



InDex Pharmaceuticals gets new patent in Japan

Mars 28, 2018 – InDex Pharmaceuticals Holding AB (publ) today announced that a new method of use patent for the drug candidate cobitolimod will be issued by the Japan Patent Office. The patent provides additional protection for treating chronic active ulcerative colitis in patients that are not responding or are intolerant to anti-inflammatory therapy, wherein cobitolimod is not administered in combination with corticosteroid or glucocorticosteroid.

The divisional patent, entitled *Method for prevention of colectomy* (patent application number 2016218270), will provide an exclusivity period until November 2032, with the possibility of up to 5 years term extension after market approval.

The company has received a notice of allowance from the Japan Patent Office. A corresponding patent was granted in the US in October 2017, and corresponding patent applications have been or will be filed in Europe and Canada and will be diligently prosecuted to grant.

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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 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

Publication

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