobitolimod, compared to 6.8% of the patients in the placebo group (p=0.0247*). The results in several clinically relevant secondary endpoints also confirm the efficacy of the highest dose. Cobitolimod was well tolerated at all dose levels and no differences in the safety profile were observed compared to placebo.

"Ulcerative colitis is a chronic and lifelong disease with an enduring unmet medical need for safe and effective treatments, where I believe topical therapies have been long ignored. Cobitolimod has a novel mechanism of action and is progressing into global phase III studies", says Professor William J. Sandborn, Chief of the Division of Gastroenterology of the University of California San Diego and co-author of the publication. "Based on the available data, cobitolimod appears to have a compelling safety profile, while delivering clinically relevant efficacy. Given also the infrequent dosage regimen, cobitolimod looks a promising candidate for moderate to severe left-sided ulcerative colitis."

The publication has the title "Cobitolimod for moderate-to-severe, left-sided ulcerative colitis (CONDUCT): a phase 2b randomised, double-blind, placebo-controlled, dose-ranging induction trial" and can be found at http://www.thelancet.com/journals/langas/article/PIIS2468-1253(20)30301-0/fulltext

The results of the CONDUCT study will also be presented orally at the two leading gastroenterology conferences during October; the United European Gastroenterology Week (UEGW) on October 12 and the American College of Gastroenterology (ACG) Annual Scientific Meeting on October 26.

**Predefined one-sided test where the significance limit was set to <0.10.*

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About the CONDUCT study
CONDUCT was a randomised, double blind, placebo-controlled, exploratory study for evaluating cobitolimod's efficacy and safety in inducing clinical remission, compared to placebo, in patients with left-sided moderate to severe active ulcerative colitis. The study objective was to identify the most efficacious dose and dose regimen for further development. The 213 patients were divided into four treatment arms receiving cobitolimod and one arm receiving placebo. Three different dose strengths of cobitolimod were investigated: 30mg, 125mg and 250mg given twice, at baseline and at week 3. Also, 125mg given four times, at baseline and each week until week 3, was investigated. In addition to cobitolimod or placebo, all patients continued with their standard of care treatment.

The primary endpoint of the study was induction of clinical remission at week 6 defined by modified Mayo sub scores, with a rectal bleeding score of 0, a stool frequency score of 0 or 1 and an endoscopy score of 0 or 1. The study was conducted at 91 sites in 12 different European countries: the Czech Republic, France, Germany, Hungary, Italy, Poland, Romania, Russia, Serbia, Spain, Sweden and the Ukraine respectively. For more details on the study please visit www.clinicaltrials.gov/show/NCT03178669.

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. Biological drugs represent the largest market segment in ulcerative colitis in terms of value with annual sales estimated to more than USD 5 billion. The total pharmaceutical market for ulcerative colitis is expected to grow to about USD 8 billion in 2023.

Cobitolimod in brief
Cobitolimod is a 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 a first-in-class compound under development for moderate to severe ulcerative colitis and met the primary endpoint in the phase IIb study CONDUCT with an outstanding combination of efficacy and safety. Data from four previous completed placebo-controlled clinical trials support the efficacy and safety demonstrated in the CONDUCT study. Cobitolimod is also known as Kappaproct® and DIMS0150.

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 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 e-mail 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

Publication
The information was submitted for publication through the agency of the contact person set out above at 08:00 CET on October 6, 2020.