InDex Pharmaceuticals enters agreement with CRO for the CONDUCT study

February 1, 2017 – InDex Pharmaceuticals Holding AB (publ) today announced that the company has entered an agreement for services with the global contract research organization (CRO) PAREXEL for the implementation of the CONDUCT study. CONDUCT is a phase IIb dose optimisation study with the drug candidate cobitolimod for the treatment of moderate to severe active ulcerative colitis.

According to the agreement, the first patient in the CONDUCT study will be enrolled during the second quarter of 2017 and the objective is to have top line results from the study in the fourth quarter of 2018. The study will be conducted at approximately 90 sites in 12 different countries: Czech Republic, France, Germany, Hungary, Italy, Poland, Romania, Russia, Serbia, Spain, Sweden and Ukraine. Many sites would like to participate and of more than 100 visted interested sites, 60 have already qualified to take part in the study. The process of getting the study approved by regulators and ethics committees in each country is underway. The study will not include any US sites due to the high cost per patient.

"We are very pleased to have PAREXEL as our partner for this important trial with cobitolimod, our lead drug candidate", says Peter Zerhouni, CEO of InDex Pharmaceuticals. "It is a leading global CRO with considerable experience from managing multinational clinical studies in inflammatory bowel disease. We are now working together to advance the CONDUCT study as efficiently and quickly as possible."

The CONDUCT study will include 215 patients with left-sided moderate to severe active ulcerative colitis, divided into four treatment arms receiving cobitolimod and one arm receiving placebo. It is a randomised, double blind, placebo controlled study for evaluating cobitolimod's efficacy and safety in inducing clinical remission compared to placebo. In addition to cobitolimod or placebo, all patients will receive standard of care treatment.

Based on the promising results of earlier clinical trials with cobitolimod this study will evaluate other doses and dose frequencies than previously investigated in order to optimise the treatment. The goal is, while maintaining the compound's excellent safety profile, to show a substantially higher efficacy than in prior studies and also in comparison with what has been reported for drugs on the market as well as other compounds in late stage clinical development.

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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 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. 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

Publication

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