

InDex Pharmaceuticals intends to carry out a fully guaranteed rights issue of approximately SEK 500 million to fund phase III development of cobitolimod

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November 25, 2020 - InDex Pharmaceuticals Holding AB (publ) (“InDex” or the “Company”) (Nasdaq First North Growth Market: INDEX) intends to carry out a fully guaranteed rights issue of approximately SEK 500 million with preferential rights for the Company’s existing shareholders (the “Rights Issue”). The Company’s Board of Directors intends to propose that an extraordinary general meeting to be held in January 2021 (the “EGM”) would authorize the Board of Directors to resolve on the Rights Issue and the terms thereof. The net proceeds from the contemplated Rights Issue are mainly intended to be used to fund the important initial induction study in a sequential phase III program in moderate to severe left-sided ulcerative colitis for the Company’s lead drug candidate, cobitolimod. A notice to the EGM will be announced through a separate press release at a later date.

Summary

- The Board of Directors intends to carry out the Rights Issue, based on an authorization to be granted at an EGM, due to be scheduled to be held in January 2021. The notice to the EGM will be made through a separate press release at a later date.
- Large existing shareholders Linc AB, Fourth AP Fund and SEB-Stiftelsen have expressed their support for the Rights Issue and have expressed their interest to participate in the transaction. The intention is to have the Rights Issue fully covered by a combination of subscription undertakings from existing shareholders as well as guarantee commitments from an external underwriting consortium at the time of the launch of the Rights Issue. Both Barclays Bank Ireland PLC and Carnegie Investment Bank AB have indicated their interest to underwrite part of the Rights Issue.
- The Rights Issue will also be subject to the EGM resolving on certain amendments of the articles of association of the Company in respect of limits regarding share capital and number of shares that can be issued.
- Given the Rights Issue is carried out, the net proceeds therefrom are intended to be used to i) fund the important initial induction study in a sequential phase III program in moderate to severe left-sided ulcerative colitis for the Company’s lead drug candidate, cobitolimod, including drug manufacturing and ii) general corporate purposes and financial flexibility.

InDex’s CEO Peter Zerhouni comments: “We have now laid out our plan for the phase III program with cobitolimod, which will form the basis for market approval. With its outstanding combination of efficacy and safety as well as the novel and unique mechanism of action, cobitolimod is positioned to become an essential part of the future treatment of ulcerative colitis, as many patients do not respond to or suffer severe side effects from current treatments.”

Background and intention

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 in late stage clinical development for the treatment of moderate to severe ulcerative colitis.

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. Today approximately 2 million people in Europe and the US suffer from ulcerative colitis, with a significant

negative impact on quality of life. The symptoms are characterized by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. Moreover, patients have a significantly elevated risk of developing colon cancer. Despite the currently available drugs, many patients with ulcerative colitis still suffer from severe symptoms.

The Company's lead drug candidate, cobitolimod, is a first-in-class Toll-like receptor 9 (TLR9) agonist, that can provide an anti-inflammatory effect locally in the large intestine, which may induce mucosal healing and relief of the clinical symptoms in ulcerative colitis. Cobitolimod is administered rectally using an enema. To induce remission, cobitolimod is given as two applications over a three-week period and is planned to be given every three weeks as maintenance therapy, in order to reduce the risk of future flare-ups.

Cobitolimod met the primary endpoint in the phase IIb study CONDUCT with an outstanding combination of efficacy and safety. CONDUCT was a randomized, double blind, placebo-controlled, exploratory study where different doses of cobitolimod were evaluated in patients with left-sided moderate to severe active ulcerative colitis not responding to conventional treatment. The study objective was to identify the most efficacious dose and dose regimen for further development. The 213 patients were divided into four treatment arms that received different doses of cobitolimod and one arm receiving placebo. The primary endpoint of the study was induction of clinical remission at week 6. The highest dose, 250 mg given twice, was the most effective with a remission rate of 21.4 percent and a delta to placebo of 14.6 percent ($p=0.0247$, predefined one-sided test where the significance limit was set to <0.10). Cobitolimod was well tolerated at all dose levels and no differences in the safety profile were observed compared to placebo. The results were recently published in the high-impact medical journal *The Lancet Gastroenterology and Hepatology*.

After meeting the primary endpoint in CONDUCT, dialogues were initiated with the FDA and EMA respectively, for the further development of cobitolimod. Both authorities endorse the advancement of cobitolimod into phase III studies in patients with moderate to severe left-sided ulcerative colitis. Based on the regulatory feedback, the Company plans a sequential phase III program with two induction studies and a maintenance study with patients that have responded to cobitolimod as induction therapy. The first induction study, to be financed by the contemplated Rights Issue, is planned to entail approximately 400 patients. In addition to the 250 mg dose it is planned to also evaluate a higher dose, 500 mg, in an adaptive study design. The Company estimates the study will take 18 to 24 months to complete from initiation. Upon a positive read-out of the first study, InDex plans to initiate the second induction study.

