Peter Zerhouni – CEO, InDex Pharmaceuticals, Sweden



There is a five-billion-dollar market for biological drugs in ulcerative colitis that in fact has a lot of room for growth

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InDex Pharmaceuticals is a Swedish biopharma company developing drugs that could help patients suffering from ulcerative colitis, an inflammatory bowel disease. CEO Peter Zerhouni gives an overview of the company's journey, including the recent phase IIb results of their lead asset, cobitolimod, and the future strategy to bring the product through full development and commercialization.

Could you introduce InDex Pharma to our international audience?

InDex is a small drug development company that focuses on immunological diseases with unmet medical need. Our lead asset is called cobitolimod and is under development for moderate to severe ulcerative colitis, an inflammatory bowel disease. We recently met the primary endpoint in a phase IIb clinical trial with cobitolimod showing an outstanding combination of efficacy and safety. The study was conducted across 12 countries in Europe, including 213 patients at 91 clinics. We are very satisfied with the outcome, demonstrating a clinically relevant effect and confirming the excellent safety profile of cobitolimod observed in previous clinical studies. We will now advance cobitolimod towards phase III and evaluate the best route to commercialization. The current organizational model of the company is having project managers employed in key functions and a network of fixed consultants; with typical outsourcing of clinical research and manufacturing services.

You were appointed as CEO in 2015. Tell us a bit about your role in taking the company to the next level, what are your priorities?

I came in at a point where there had been a clinical study conducted with cobitolimod in ulcerative colitis. Even though we had not met the primary endpoint, we observed promising signals in that study and the question was where the company should be heading next. Around that same time, our then partner Almirall decided to focus on their dermatology assets, divesting their respiratory assets and exiting from the gastrointestinal field, thus returning the full rights of cobitolimod to InDex. My priority was to really set the new direction of the company and a new positioning and development plan for cobitolimod.

We decided on a modified positioning of the asset, while still within ulcerative colitis targeting a different patient population. The phase IIb study that we just completed, was then designed with input from the regulatory authorities in the US and EU. To fund the phase IIb study, InDex went public on the Nasdaq First North Stockholm in October of 2016 and raised USD 25 million. A significant portion was raised from retail investors and we gained 5,000 new shareholders. The first patient was enrolled in June 2017 and in August 2019 we could announce the positive outcome of the phase IIb study.

Could you explain what is the unmet medical need you are trying to cover?

Ulcerative colitis is a chronic inflammation of the colon, which has a severe negative impact on the quality of life of patients. Typical symptoms involve frequent and sudden blood and mucus mixed diarrhoea. Hence, a portion of patients become trapped in their homes, as they need to be close to the toilet at all times. Even though it is not a lethal disease, it is a very stigmatizing illness with a high patient burden.

Cobitolimod is under development as a new therapy for moderate to severe ulcerative colitis patients, that are not responding to conventional therapy. The currently marketed drugs only help a subset of the patients and are associated with significant side effects, so a big segment lack treatment options with a satisfactory combination of efficacy and safety. Current drugs include biological therapies such as TNF inhibitors, like Remicade and Humira, two of the best-selling drugs in the world. These are tough drugs, which suppress your immune system and increase the risk of severe infections for example.

There is a five-billion-dollar market for biological drugs in ulcerative colitis that in fact has a lot of room for growth. The unmet medical need, combined with the commercial opportunity, has attracted a lot of interest from industry to develop new drugs. With cobitolimod, InDex has a first-in-class compound, which has shown an outstanding combination of efficacy and safety. Cobitolimod is a Toll-like receptor 9 (TLR9) agonist, that can provide an anti-inflammatory effect locally in the colon and relief of the clinical symptoms in ulcerative colitis. Our approach is novel and unique, and we are the furthest advanced TLR9 agonist within inflammatory bowel disease and ulcerative colitis.

You said the other drugs on the market are associated with side effects, so can you summarize the safety profile of cobitolimod?

In the recent phase IIb study there were no differences in the side-effect profile between cobitolimod and placebo. In fact, there have not been any negative safety signals with cobitolimod in any of our clinical studies. We think that this is to a large extent due to the way the drug is administered. It is delivered rectally by an enema solution, directly to the inflamed colon, which means you minimize off-target effects. One of the issues with TNF inhibitors, for example, is that the drug reaches throughout your body, although you only need it in the colon, so you get negative effects in other organ systems.

What are your priorities moving forward?

Our main priority is to advance cobitolimod towards phase III with the plan to be able to include the first patient during the second half of 2020. Key activities include regulatory interaction with FDA and EMA, protocol development, market research, manufacturing of study drug, CRO set-up etc. InDex secured the financing for these phase III preparatory activities through a directed share issue to Swedish and international investors of USD 14 million in September 2019. We are evaluating the best route to commercialization and will continue our business development activities with potential licensing partners for key regions.

What should be the top priority for the government, and also the industry, to attract more foreign investment in life sciences in Sweden?

More capital is certainly needed. I think Swedish Biotech needs to market ourselves better internationally, to US financial investors in particular. Everyone will agree that Swedish company valuations are much lower than in the US, but they still prefer to invest in US assets. Maybe with some trailblazing Swedish success stories we can get their attention. One observation has to do with size; a 100-million-dollar company is a micro-cap in the US, but in Sweden, there aren't many of that size yet. We see some US investors in the more sizeable listed Swedish biotech companies like Oncopeptides and Hansa Biopharma.

Swedish companies have been going public at an earlier stage of development, which they wouldn't do in the US, and that has to do with the Swedish retail investors that fund a big part of the smaller biotech companies here. It's a unique feature of the Swedish biotech ecosystem that a company can go public early on and attract funding from retail investors; the downside is that the retail market might not be deep enough to support subsequent stages of development which require more significant amounts of capital. Also, these investors are not professionals, so it's hard for them to determine the quality of the companies. It is sometimes more about marketing than actual drug development.

The next level of investors is the Swedish institutional investors, like the AP funds (Swedish National Pension Funds), which can take companies further. However, to source sufficient capital to realize the full potential and build really large companies of the many small ones we have today will require international institutional investors.

You have both a finance and science background, how has this experience helped you to lead InDex Pharma?

I think it's a very good combination. I used to work in banking and have a master's degree in biology. Being able to cover both sides has been very helpful, I understand the science behind our business, but I also understand investors and the financial system.

Where do you hope to see InDex Pharmaceuticals in the next five years?

With an outstanding combination of efficacy and safety, cobitolimod is set to take a leading position within the field of inflammatory bowel disease. I can see InDex growing into a bigger company than today going forward, and this would also allow us to do more with our other assets. Cobitolimod comes from a platform technology, it's a DNA-based Immunomodulatory sequence

(DIMS), that can be used to modulate the immune system in all sorts of diseases. The example of cobitolimod validates the rest of the platform. We could be part of the final development and eventual commercialization of cobitolimod, while we develop additional compounds in other therapeutic areas in parallel, that would be very exciting.

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