InDex Pharmaceuticals meets primary endpoint in the phase IIb study CONDUCT with cobitolimod in ulcerative colitis

- **Outstanding combination of efficacy and safety**
- **15% delta vs. placebo for clinical remission**

August 27, 2019 – InDex Pharmaceuticals Holding AB (publ) today announced positive top line results from the dose optimisation study CONDUCT, which is evaluating cobitolimod for the treatment of moderate to severe ulcerative colitis. The study met the primary endpoint of clinical remission, demonstrating a superior efficacy of 15% (delta) in patients receiving the highest dose of cobitolimod compared to placebo. Cobitolimod was well tolerated at all dose levels and no differences in the safety profile were observed compared to placebo.

The CONDUCT study is evaluating the first-in-class TLR9 agonist cobitolimod and includes 213 patients with left-sided moderate to severe active ulcerative colitis not responding to conventional therapy. Cobitolimod met the study's primary endpoint with a significantly superior efficacy in clinical remission, as defined by modified Mayo score, at week 6 for the dose group receiving 250mg x 2 of cobitolimod compared to placebo (p=0.0495, OR=3.8).

"We are very pleased that the CONDUCT study achieved its primary objective to identify the most efficacious dosing regimen and also confirmed the excellent safety profile of cobitolimod observed in previous clinical studies," said Peter Zerhouni, CEO of InDex Pharmaceuticals. "With an outstanding combination of efficacy and safety, cobitolimod is set to take a leading position within the field. We will now advance cobitolimod towards phase III and in parallel evaluate the best route to commercialisation."

The observed proportions of patients in clinical remission in the respective dose groups were: 21.4% for the 250mg x 2; 9.5% for the 125mg x 4; 4.7% for the 125mg x 2; 12.5% for the 30mg x 2; compared to 6.8% for placebo.

"The significant and clinically relevant effect demonstrated with cobitolimod in this difficult to treat patient population is very encouraging," said Professor Raja Atreya at the University of Erlangen-Nürnberg and principle investigator of the CONDUCT study. "Despite existing treatment options, there is a substantial proportion of patients with moderate to severe ulcerative colitis who do not respond to available therapies and for whom there is a great medical need for new treatment options. Cobitolimod with its novel and unique mechanism of action and very favourable safety profile represents new hope for these severely ill patients."

The company plans to publish complete study results in a scientific journal and to present them at upcoming medical conferences.

At 10:00 CET today, InDex Pharmaceuticals will host a webcasted presentation in English of the study results at Redeye's premises on Mäster Samuelsgatan 42 in Stockholm. The webcast can be followed on: https://www.redeye.se/live/1962 and will afterwards be available on the company's website. Questions can be emailed to info@indexpharma.com

InDex Pharmaceuticals has appointed Carnegie Investment Bank AB (publ) and Pareto Securities AB as financial advisors to evaluate the capital structure and potential future financing alternatives.

Delta = the difference in the percentage of patients reaching clinical remission between cobitolimod and placebo
Clinical remission (modified Mayo score) defined as Mayo subscore for blood in stool =0, Mayo subscore for stool frequency ≤1 and endoscopic Mayo subscore ≤1

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About the CONDUCT study
CONDUCT is 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 213 patients are divided into four treatment arms receiving cobitolimod and one arm receiving placebo. Three different dose strengths of cobitolimod are being 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, is being investigated. In addition to cobitolimod or placebo, all patients will continue with their standard of care treatment.

The primary endpoint of the study is 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 is being 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. 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.

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 has previously achieved clinical proof-of-concept in moderate to severe active ulcerative colitis, with a very favourable safety profile. Data from four previous placebo-controlled clinical trials indicate that cobitolimod has statistically significant effects on those endpoints that are most relevant in this disease, both from a regulatory and clinical perspective. These endpoints include the key clinical symptoms such as blood in stool, number of stools, and mucosal healing, respectively. 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 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
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 07:00 CET on August 27, 2019.