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Dr. Chris Lu, CEO and cofounder of Laekna Therapeutics, shares Laeknaâ??s ambition to deliver cures and improve the quality of life of patients globally, captured by the word â??Laeknaâ??, which is Old Norse for â??to cure, to healâ??. He also outlines Laeknaâ??s focus on disease biology, specifically the areas of oncology and hepatology, as well as their comprehensive portfolio strategy, bolstered by their strategic partnership with Novartis, which includes three promising in-licensed compounds.

Chris, could you please introduce Laekna Therapeutics to our international audience â?? starting with the origin of the rather unique name, Laekna?

The word â??Laeknaâ?? is actually Old Norse, meaning â??to cure, to healâ??. It is a language currently used in Iceland as well as parts of Norway. The word â??Laeknaâ?? really represents our long-term mission: to treat, to cure and to eventually eradicate disease.

This sets a pretty high bar but of course, as a new biotech, our initial focus is still on treating disease to help patients. Looking at the recent American Society for Clinical Oncology (ASCO) conference, we can see that extending progression-free survival (PFS) by six months would still be a rather incredible feat.

When we established Laekna Therapeutics, we decided to set up our company more towards international standards, focusing on innovative drug discovery and development to meet high unmet medical needs globally. We focus on disease biology rather than a particular technology platform, and built a product pipeline highly competitive globally through in-licensing approach and developing our internal discovery capabilities. Based on our teamâ??s expertise, we have decided to focus on oncology and hepatology.

Laekna has in-licensed three very promising compounds from Novartis. Could you outline your strategy behind these three assets?

Given our focus on disease biology, we started to build a business model of balanced product portfolio with near term success opportunities and long-term sustainability. The purpose of in-licensing is to quickly assemble a pipeline with more mature drug candidates, i.e. at clinical stage. In the meantime, we develop our internal innovative capabilities to generate projects for the longer-term success.

In the near-term, we wanted to have assets close to or in the clinic. We chose to focus on oncology because it is quite a mature area, particularly in terms of clinical development and regulatory processes. For instance, the U.S. FDA offers many incentives for oncology drug development, such as fast track, priority review and Breakthrough Therapy Designation. Therefore, it is relatively easier to design the clinical path for oncology assets.

When it comes to Novartis, we have more confidence in their quality of assets because we are familiar with their drug discovery and development process and rigorous governess. through our previous tenure at Novartis. For the three assets we acquired, I have either direct or indirect experience working on them. Novartis did not give them up because of a lack of Proof-of-Concept (POC) but rather their changes of internal business strategy. Novartis is a world-leading pharmaceutical company. In my observation, both as an insider and outsider, they are always trying to lead the pharmaceutical innovation and setting up higher standards for themselves and industry, such as curing cancer, paying by outcome, etc.

How do you plan to maximize the potential of these three assets?

We are an innovative R&D biotech company, which is well demonstrated in our practice. In oncology, we are working on drug-like candidates with proven targeting mechanisms and potential to meet high unmet medical needs. We demonstrate innovation more through our clinical development strategy. Cancer drug development relies heavily on understanding target biology and linking target biology to disease causative mechanisms in order to identify a drug candidate that can really engage relevant cancer indications. That offers a much higher chance of success.

Looking at the first molecule, LAE001, an oral androgen inhibitor, we believe that this might have best-in-class potential. When it comes to cancer, late-stage patients care more about efficacy, but earlier-stage patients care both about efficacy and safety. We are developing this compound for earlier-stage prostate cancer because we believe that this asset has a great safety profile and efficacy. Novartis has previously completed a Phase I study in the U.S. but as we have changed the targeted patient population and dosage regimen, we decided to run another Phase I trial in order to demonstrate its unique strength.

In mid-2018, we in-licensed two oral pan-Akt kinase inhibitors from Novartis. These compounds have been highly validated in the clinical setting and involved in more than 20 clinical trials, with some showing promising results, including a strong anti-tumor efficacy and good safety profile. We have identified an ovarian cancer indication with high unmet medical needs based on a promising PhIb study result. We will run a PhII registration trial in order to rapidly develop the drug to the market approval.

In addition, new data has emerged within the industry that Akt kinase inhibitors could partner with androgen inhibitors in combination therapy. Therefore, we plan to combine both assets to treat late-stage prostate cancer when patients become resistant to androgen-inhibitor therapies. Sometimes,

monotherapies for a few indications work beautifully and other times, we need to explore combination therapies. Many companies have been willing to take quite bold and creative moves in cancer combination trials. For instance, we are starting to see triple-combination trials. More is not necessarily always better but sometimes these combinations do bring more value to patients.

