InDex Pharmaceuticals publishes results from COLLECT study

***July 13, 2016* - InDex Pharmaceuticals AB today announced the publication of the results from COLLECT, a clinical study of the Toll-like receptor 9 (TLR9) agonist cobitolimod as a first-in-class treatment for patients with moderate to severe ulcerative colitis (UC). The paper, published in the peer-reviewed *Journal of Crohns and Colitis (JCC)*, supports the potential of cobitolimod as a novel treatment for moderate to severe active ulcerative colitis.**

In the COLLECT study, 131 patients with moderate to severe active UC and an inadequate response to conventional therapy received either 30 mg of cobitolimod or placebo as two single rectal doses at week 0 and week 4, in addition to standard of care therapies. The study was conducted at 38 sites in seven European countries.

Despite not meeting the primary endpoint of inducing clinical remission measured at week 12, defined by a clinical activity index (CAI)/Rachmilewitz score of ≤4, cobitolimod showed statistically significant improvement on important secondary endpoints at week 4. These included:

- symptomatic remission (no blood in stool together with a normal stool frequency), reached in 32% of the patients in the cobitolimod group compared to 14% in the placebo group (p=0.02),
- registration remission (clinical remission with concurrent mucosal healing), achieved in 21% of the patients in the cobitolimod group versus 4.7% in the placebo group (p=0.02).

A statistical significant improvement was also evident in the combined score of symptomatic remission and mucosal healing, achieved in 21% in the cobitolimod group vs. 2.3% in the placebo group (p=0.02). This is the endpoint that the regulatory authorities as well as the scientific community consider the most relevant for the disease. Moreover, a significant improvement was seen in the histology score at week 4. Cobitolimod was well tolerated and no safety signals compared to the placebo group were evident.

"The data from the COLLECT study shows that cobitolimod is a promising and well-tolerated potential novel therapeutic option for patients with moderate to severe active ulcerative colitis, for which there is an unmet medical need," said Peter Zerhouni, CEO of InDex Pharmaceuticals. "InDex is currently preparing for the next clinical study with cobitolimod, which will be a phase IIb study to optimize the dosing regimen with the goal to provide substantially higher efficacy, while maintaining the compound's superior safety profile."

Principal investigator of the COLLECT study, Professor Christopher Hawkey commented: "In active ulcerative colitis the goal of treatment is to induce remission, characterized by a reduction in stool frequency and blood in stool, accompanied by an improved or normalized endoscopic score. The COLLECT study demonstrates that cobitolimod can achieve these goals, also in patients who are refractory to some currently available treatments."

The publication has the title "Clinical effects of a topically applied Toll-like receptor 9 agonist in active moderate to severe ulcerative colitis". The publication and the acknowledgement to all investigators can be found at http://ecco-jcc.oxfordjournals.org, Atreya R et al. J Crohns Colitis. 2016 May 20. pii: jjw103.

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About cobitolimod
Cobitolimod is InDex Pharmaceutical's lead drug candidate in late-stage clinical development for moderate to severe active ulcerative colitis, a debilitating, chronic inflammation of the large intestine. Cobitolimod is a first-in-class Toll-like receptor (TLR) 9 agonist that functions as an immunomodulatory agent by mimicking microbial DNA, the natural ligand of the receptor.

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 indicates 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.

In January 2016, WHO recommended the INN name cobitolimod. The substance is also known as Kappaproct® and DIMS0150.

About InDex Pharmaceuticals
InDex Pharmaceuticals is based in Stockholm, Sweden. Among the main shareholders are SEB Venture Capital, Industrifonden and NeoMed Management.

The Company's lead drug candidate is cobitolimod (Kappaproct®) - a new type of drug that can help patients with moderate to severe active ulcerative colitis back to a normal life. 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.
For more information, please visit www.indexpharma.com