InDex Pharmaceuticals provides status update on the patient recruitment in the CONDUCT study

April 11, 2019 – InDex Pharmaceuticals Holding AB (publ) today announced that 197 patients, of the total 215 planned, have been enrolled to date in the CONDUCT study evaluating the drug candidate cobitolimod. The patient recruitment has varied significantly on a monthly basis, with between 6 and 19 patients enrolled, which makes it challenging to predict the remaining recruitment time. The company estimates that the patient recruitment will be completed during the month of June at the latest, which represents a delay compared to the previously communicated timeline. The company will announce when the last patient has been enrolled in the study and the top line results are expected to be available within 8-10 weeks thereafter.

Cobitolimod is a new type of drug under development for the treatment of moderate to severe ulcerative colitis. The CONDUCT study 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 study is conducted at approximately 90 clinics in 12 European countries. The aim of the dose optimisation study is that more frequent and higher doses of cobitolimod will result in a significantly higher effect than in previous clinical studies with cobitolimod and also compared to what has been reported for products on the market and those in late stage clinical development.

"We will soon have enrolled all the patients in the CONDUCT study and are preparing to analyse the results, which will be a crucial milestone for the company," said Peter Zerhouni, CEO of InDex Pharmaceuticals. "With positive data we will take a big step towards our goal to make cobitolimod available for these severely ill patients."

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Cobitolimod in brief
Cobitolimod is a new type of drug that can help patients with moderate to severe ulcerative colitis back to a normal life. It is a so-called 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 active ulcerative colitis. Cobitolimod has achieved clinical proof-of-concept in moderate to severe active ulcerative colitis, with a very favorable 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. Based on the encouraging results from earlier studies InDex is now performing the phase IIb study CONDUCT to evaluate higher doses and dose frequencies than investigated in previous studies with cobitolimod. The goal of the study is to optimise the treatment and achieve substantially higher efficacy, while maintaining the compound's excellent safety profile. The CONDUCT study will include 215 patients with left-sided moderate to severe active ulcerative colitis. It is a randomised, double blind, placebo-controlled study for evaluating cobitolimod's efficacy and safety in inducing clinical remission compared to placebo. The dose optimisation study investigates three different dose strengths of cobitolimod and two different dose frequencies. 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 foremost 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.

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