InDex Pharmaceuticals updates timeline for top line results from the CONDUCT study to first half of 2019

August 9, 2018 – InDex Pharmaceuticals Holding AB (publ) today announced an updated timeline for patient recruitment in the ongoing phase IIb study CONDUCT with the drug candidate cobitolimod. Top line results from the study are now expected in the first half of 2019 instead of in the fourth quarter of 2018 as previously communicated.

Cobitolimod is a new type of drug under development for the treatment of moderate to severe ulcerative colitis. The CONDUCT study is a phase IIb study that will include 215 patients with left-sided moderate to severe active ulcerative colitis at approximately 90 sites in 12 countries. The study is now approved in all the countries and hence the last clinics will be able to start enrolling patients shortly. To date 119 patients have been enrolled in the study. The aim of the dose optimisation study is that more frequent and higher doses 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.

"The patient recruitment for the CONDUCT study is well under way across Europe, but we have not yet reached the anticipated rate", said Peter Zerhouni, CEO of InDex Pharmaceuticals. "Given the recruitment rate until now, we will be able to report the top line results no later than the second quarter of 2019. However, our team is working hard to increase the recruitment rate to be able to present the results earlier."

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 3 months thereafter.

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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 at approximately 90 sites in 12 countries. 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 active 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 are traded on Nasdaq First North Stockholm. Redeye AB is the company's Certified Adviser. For more information, please visit www.indexpharma.com

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