InDex Pharmaceuticals discontinues the development of cobitolimod

26 February, 2024 – InDex Pharmaceuticals Holding AB (publ) ("InDex Pharmaceuticals") today announced that the company will discontinue development of their drug candidate cobitolimod. Thorough analysis of the data from Induction Study 1 of the phase III program CONCLUDE has not provided any results justifying continued development.

Induction Study 1 of the phase III program CONCLUDE, evaluating cobitolimod as a new treatment for moderate to severe left-sided ulcerative colitis, was discontinued on November 21, 2023 based on the advice from an independent Data Monitoring Committee (DMC). The DMC had performed a pre-specified and independent analysis including 130 patients who had completed the 6-week induction study. A futility assessment showed that cobitolimod was unlikely to meet the primary endpoint upon completion of Induction Study 1.

A thorough analysis of the data, including relevant subgroup analyses, has now been completed and the results do not support continued development of cobitolimod.

The primary endpoint, clinical remission* at week 6 was achieved by 4.9% (2 out of 41) of the patients in the 250 mg cobitolimod group and by 6.8% (3 out of 44) of the patients in the 500 mg cobitolimod group, compared to 6.7% (3 out of 45) of the patients in the placebo group. The lack of efficacy in cobitolimod treated patients was confirmed by the outcome in secondary endpoints and subgroup analysis. Cobitolimod was well tolerated at both dose levels and no differences in the safety profile were observed compared to placebo.

"We are very disappointed that we cannot detect a treatment benefit of cobitolimod compared to placebo, and that we have not been able to find an explanation for the lack of efficacy compared to previous studies. I again would like to express my sincere gratitude to all the patients, investigators and study personnel, as well as InDex team members for their engagement, support and hard work," said Jenny Sundqvist, CEO of InDex Pharmaceuticals.

The closure of the phase III program is progressing according to plan and is expected to be completed before summer 2024.

**Clinical remission was defined as Mayo subscore for blood in stool =0, Mayo subscore for stool frequency ≤1 and endoscopic Mayo subscore ≤1.*

Investor update
The company will hold an investor update on 28 February at 09:00. The investor update will be hosted by CEO Jenny Sundqvist, CFO and deputy CEO Johan Giléus and CDO Eva Arlander. A short presentation, which will be held in English, will be followed by a Q&A session open to all viewers via the chat function. If you wish to attend the call, please log in at: https://www.redeye.se/events/975481/investor-update-index-pharmaceuticals-2

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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 17.10 CET on February 26, 2024.

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. Information in this press release is intended for investors.

InDex Pharmaceuticals in brief
InDex Pharmaceuticals has a vision to help patients with immunological diseases where there is a high unmet medical need. Cobitolimod was being evaluated in the phase III program CONCLUDE for moderate to severe left-sided ulcerative colitis – a debilitating, chronic inflammation of the large intestine.

InDex Pharmaceuticals 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.