InDex Pharmaceuticals updates the timeline of the phase III study CONCLUDE with cobitolimod

January 27, 2023 – InDex Pharmaceuticals Holding AB (publ) today announced an update in the timing of the dose selection in the ongoing phase III study CONCLUDE with the drug candidate cobitolimod. The outcome of the dose selection is expected to be available Q4 2023. At that point in time InDex will have finalised the assessments of consequences on the overall development timeline including topline results in CONCLUDE.

"Patient recruitment for the global phase III study CONCLUDE is under way. However, as previously communicated, lingering post-pandemic effects, Russia's invasion of Ukraine resulting in the need to find additional participating sites, as well as an increased competitive environment for clinical studies has resulted in a slower start up and lower patient recruitment rate than expected. We can now confirm that this unfortunately will result in a delay to the study timeline," said Jenny Sundqvist, CEO of InDex Pharmaceuticals. "We are working hard together with our CRO to continuously assess what actions are required and implement measures to increase the patient recruitment rate going forward. We expect to present the outcome from the cobitolimod dose selection Q4 2023, after which we should have enough information to be able to present a new overall development timeline."

The CONCLUDE study is a phase III study evaluating the first-in-class TLR9 agonist cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis. The study will include approximately 440 patients and is conducted at several hundred clinics in over 30 countries in Europe, the Americas and the Asia-Pacific region. When 30% of the patients in the study have been randomised, a dose selection will be performed in a blinded fashion to choose the best dose of either 250 or 500 mg cobitolimod. Following the blinded dose selection, new patients entering the study will be treated with the selected dose of cobitolimod or placebo.

InDex ended 2022 with a strong cash position of SEK 345m. The company forecasts that additional capital may be needed before study completion and will come back on this once the overall development timeline is confirmed.

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About the CONCLUDE study
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
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 13.35 CET on January 27, 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 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 is the company's Certified Adviser. For more information, please visit www.indexpharma.com.