InDex Pharmaceuticals announces positive results from a pharmacokinetic (PK) study with cobitolimod

March 15, 2023 – InDex Pharmaceuticals Holding AB (publ) today announced positive results from a pharmacokinetic (PK) study with cobitolimod in patients with moderate to severe ulcerative colitis. The systemic uptake was limited both for patients with active disease and in clinical remission. For the first time patients have been treated with doses of 500 mg, and in line with previous studies cobitolimod was well tolerated.

"One of the potential benefits of a locally acting treatment in the colon is low systemic exposure. We are therefore excited that the study has confirmed this benefit also with the higher dose of 500 mg cobitolimod," said Jenny Sundqvist, CEO of InDex Pharmaceuticals. "This is the first time that the 500 mg dose of cobitolimod has been administered to patients, and it is reassuring that it was well tolerated. The study is also essential for, and required in, future regulatory applications for market approval."

The study results include PK data from 7 patients with moderate to severe ulcerative colitis treated with doses of 500 mg of cobitolimod administered rectally. Plasma concentrations of cobitolimod were first measured after administration of 500 mg cobitolimod in all the 7 patients during a flare. The patients were then treated with a second dose of 500 mg cobitolimod at week 3, after which the degree of clinical remission was evaluated at week 6. Even though it was a small-scale open-label study, it was encouraging that 4 out of 7 patients achieved clinical remission at week 6. A second PK-analysis was conducted after these patients had received a third dose of 500 mg cobitolimod. This analysis aimed to investigate the systemic uptake of cobitolimod also in patients with remission.

The results showed a limited systemic uptake following the 500 mg cobitolimod dose both for patients in a flare and in remission, with the majority of patients having undetectable levels of cobitolimod in the plasma after 8 hours. Cobitolimod was well tolerated, and no serious adverse events were reported in the study.

The company plans to publish complete study results in a scientific journal and present them at an upcoming medical conference.

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Publication
The information was submitted for publication through the agency of the contact person set out above at 10:00 CET on March 15, 2023.

This is an English translation of the Swedish press release. In case of discrepancies between the English translation and the Swedish press release, the Swedish press release shall prevail.

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 lead asset is the drug candidate cobitolimod, which is being evaluated in the phase III program CONCLUDE as a novel treatment of moderate to severe

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 the treatment of various immunological diseases.

InDex is based in Stockholm, Sweden. The company's shares (ticker INDEX) are traded on Nasdaq First North Growth Market Stockholm. Redeye AB is the company's Certified Adviser. For more information, please visit www.indexpharma.com.