We have tried to add our innovation to the clinical trial strategy, in particular, to approach clinical design and development in novel ways. For instance, we have initiated three trials, and only one was built on Novartisâ?? old POC trial. The other two are new designs with new indications derived from our internal exploratory studies.

In addition to out-licensing these assets to you, Novartis also took a strategic stake in Laekna. Why were they willing to take this leap of faith?

It is hard to speak on their behalf, but I guess these might be the reasons. Firstly, Novartis truly believes in these assets, quality of drug like ability, and value to benefit patients, etc., otherwise they wouldnâ??t be bothered to make effort to out-license them. I believe Laekna has demonstrated to Novartis that we are a trustworthy partner and that we have the capability to finance and design the right clinical trials to take these assets to the market, so they choose us in return as their partner on more than one occasion. In my opinion, Novartisâ?? willingness to take equity in Laekna also demonstrates the strong vote of confidence in our capabilities, for which we are very grateful. Laekna is committed to remaining a highly professional team and we keep our promises. To date, whatever we promised, we have delivered. This attitude makes it easy for us to work with Big Pharma companies like Novartis since we share the same belief in helping patients and expectations on delivery. We are happy to have started building a long-term relationship with them.

In addition to oncology, Laekna also focuses on hepatology. How does that fit within your business strategy?

Liver disease is an area with extremely high unmet medical needs where we believe we can be really innovative. For instance, Nonalcoholic steatohepatitis (NASH) is a very significant unmet medical need globally. There have been many NASH trials, more failures than successes, so it is clearly a very difficult disease to treat. In the U.S., NASH is a main cause of liver diseases, cirrhosis and cancer, which eventually kill people. While in China, it is more of hepatitis B (HBV) and hepatitis C (HCV) infections that are causes of liver disease. However, at some point during the disease progression into liver cirrhosis and liver cancer, the phenotypes are very similar so the fundamental cause could be the same in the U.S. and China. There have been many research reports showing that it could be the same group of pathogenic cells, hepatic myofibroblasts, that drive liver diseases caused by the infections, as well as NASH. This offers a great opportunity of treating the diseases, i.e. targeting this common cause of liver cirrhosis. There are multiple ways to engage them. We have noticed that liver disease mainly occurs in elderly people. In young people, the liver has a great capability of repair itself. In sick or older people, this process is compromised gradually, so myofibroblasts failed to be cleared completely by the immune system and accumulated, which results in liver cirrhosis. We hope to find a way to clear these pathogenic cells. There are clinical studies that show that once these pathogenic cells are cleared, the liver is able to regenerate on its own, even if the patient is in a very late stage of liver disease.

We have built our own discovery programs, labs and partners to explore new therapeutics based on this approach. In the past 2.5 years, we have taken a very aggressive approach to discovery new therapeutic molecules in this area. Hopefully, we will soon be able to have an IND filing from our

internal discovery.

With the biotech boom in China these days, there is a lot of â??hot moneyâ?? pouring into this industry. How can a biotech like Laekna leverage this?

We are happy to see more and more investments in R&D areas recently. We commit ourselves to being honest to our investors and their investments. While the VC environment is still very active, many have become highly selective and the onus is on the biotech company to really demonstrate the strengths and value proposition of their business.

Unlike some other biotechs that received very quick starts with huge VC investments, we have taken a different approach. We model ourselves more like these U.S. start-ups that germinated from an idea in someoneâ??s garage! We just want to ensure that we have sufficient capital for us to develop our business ideas. Laekna was actually fortunate because our first angel investor was an individual with whom I had a long-term friendship. He trusted us to invest in us when all we had was an idea! At that point, we would have really struggled to receive VC funding. I believe in more organic growth and development. To receive too much money too quickly would put a lot of stress and pressure on our operations so we prefer to advance step-by-step.

Looking ahead, we will see how our various projects develop. We will eventually need to raise more money and while it is easier to raise from private markets, in a few more years, we will also seriously consider an IPO at a suitable time to lead the company to the next milestone development.

On a more personal side, after two years as a biotech entrepreneur, what are your reflections on the journey so far?

It has been quite a journey for me so far. Having worked in big pharma companies for many years, I started to lose myself. Big Pharma executives that spend many years in large organizations often fall into two extremes: either we believe ourselves to be exceptional but forget that we have the backing of a huge organization, or we believe ourselves to be completely insignificant because we see ourselves as only a cog in the machine.

Once I left Novartis, everything became amplified. I see my strengths but also my weaknesses very clearly. That is why building a strong team for Laekna was so important. We want to build a diverse team with complementary strengths so that together we can drive Laeknaâ??s mission. While Laekna may be a new company, the team is certainly not. Our team might be small, but each individual is worth a platoon. Together, we will work towards the future success of Laekna Therapeutics to cure diseases and improve quality of life. I am still sailing together with my crew, and I want them to be captains in the future.

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