November 24, 2021

InDex Pharmaceuticals Holding AB (publ) interim report January – September 2021

Ready to initiate patient recruitment in phase III study CONCLUDE

"We have now several clinics activated in the phase III study CONCLUDE and look forward to enrol the first patient in the near term", says Peter Zerhouni, CEO of InDex Pharmaceuticals. "It was quite dramatic in September when the FDA updated their safety warnings for JAK inhibitors as a class. It is a reminder that a product's safety profile is very important."

Period July – September 2021
- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –28.2 (–7.7) million
- Result after tax amounted to SEK –28.2 (–7.7) million, corresponding to SEK –0.05 per share (–0.03) before and after dilution
- Cash flow from operating activities amounted to SEK –26.5 (–8.3) million

Period January – September 2021
- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –80.2 (–47.3) million
- Result after tax amounted to SEK –80.2 (–47.3) million, corresponding to SEK –0.16 per share (–0.20) before and after dilution
- Cash flow from operating activities amounted to SEK –80.1 (–63.1) million
- Cash and cash equivalents at the end of the period amounted to SEK 463.1 (62.3) million
- Number of employees at the end of the period was 8 (7)
- Number of shares at the end of the period was 532,687,650

All comparative amounts in brackets refer to the outcome during the corresponding period 2020.

Significant events during the quarter
- InDex received first regulatory approval from the Swedish MPA to start the phase III study CONCLUDE with cobitolimod
- InDex received FDA clearance to start the phase III study CONCLUDE

Significant events after the quarter
- InDex got new patent for cobitolimod granted in the US
- InDex got new patent for cobitolimod granted in Canada

Other events
- InDex announced that the company will conduct a clinical pharmacokinetic study (PK study) with cobitolimod in Sweden
- InDex announced that two new employees have been appointed in the clinical development organisation in preparation of the start of the phase III study CONCLUDE with cobitolimod

CEO statement
We have now several clinics activated in the phase III study CONCLUDE and look forward to enrol the first patient in the near term. We are pushing hard to get more and more clinics ready to enrol patients as we receive regulatory approval to start the study in the respective countries. We have already approval in the US, Sweden, Hungary, and France, and expect approval in several more countries in the coming weeks.

CONCLUDE is a global clinical study, which will include 440 participants to evaluate cobitolimod as a new treatment for patients with moderate to severe left-sided ulcerative colitis. The study will be conducted at several hundred clinics in over 30 countries.

The pandemic continues to affect the start-up of new clinical studies in that the clinics report resource constraints and a need to prioritize their regular care and to manage the backlog. Once our study is up and running, we expect to reach the planned patient recruitment rate.

There continues to be a lot of news coming out of the field of ulcerative colitis. It was quite dramatic in September when the FDA updated their safety warnings for JAK inhibitors as a class. The FDA added serious heart-related events, cancer, blood clots, and death to the already boxed warnings of JAK inhibitors. They also limited all approved uses to patients who have failed TNF blockers. FDA's decision firmly positions the JAK inhibitors as a last line treatment in ulcerative colitis. It is a reminder that a product's safety profile is very important, and good news for cobitolimod that has demonstrated an excellent safety profile to date. Overall, the competitive landscape has clearly evolved in cobitolimod's favour over the last 18 months.

We recently got a new patent for cobitolimod granted in the US, which is the most important pharmaceutical market in the world. This new patent provides protection for the 250 mg dose, which was successful in the phase IIb study CONDUCT and is now included in phase III. The patent will provide an exclusivity period until May 2038, with the possibility of up to 5 years term extension after market approval. It is a good example of our IP strategy to build a thicket of patents around cobitolimod. We continue to file new patent applications in the light of advances in the formulation and clinical development of cobitolimod, to provide exclusivity beyond the term of InDex's already granted patents.

I am excited that we are close to enrol the first patient in the phase III study and I hope you will tune in to our upcoming investor presentations at HC Andersen Capital today and Erik Penser Bank tomorrow.

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The full report is attached as a PDF and is available on the company's website https://www.indexpharma.com/en/financial-reports/

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 8:00 CET on November 24, 2021.

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 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 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.