InDex Pharmaceuticals publishes post-hoc analysis of the COLLECT study

October 19, 2018 – InDex Pharmaceuticals Holding AB (publ) today announced the publication of a post-hoc analysis of COLLECT study data. COLLECT was a clinical study of the Toll-like receptor 9 (TLR9) agonist cobitolimod, a first-in-class treatment for patients with moderate to severe ulcerative colitis (UC). The paper, published in the October issue of the peer-reviewed journal *Digestive and Liver Disease (DLD)*, presents the clinical effect of cobitolimod on patient-reported outcomes (PRO) defined endpoints and in different patient subgroups defined by disease activity or anti-TNFα therapy exposure.

In the COLLECT study, 131 patients with moderate to severe active UC and an inadequate response to conventional therapy received either cobitolimod or placebo, in addition to standard of care therapies. The study was conducted at 38 sites in seven European countries. The main results including primary and secondary endpoints were previously published in the *Journal of Crohn's and Colitis* in November 2016.

104 patients with available e-diary data were included in a post-hoc analysis, out of which 70 had been treated with cobitolimod and 34 with placebo. Symptomatic remission, defined as absence of blood in stool and a mean daily stool frequency <4, based on e-diary records was achieved at week 4 in 17.1% of cobitolimod vs. 5.9% of placebo treated patients (p=0.13), at week 8 in 35.7% of cobitolimod vs. 17.6% of placebo treated patients (p=0.07), and at week 12 in 38.6% of cobitolimod vs. 17.6% of placebo treated patients (p=0.04). As expected, symptomatic remission rates in the cobitolimod and placebo group were smaller for anti-TNFα experienced patients, but with a similar relative effect-size compared to anti-TNFα naïve patients. In addition, clinical efficacy was in general higher in patients with moderate compared to severe disease, which is in line with what has been reported for other therapies in this indication. The data have previously been presented at the United European Gastroenterology Week (UEGW), the Digestive Disease Week (DDW) and the annual congress of the European Crohn's and Colitis Organisation (ECCO).

"The post-hoc analysis shows that cobitolimod is able to induce symptomatic remission in clinically relevant subgroups of UC patients," said Peter Zerhouni, CEO of InDex Pharmaceuticals. "We are pleased that our results continue to meet considerable interest from the scientific community as we continue the work of taking cobitolimod through the ongoing phase IIb dose optimisation study CONDUCT."

The publication has the title "Clinical efficacy of the Toll-like receptor 9 agonist cobitolimod using patient-reported-outcomes defined clinical endpoints in patients with ulcerative colitis", and the publication can be found at www.dldjournalonline.com, Atreya R et al. Dig Liver Dis. 2018 Oct;50(10): 1019-1029.

Contact InDex Pharmaceuticals:
Peter Zerhouni, CEO
Tel: +46 8 508 847 35
peter.zerhouni@indexpharma.com

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 first half of 2019. 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