

InDex Pharmaceuticals provides complementary information on the phase III program CONCLUDE with cobitolimod

February 14, 2023 – InDex Pharmaceuticals Holding AB (publ) is today making a presentation with CEO Jenny Sundqvist available in light of the press release issued January 27, 2023 regarding the updated timeline of the CONCLUDE program.

The presentation highlights the phase III study design, the cobitolimod dose selection, provides clarification and transparency of site and patient recruitment, reviews actions taken to facilitate patient recruitment and finally touches upon study economics. The presentation was organised by Redeye AB and the recording can be found on InDex's web site, <https://www.indexpharma.com/en/presentations/>.

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About Induction Study 1 of the CONCLUDE program

Induction Study 1 of the phase III program CONCLUDE is a global randomised, double-blind, placebo-controlled, clinical phase III study to evaluate cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis with an inadequate response or failure to tolerate conventional therapy, biological therapy or JAK inhibitors. The study has been designed in consultation with both the US and European regulatory authorities, the FDA and EMA respectively. The induction study will include approximately 440 patients, and the primary endpoint will be clinical remission at week 6, which is the same primary endpoint as used in the successful phase IIb study CONDUCT. Apart from the dosing 250 mg given at baseline and week 3, which was the highest dose and the one that showed the best efficacy in the phase IIb study, the phase III study also evaluates a higher dose, 500 mg, in an adaptive study design. Patients responding to cobitolimod in the induction study will be eligible to continue in a one-year maintenance study, where they will be treated with either cobitolimod or placebo once every three weeks.

Publication

The information was submitted for publication through the agency of the contact person set out above at 12.20 CET on February 14, 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.