InDex Pharmaceuticals discontinues cobitolimod phase III program

- **Independent Data Monitoring Committee (DMC) advises that cobitolimod is unlikely to meet the primary endpoint upon completion of Induction Study 1**
- **More information regarding next steps will be provided once a thorough analysis of the data from Induction Study 1 has been completed**

21 November, 2023 – InDex Pharmaceuticals Holding AB (publ) ("InDex Pharmaceuticals") today announces that an independent DMC has completed the planned dose selection analysis including safety review and assessment for futility in Induction Study 1 of the phase III program CONCLUDE. The DMC advises that cobitolimod is unlikely to meet the primary endpoint upon completion of Induction Study 1. The advice to stop the study was not based on safety concerns.

"This surprising and disappointing news confirms the complexity of the disease and the need for further research within this field, especially as moderate to severe ulcerative colitis is an indication with high unmet medical need for new treatment options. We are incredibly grateful to all the patients, investigators and study personnel for their engagement to date," said Jenny Sundqvist, CEO of InDex Pharmaceuticals. "We will conduct a comprehensive analysis of all the study data before announcing next steps."

The pre-specified and independent analysis included the first 133 patients (i.e., approximately 30% of the total 440 patient enrollment in Induction Study 1) who had completed the 6-week induction study. As part of the analysis, the DMC performed a safety review and a futility assessment based on the primary endpoint clinical remission at week 6. A futility assessment is performed to stop a trial if the chance to reach a significant primary endpoint at the end of a study is too low.

Investor call
The company will hold an investor call on 22 November at 15:00. If you wish to attend the call, please log in at: https://boxcast.tv/view/index-pharmaceuticals-prr5gaqpcydqusxe83kc

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Publication
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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. The company is focusing on the drug candidate cobitolimod, a first in class mode-of-action, with the aim to offer an effective and safe treatment option. Cobitolimod is currently 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.