InDex Pharmaceuticals enrolls first patient in the phase IIb study CONDUCT with cobitolimod

**June 21, 2017 –** InDex Pharmaceuticals Holding AB (publ) today announced that the first patient has been enrolled in the clinical study CONDUCT – a phase IIb dose optimisation study with the drug candidate cobitolimod. Cobitolimod is a first in class immunotherapeutic, which is being developed for the treatment of moderate to severe active ulcerative colitis.

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.

“This is an important milestone for InDex and represents another step towards our mission of providing more effective and safer drugs for this unmet medical need. SEK 250 million was raised in our IPO in October 2016, primarily to finance the CONDUCT study, and we are delivering according to plan”, said Peter Zerhouni, CEO of InDex Pharmaceuticals.

“The goal of CONDUCT, while maintaining cobitolimod’s excellent safety profile, is to show a substantially higher efficacy than in previous studies, and also in comparison with what has been reported both for drugs on the market and other compounds in late stage clinical development for moderate to severe active ulcerative colitis”, he concluded.

The study is conducted in collaboration with the leading global biopharmaceutical services company PAREXEL. Study drug for the complete study has been manufactured at APL in Sweden. The objective is to have top line results from the study in the fourth quarter of 2018.

“It is highly satisfying that the study is now up and running. Despite modern treatment options, a significant percentage of patients with moderate to severe active ulcerative colitis do not respond to available medical therapies, or will eventually develop loss of response to treatments or suffer from severe side effects. I see a great need for new effective and safe therapeutic options for these patients”, said Professor Raja Atreya of the University of Erlangen-Nürnberg in Germany, who enrolled the first patient and is the principle investigator of the CONDUCT study.

“With its novel and unique mechanism of action I believe that cobitolimod has great potential as a future alternative to the biological drugs used today. Cobitolimod has shown promising results in clinical studies to date. By optimising the dosing regimen in the CONDUCT study the therapeutic effect may be even higher”, he concluded.

Professor Walter Reinisch at the Medical University of Vienna and Medical Advisor in the study added, “Ulcerative colitis is a chronic disabling disorder that has a very negative impact on a patient’s quality of life. Cobitolimod represents a novel and promising approach to targeted treatment of the colonic inflammation. Its local application is intended to result in low risk of systemic side-effects, but a quick onset of action, both highly valued benefits by patients”.

**For more information:**

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About the CONDUCT study

CONDUCT is a randomised, double blind, placebo-controlled study for evaluating cobitolimod’s efficacy and safety in inducing clinical remission compared to placebo. The 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. Three different dose strengths of cobitolimod are being investigated: 30 mg, 125 mg and 250 mg given twice, at baseline and at week 3. Also, 125 mg given four times, at baseline and each week until week 3, is being investigated. In addition to cobitolimod or placebo, all patients will continue with their standard of care treatment.

The primary endpoint of the study is induction of clinical remission at week 6 defined by modified Mayo sub scores, with a rectal bleeding score of 0, a stool frequency score of 0 or 1 and an endoscopy score of 0 or 1. The patients will be followed for a total of 10 weeks. The study is being conducted at approximately 90 sites in 12 different European countries: the Czech Republic, France, Germany, Hungary, Italy, Poland, Romania, Russia, Serbia, Spain, Sweden and the Ukraine respectively. For more details on the study please visit www.clinicaltrials.gov/show/NCT03178669.

About ulcerative colitis

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, abdominal pain, fever, weight loss and anemia. Moreover, patients have a significantly elevated risk of developing colon cancer. Despite the currently available drugs, many patients with ulcerative colitis still suffer from severe symptoms. For those patients that do not respond to medical treatment, the last resort is to surgically remove the colon.

Cobitolimod in brief

Cobitolimod is a new type of drug that can help patients with moderate to severe active 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 favourable 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

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