Interview: David Main – CEO and President, Aquinox Pharmaceuticals, Canada

"Health Canada has done a good job of harmonizing the approval process based upon safety and efficacy, but there are numerous agencies, both federal and provincial, involved in pricing and reimbursement."

26.01.2018

Tags: Canada, Aquinox, Biotech, Innovation, R&D

David Main, CEO and president of Aquinox Pharmaceuticals Inc., introduces the company he founded in 2006, which now is in the late stages of development of a drug targeting the SHIP1 enzyme, with a focus on treating interstitial cystitis/bladder pain syndrome. Other applications may include blood cancers and chronic prostatitis/chronic pelvic pain syndrome. Aquinox Pharmaceuticals has the ambition to become a global biotechnology player.

How was Aquinox Pharmaceuticals founded and what have been the beginnings of the company?

In the early 2000s, four scientists at the University of British Columbia made the decisive discovery that there is an enzyme called SHIP1 that regulates immune cell function. I co-founded Aquinox Pharmaceuticals in 2006 with these scientists, as a company focused on developing new drugs addressing inflammatory diseases by targeting the SHIP1 enzyme. After the initial discovery at the University of British Columbia, the drug development activity was thus moved to Aquinox Pharmaceuticals' pipeline. In 2007 we completed a successful $14.5 million Series A financing.

From the very beginning, our outlook has been to create a global biotechnology company. We think forward, beyond the borders of our Canadian headquarters and science, so that the drugs we develop may benefit patients all around the world. Therefore, whenever we take on a new development step, we take it according to international standards. The US alone is still the largest

pharmaceutical market in the world, something we cannot ignore, and hence we make sure all of our work is satisfying FDA requirements for drug development. We have a US office in San Bruno, California, where the leadership of our regulatory, clinical development, and commercial operations are located.

The focus of Aquinox in its drug development is on inflammation and oncology. Why have you chosen those two specific areas?

[Featured_in]

SHIP1 has shown to be a key regulator of immune cell function. In inflammation, this enzyme sometimes does not play as strong a role as it should. Our drug discovery candidates thus target the SHIP1 enzyme in order to help it increase its role in fighting inflammation. Applications can thus be found in various diseases where we believe inflammation plays a role, such as interstitial cystitis/bladder pain syndrome (IC/BPS), but also in certain types of blood cancers, where activating SHIP1 may also be beneficial.

How significant are the unmet needs in bladder conditions in Canada your drugs will be addressing?

Our most important clinical development program, the rosiptor clinical development program, addresses IC/BPS, which represents a tremendous unmet medical need. In the US alone, it is estimated that 5.5 million people have IC/BPS symptoms. We estimate that Canadians are affected at a similar rate. Moreover, the disease is not extremely well understood; the theories as to what causes it and how it occurs are numerous. However, we believe that one component of the disease is a chronic inflammation that develops in the bladder, causing the bladder wall and nerves to be irritated and thus unleashing pain. The pain symptom gets more intense as the bladder fills and stretches, diminishing after urination, although some pain lingers on. Series of drugs have been tried in fighting the symptoms of IC/BPS, from drugs targeting nerve pain to opioid narcotics and various anti-inflammatories, but none have proven efficient. The pain in IC/BPS has been found to be very recalcitrant or refractory, not showing any significant response to available medicines. We saw a potential way to address the inflammatory pain by targeting the SHIP1 enzyme. Additionally, we learned in our early development efforts that rosiptor, after oral administration, is cleared from the blood through the kidneys and then enters the urine thereby increasing its exposure in the bladder.

[related_story]

Are you planning to venture into new therapeutic areas in the future?

We know that inflammation is playing a role in many diseases, and by targeting SHIP1, the drug we are currently developing may well have further applications than those discovered to date. Furthermore, we are conducting discovery activities around second-generation compounds.

In 2018, we will be starting a new clinical trial in a urological disease affecting men, called chronic prostatitis/chronic pelvic pain syndrome. As with IC/BPS, the inflammatory pain that can result from prostatitis seems to be refractory, and we will test whether our developmental drug compound offers a possibility to fight it.

