# InDex Pharmaceuticals advances cobitolimod further towards phase III following successful interactions with FDA and EMA

**April 16, 2020 – InDex Pharmaceuticals Holding AB (publ) today announced that the company has received positive responses from FDA and EMA regarding phase III development of the company's TLR9 agonist cobitolimod, for the treatment of moderate to severe ulcerative colitis. The company is continuing its phase III preparations, including efforts to secure financing.**

Following the phase IIb study CONDUCT meeting its primary endpoint in August 2019, dialogues were initiated with FDA and EMA respectively, for the further development of cobitolimod. These processes have now been completed and both authorities endorse the advancement of cobitolimod into phase III studies in patients with moderate to severe left-sided ulcerative colitis. This regulatory feedback gives flexibility for different designs of the phase III program, for example, to conduct studies sequentially and potentially to include a higher dose in addition to the highest dose regimen tested in the phase IIb study (2x250 mg). The company continues to evaluate the most advantageous study design based on, among other things, development risk, commercial potential, time to market and cost.

”The positive responses from the regulators is an important external validation of our study results and cobitolimod’s potential. These constructive dialogues demonstrate a common desire to see new treatment options that can help more patients with ulcerative colitis return to a normal life, which also would save considerable resources for society as a whole,” said Peter Zerhouni, CEO of InDex Pharmaceuticals.

The covid-19 pandemic affects the healthcare systems and the investor sentiment globally and must be taken into account in the company’s strategic planning. However, InDex is well capitalized and given the current level of activity and financial commitments, cash and cash equivalents, which at March 31 amounted to just over SEK 100 million, are sufficient to finance the business for at least 12 months.

”The turmoil in our world as a result of covid-19 means that we need to consider additional parameters in our planning. So far, our phase III preparations are proceeding according to plan and we are taking appropriate actions to use our resources wisely under the present circumstances. Before we can start phase III, the healthcare situation must have normalised, and the necessary funding be secured. In addition to assessing the conditions for InDex conducting the phase III program, we continue to engage with potential partners, presenting the positive CONDUCT results and development activities,” concluded Peter Zerhouni.

**Teleconference for investors, analysts and the media**
The company invites to a teleconference where CEO Peter Zerhouni will give an update on the phase III preparations. The teleconference will be held on Monday, April 20, 2020, at 11:00 (CET). During the teleconference, which will be held in Swedish, there will be the opportunity to ask questions.

The teleconference can be followed via https://tv.streamfabriken.com/2020-04-20-index-pharmaceuticals-presskonferens

Participant dial-in: +46 8 56642693

**For more information:**
Peter Zerhouni, CEO
Phone: +46 8 508 847 35
E-mail: peter.zerhouni@indexpharma.com

**About 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. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, abdominal 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. Biological drugs represent the largest market segment in ulcerative colitis in terms of value with annual sales estimated to more than USD 5 billion. The total pharmaceutical market for ulcerative colitis is expected to grow to about USD 8 billion in 2023.

**Cobitolimod in brief**
Cobitolimod is a 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. In 2019 cobitolimod met the primary endpoint of clinical remission in the phase IIb study CONDUCT and demonstrated an outstanding combination of efficacy and safety. InDex has already in previous clinical trials shown that cobitolimod has a very favorable safety profile and has statistically significant effects on those endpoints that are most relevant in this disease, such as blood in stool, number of stools, and mucosal healing. Given the outstanding combination of efficacy and safety, InDex is now advancing cobitolimod towards phase III.

**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 Stockholm. Redeye AB with e-mail 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

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