# InDex Pharmaceuticals announces that all patients needed for the cobitolimod dose selection milestone have completed Induction Study 1 of the phase III program CONCLUDE

**October 11, 2023 – InDex Pharmaceuticals Holding AB (publ) today announced that 30% of patients have completed the final visit in Induction Study 1 of the phase III program CONCLUDE, which is evaluating cobitolimod as a novel treatment for patients with moderate to severe, left-sided ulcerative colitis. The outcome of the cobitolimod dose selection analysis will be presented in Q4 this year according to plan.**

"We are pleased to announce that the final patient visit needed for the dose selection analysis has occurred. We have seen great progress in the study and an accelerated patient recruitment rate since January this year. We are very grateful to the patients, investigators and study personnel for their time and commitment. We will present the outcome of the dose selection analysis in Q4 this year, as previously communicated," said Jenny Sundqvist, CEO of InDex Pharmaceuticals.

**Phase III program**
Induction Study 1 will include approximately 440 patients and is conducted at several hundred clinics in 30 countries in Europe, the Americas and the Asia-Pacific region.

The CONCLUDE program consists of two sequential induction studies which both feed into a maintenance study with patients who have responded to induction therapy. Each patient remains in the maintenance study for approximately one year.

**Dose selection analysis**
With 30% of patients having completed Induction Study 1, data cleaning, review and analysis will now be finalised and is estimated to take up to 2 months. An independent Data Monitoring Committee (DMC) will make two recommendations regarding the continuation of the study:

1. Whether or not the study can continue.

2. Which dose of cobitolimod (250 mg or 500 mg) to use for the remainder of the study (assuming continuation).

It is important to note that this analysis is blinded to all but the DMC. No efficacy or safety data will be available to InDex, patients, investigators or study personnel. Patient recruitment into Induction Study 1 continues throughout this analysis.

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**Publication**
The information was submitted for publication through the agency of the contact person set out above at 08.35 CET on October 11, 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.*

**About the CONCLUDE Program**
The phase III program CONCLUDE is evaluating cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis, and consists of two sequential induction studies which both feed into a maintenance study, in which patients who have responded to cobitolimod as induction therapy, receive maintenance treatment with cobitolimod or placebo for approximately one year. Induction Study 1 will include approximately 440 patients and is evaluating two doses, 250 mg and 500 mg, given at baseline and week 3, in an adaptive study design. With 30% of the patients having completed Induction Study 1 with eligible data for the primary endpoint at week 6, an analysis will now be performed to select the best dose of 250 mg and 500 mg cobitolimod. The analysis will be conducted by a DMC (Data Monitoring Committe) consisting of experts in the field, who will, based on pre-specified criteria, recommend which dose to continue with. In addition, the DMC will review the data for safety and futility. To maintain the integrity of the phase III program, the analysis will be completely blinded to InDex, patients and investigators. InDex will only receive information on which dose out of 250 mg and 500 mg cobitolimod that the DMC has recommended and whether the phase III program can proceed. Following the dose selection, new patients entering the study will be treated with the selected dose of cobitolimod or placebo. Upon a positive read-out of Induction Study 1, InDex plans to initiate Induction Study 2.

**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 left-sided 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 developed for 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.

*Information in this press release is intended for investors.*