InDex Pharmaceuticals to present the successful results of the CONDUCT study at two leading medical conferences

August 24, 2020 – InDex Pharmaceuticals Holding AB (publ) today announced that the results of the CONDUCT study will be presented orally at two leading gastroenterology conferences; the United European Gastroenterology Week (UEGW) and the American College of Gastroenterology (ACG) Annual Scientific Meeting. 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 with an outstanding combination of efficacy and safety.

"We are very pleased that the abstract with the CONDUCT study results has been selected for oral presentation at both the UEGW and the ACG Annual Scientific Meeting", says Peter Zerhouni, CEO of InDex Pharmaceuticals. "These events are great opportunities for us to further reach the international scientific community with the successful results."

UEGW is the largest scientific meeting for gastroenterologists in Europe and is this year held virtually October 11–13. The CONDUCT study will be presented on October 12 during the session "IBD: Clinical trials III" which starts at 16:30 CET. The abstract (OP117) is titled "COBITOLIMOD FOR MODERATE-TO-SEVERE LEFT-SIDED ULCERATIVE COLITIS (CONDUCT): A PHASE IIB, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-RANGING TRIAL".

ACG Annual Scientific Meeting is the premier clinical conference for gastroenterologists in the US. ACG's meeting is also virtual this year and will be held October 23–28. The CONDUCT study will be presented on October 26 at 8:00 ET. The abstract (S0642) has the same title as at UEGW.

The CONDUCT study included 213 patients with left-sided moderate to severe active ulcerative colitis not responding to conventional therapy. The 213 patients were divided into four treatment arms receiving cobitolimod and one arm receiving placebo. As previously reported, the CONDUCT 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*). Cobitolimod was well tolerated at all dose levels and no differences in the safety profile were observed compared to placebo.

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

For more information:
Peter Zerhouni, CEO
Phone: +46 8 122 038 50
E-mail: peter.zerhouni@indexpharma.com

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 August 24, 2020.