InDex Pharmaceuticals prepares for commercialisation of cobitolimod

March 13, 2022 – InDex Pharmaceuticals Holding AB (publ) is planning for self-commercialisation of the drug candidate cobitolimod in the US with strategic collaborations in other regions. Launch is expected in 2027, with the potential for annual sales to reach more than USD 1 billion, in moderate to severe left-sided ulcerative colitis. An in-depth presentation of the strategy and market potential, together with the execution of the phase III study CONCLUDE with cobitolimod will be provided at InDex's Capital Markets Day, tomorrow March 14, 15.00-17.00 CET.

Approximately 400,000 patients suffer from moderate to severe left-sided ulcerative colitis despite treatment with conventional therapies. Cobitolimod is the only advanced drug candidate with a specific focus on this patient population. Cobitolimod has shown competitive efficacy compared to currently available treatment options but in contrast to these therapies, has no known side effects.

"Provided that CONCLUDE confirms the results of previous positive clinical trials with cobitolimod, patients can get access to a treatment with as good, or higher efficacy, than today's advanced therapies but without the serious side effects that these may cause. In addition, cobitolimod is easy to self-administer and has an infrequent dosing regimen – in contrast to current market leading products, which require injections at the clinic or at home. With the phase III program up and running we are starting to prepare for commercialisation of cobitolimod," says Peter Zerhouni, CEO of InDex Pharmaceuticals.

Market potential
The total market for ulcerative colitis has, during the last four years, reported an average CAGR of 10% and represented approximately USD 7.5 billion in 2020[1]. The market is expected to grow with a CAGR of approximately 6% and reach USD 11-12 billion by 2026[1]. InDex estimates that the market segment of moderate to severe left-sided ulcerative colitis will amount to more than USD 5 billion, by the time of cobitolimod's launch.

Cobitolimod's target product profile has been evaluated in several primary market research studies, demonstrating that cobitolimod has strong potential to be positioned as the first treatment option for patients with moderate to severe left-sided ulcerative colitis, that do not respond to conventional treatments. InDex estimates that cobitolimod can reach a market share of 20-30%, corresponding to global peak annual sales of more than USD 1 billion.

Strategy for commercialisation
InDex has together with external experts analysed the commercialisation options for cobitolimod in the US and Europe. The US accounts for approximately 65% of the total market for ulcerative colitis[1]. The conclusion is that the market potential, the required commercial footprint, and the profitability profile in the US respectively are well suited for self-commercialisation by a focused commercial organisation to be built closer to launch.

The fragmented European market, as well as other regions, offer attractive opportunities to enter strategic collaborations as cobitolimod advances towards launch.

Timetable to launch
Results from the ongoing first phase III study with cobitolimod are expected to be available during H2 2023. An interim analysis to select the best dose is planned when approximately 30% of the participants have completed the study. The complete phase III program, including a second induction study and a one-year maintenance study, is expected to be completed during 2026. Applications for marketing approval will then

be submitted to the regulatory authorities, with an expected launch of cobitolimod in 2027. The key milestones are summarized below:

- Results from the first phase III study are expected H2 2023
- The phase III program is expected to be completed in 2026
- Marketing approval and launch are expected in 2027

Expansion of cobitolimod's potential
The current development is focused on the rectal formulation of cobitolimod for moderate to severe left-sided ulcerative colitis. InDex also sees significant potential for cobitolimod in related indications. For that reason, the development of an oral formulation, as a potential follow-on product, is ongoing in parallel. An oral formulation that enables delivery of cobitolimod to other parts of the gastrointestinal tract would open the possibility to broaden the therapeutic use of cobitolimod and thereby increase the commercial potential severalfold.

Capital Markets Day on March 14, 2022
At InDex's Capital Markets Day, tomorrow March 14, 15.00-17.00 CET, CEO Peter Zerhouni together with external experts on US commercialisation and members of the InDex development team for cobitolimod, will provide an in-depth presentation of the strategy, the market potential of cobitolimod, together with the execution of the phase III study CONCLUDE. The Capital Markets Day will be held in Krügersalen at Kapitel 8, Tändstickspalatset, Västra Trädgårdsgatan 15 in Stockholm. Presentations will start at 15.00 CET with registration from 14.30 CET. The Capital Markets Day will be held in English and be live streamed on https://tv.streamfabriken.com/index-pharmaceuticals-cmd-2022. A recording will be available afterwards on InDex's website.

[1]Rami Al-Horani et al Nat Rev Drug Discov. 2022 Jan;21(1):15-16

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Publication
This information is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (MAR). The information was submitted for publication through the agency of the contact person set out above at 21:25 CET on March 13, 2022.

Cobitolimod in brief
Cobitolimod is a first-in-class 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 is being evaluated in the phase III study CONCLUDE as a novel treatment of moderate to severe ulcerative colitis. Cobitolimod met the primary endpoint in the phase IIb study CONDUCT and demonstrated an outstanding combination of efficacy and safety. The results were recently published in the reputable medical journal, The Lancet Gastroenterology & Hepatology. Data from four previous completed placebo-controlled clinical trials support the efficacy and safety demonstrated in the CONDUCT study.

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 study 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 with email address certifiedadviser@redeye.se and phone number +46 8 121 576 90 is the company's Certified Adviser. For more information, please visit www.indexpharma.com.