InDex's key focus is to start the phase III program on the back of the positive results in the CONDUCT study, the successful regulatory interactions and the supportive findings in market research commissioned by InDex underbuilding the Company's belief in the market potential of the drug candidate. With cobitolimod's novel and unique mechanism of action, competitive efficacy and favourable safety profile, InDex believes that the drug candidate has blockbuster potential.

In order to conduct the first induction study, InDex intends to carry out the Rights Issue and ensure continued successful development in accordance with the Company's business plan and strategy. The Board of Directors assesses the working capital requirement for the intended clinical study to be met by available cash and the net proceeds from the contemplated Rights Issue. The Rights Issue aims at raising approximately SEK 500 million before deduction of transaction costs. The intention of the Rights Issue is primarily to i) fund the important initial induction study in a sequential phase III program for the Company's lead drug candidate, cobitolimod, including drug manufacturing and ii) general corporate purposes and financial flexibility.

Subscription undertakings and guarantee commitments

Large existing shareholders Linc AB, Fourth AP Fund and SEB-Stiftelsen have expressed their support for the Rights Issue and have expressed their interest to participate in the transaction. The intention is to have the Rights Issue fully covered by a combination of subscription undertakings from existing shareholders as well as guarantee commitments from an external underwriting consortium at the time of the launch of the Rights Issue. Both Barclays Bank Ireland PLC and Carnegie Investment Bank AB have indicated their interest to underwrite part of the Rights Issue.

EGM and expected timetable for the Rights Issue

The Board of Directors intends to convene an EGM through a separate press release and the EGM is intended to be scheduled to take place in January 2021. The Board of Directors will also propose that the EGM resolves on certain amendments of the articles of association of the Company in respect of limits regarding share capital and number of shares that can be issued. A more detailed timetable and the terms of the Rights Issue will be announced if the Board of Directors resolves on the Rights Issue.

Advisers

In connection with the intended Rights Issue InDex has appointed Barclays Bank Ireland PLC and Carnegie Investment Bank AB (publ) as Joint Global Coordinators. Setterwalls Advokatbyrå acts as legal adviser to the Company and Baker McKenzie acts as legal adviser to Barclays Bank Ireland PLC and Carnegie Investment Bank AB (publ).

Conference call for investors, analysts and media

A conference call on the company's interim report for Q3 2020 and description of the phase III program for cobitolimod and the financing of the important initial induction study will be held with CEO Peter Zerhouni on Wednesday November 25, 2020 at 11:00 (CET). During the conference call, which will be held in English, it will be possible to ask questions to the company. Questions can also be sent in by e-mail to info@indexpharma.com.

The conference call can be followed at <https://tv.streamfabriken.com/index-pharmaceuticals>

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This information disclosed by InDex Pharmaceuticals Holding AB (publ) constitutes inside information as defined in the EU Market Abuse Regulation 596/2014. The information was submitted for publication, through the agency of the contact person above, on November 25, 2020 at 07:45 (CET).

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 in late stage clinical development for the 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 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. Redeye AB with email address certifiedadviser@redeye.se and phone number +46 8 121 576 90 is the Company's Certified Adviser. For more information, please visit www.indexpharma.com.

Important information

This announcement is not an offer to sell or a solicitation of any offer to buy any securities issued by InDex Pharmaceuticals Holding AB (the "**Company**") in any jurisdiction where such offer or sale would be unlawful.

Any investment decision in connection with the potential Rights Issue or as a consequence of this press releases must be made on the basis of all publicly available information relating to the Company

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Any offering of the securities referred to in this announcement will be made by means of a prospectus. This announcement is not a prospectus for the purposes of Regulation (EU) 2017/1129 (together with any applicable implementing measures in any Member State, the "**Prospectus Regulation**"). Investors should not invest in any securities referred to in this announcement except on the basis of information contained in the aforementioned prospectus.

In any EEA Member State other than Sweden (each, a "**Relevant Member State**" (including, for the avoidance of doubt, the United Kingdom during the Brexit transition period)), this communication is only addressed to and is only directed at qualified investors in that Relevant Member State within the meaning of article 2(e) of the Prospectus Regulation, that is, only to investors who can receive the offer without an approved prospectus in such Relevant Member State.

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Forward-looking statements

Matters discussed in this announcement may constitute forward-looking statements. Forward-looking statements are statements that are not historical facts and may be identified by words such as "believe", "expect", "anticipate", "intends", "estimate", "will", "may", "continue", "should" and similar expressions. The forward-looking statements in this release are based upon various assumptions, many of which are based, in turn, upon further assumptions. Although the Company believes that these assumptions were reasonable when made, these assumptions are inherently subject to significant known and unknown risks, uncertainties, contingencies and other important factors which are difficult or impossible to predict and are beyond its control. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this release by such forward-looking statements. The information, opinions and forward-looking statements contained in this announcement speak only as at its date, and are subject to change without notice. The Company does not undertake any obligation to review, update, confirm or to release publicly any revisions to any forward-looking statements to reflect events that occur or circumstances that arise in relation to the content of this press release, unless it is not required by law or Nasdaq First North Growth Market's rule book for issuers.