InDex Pharmaceuticals enrolls last patient in phase IIb study CONDUCT with cobitolimod

June 26, 2019 – InDex Pharmaceuticals Holding AB (publ) today announced that patient enrolment was completed in the dose optimisation study CONDUCT, which is evaluating cobitolimod for the treatment of moderate to severe ulcerative colitis. Top line results are expected to be available in 8-10 weeks.

The CONDUCT study is a randomised, double blind, placebo-controlled phase IIb study designed to evaluate the TLR9 agonist cobitolimod's efficacy and safety in inducing clinical remission, compared to placebo, in patients with left-sided moderate to severe active ulcerative colitis who have not responded to conventional therapy. The study has enrolled a total of 213 patients at 91 clinics in 12 European countries and investigates three different dose strengths and two different dose frequencies of cobitolimod.

"We are pleased to have achieved this significant milestone for InDex and are looking forward to the study results by the end of the summer," said Peter Zerhouni, CEO of InDex Pharmaceuticals. "Positive results will take us closer to our goal of making cobitolimod available to patients suffering from ulcerative colitis who today lack treatment options with a satisfactory combination of efficacy and safety. We would like to thank all patients, investigators and their clinical study teams participating in the study."

The study objective is to identify the dosing regimen that provides the optimal efficacy, defined by FDA and EMA agreed endpoints for the indication, while maintaining the favourable safety profile seen with the compound in previous clinical studies. No safety issues have been noted in the more than 180 patients that have already completed the study.

As per industry standards, after the last patient has undergone requisite study visits and all the data is quality controlled, the database will be locked and the study unblinded for data analysis. Top line results are expected to be available in 8-10 weeks.

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About the CONDUCT study
CONDUCT is a randomised, double blind, placebo-controlled 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: 30 mg, 125 mg and 250 mg given twice, at baseline and at week 3. Also, 125 mg 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 patients will be followed for a total of 10 weeks. 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 achieved clinical proof-of-concept in moderate to severe active ulcerative colitis, with a very favourable safety profile. Data from four 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 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.

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 09:34 CET on June 26, 2019.