InDex Pharmaceuticals presents mechanism of action data for cobitolimod at the ECCO congress

February 13, 2018 – InDex Pharmaceuticals Holding AB (publ) today announced that the recently reported new mechanism of action data for the drug candidate cobitolimod has been selected for an oral presentation at the 13th congress of the European Crohn’s and Colitis Organisation (ECCO).

The scientific abstract, prepared in collaboration with the University of Erlangen-Nürnberg in Germany, has been selected amongst the top 10 out of 1,366 submitted abstracts, and it will feature in the Highlights of ECCO’18 video. The video will contain the most important scientific insights and take-home messages from the congress. The ECCO congress is the largest congress in the world with a specific focus on inflammatory bowel disease (IBD) and is held in Vienna, Austria on February 14-17, 2018. More than 6,000 delegates from all over the world are expected to attend the single track scientific programme.

“We are very pleased that the scientific committee at ECCO considers the new mechanism of action data for cobitolimod to be one of the most interesting findings during this years’ congress”, says Peter Zerhouni, CEO of InDex Pharmaceuticals. “This event is a great opportunity for us to increase visibility in the scientific community and meet the investigators in our ongoing clinical study CONDUCT. It is a phase Ib dose optimisation study with cobitolimod in moderate to severe active ulcerative colitis and the objective is to have top line results from the study in the fourth quarter of this year.”

The presentation (OP004) with the title The TLR9 agonist cobitolimod induces anti-inflammatory effects and balances the Th17/T-reg cell response in Ulcerative Colitis will be given by Dr Heike Schmitt from the University of Erlangen-Nürnberg on Thursday, February 15, 2018 in the Plenary Hall at 14:50 CET during the session Novel treatment strategies. The presentation will include mechanism of action data on cobitolimod in the standard experimental model of colitis as well as in ulcerative colitis patients, showing that cobitolimod can modulate the immune system in ulcerative colitis by balancing the mucosal Th17/Treg cell response. Cobitolimod treatment decreases IL-17 expression and the number of Th17 cells, while it increases mucosal IL-10 expression and the quantity of T-reg cells. In conclusion, cobitolimod addresses new therapeutic targets in the immunopathogenesis of ulcerative colitis, leading to pronounced anti-inflammatory effects.

The abstract of the oral presentation is available on the ECCO homepage (www.ecco-ibd.eu).

The Highlights of ECCO’18 video will be available in the eLibrary on the ECCO homepage (www.ecco-ibd.eu/highlights) right after the congress.

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About the European Crohn’s and Colitis Organisation (ECCO)
ECCO is the largest forum for specialists in inflammatory bowel disease (IBD) in the world. ECCO produces scientific guidelines for the treatment of IBD, organises educational activities, promotes research and represents IBD specialists, and works with patient associations and industry to reduce the burden of disease for the patients. The annual congress attracted more than 6,200 delegates in 2017 and is the largest IBD congress in the world.

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 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. The objective is to have top line results from the study in the fourth quarter of 2018. 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