Amongst the second generation compounds we are now moving towards the clinical stage, we have a second-generation anti-inflammatory drug also targeting SHIP1, and that is our most advanced project to date. It has different properties and may have applications for different diseases in which treatment with our lead developmental compound would not prove efficient.

We are also pursuing an application for treating certain blood cancers with a second-generation compound. In this field we are conducting our research with Dr. Graham Packham at the University of Southampton in the UK. It is very exciting, because by targeting SHIP1, we are looking to develop a blood cancer therapy that is entirely different from any available today.

What are the coming milestones in the development of rosiptor (AQX-1125)?

The first main milestone on rosiptor’s path was in 2015, when we announced the results from our LEADERSHIP 201 study, which was a phase II study on interstitial cystitis/bladder pain syndrome. In 2016 we started a phase III trial, LEADERSHIP 301. The topline data will be shared in the third quarter of 2018.

With the experience of having been part of creating three companies in Canada, how do you assess conducting research in Canada?

The fact alone that I was able to be part of building three successful companies in Canada speaks of the quality of science available in Canada, as a solid foundation for starting and creating companies in the country. This is first and foremost the result of a very strong commitment from both the federal and the provincial governments to fund basic research. In addition to that, the universities in Canada tend to be a well of excellent quality research and generation of intellectual property.

These possibilities are further illustrated by venture capital firms coming to Canada as they see untapped potential in the country. In life sciences, the limiting factor for development in Canada has always been a lack of capital. The capital pool in Canada is for instance much shallower than in the US. However, this is now changing as US venture capital firms not only see excellent science, but also little competition in the venture capital market to uncover opportunities.

At Aquinox Pharmaceuticals, we have been lucky that capital has never been an issue. We started in Vancouver and were private until 2014. During that time, two of our most notable investors were Johnson & Johnson and Pfizer. We further attracted the interest of venture capital firms; one Canadian firm, Ventures West, in particular. Also from the beginning we attracted a very important specialized biotechnology fund from New York, Baker Brothers Investments, whom have increased their stake and are now our largest shareholders.

Both industry and government have said they would like to see others do more to invest in and promote R&D and innovation in Canada. From your perspective, have both sides done their fair share – and what more can be done to harvest and foster innovation in Canada?

When you add up all the investments of federal and provincial governments in Canada, you come to the conclusion that the government is doing more than its fair share. Nonetheless, the coordination is poor and the investment landscape highly fragmented. It is composed of a multitude of individual initiatives rather than pursuing a concerted focus which would encourage efficiency.

The initiatives are there, Canada spends a lot on basic research, all universities are subsidized by one government, there are funding agencies such as the National Research Council. But nothing translates truly into action. For instance, having a life sciences dimension in the recent super cluster initiative that identified industries of focus, would have been very beneficial and an important sign for the right direction. What is lacking in Canada is the focus on moving research from the early stages all the way through to commercialization, to capture the value of the full ecosystem.

Should Canada’s role be more than just the early-stage incubator for research?

In Canada, we have the ability to start companies. And while we cannot just say we will be creating more global companies, we can achieve this by ensuring more companies are financed all the way through. Some will be acquired and some will not, but in itself, acquisition is not a bad thing, as it is a sign of value. In other parts of the world, a highly effective system of scientists rotating between

company creations is in place. In Canada, the process takes too long to allow for such a system to be effective. While the researchers are just as excellent as elsewhere, it takes them too long to go from one successful exit in one company to the creation of the next.

What should be changed in Canada to ensure more investment comes to the country and stays here?

Today, the market access in Canada involves too many restrictions for new branded products, and regulation seems to only be a way to limit access to pharmaceutical products. Health Canada has done a good job of harmonizing the approval process based upon safety and efficacy, but there are numerous agencies, both federal and provincial, involved in pricing and reimbursement. The pharmaceutical industry is a global one and Canada is a relatively small market overall, so having a complex system for market access disadvantages Canadian patients. So, in addition to funding good science, we need to speed new drugs to market to ensure Canadians have the best healthcare available. This will ensure Canada is an attractive investment location.

It is a shame to see great products that could help Canadians not being brought to Canada quickly because the patent laws, and pricing and reimbursement hurdles, are inconsistent with larger markets and discourage developers.

The trend within Big Pharma has lately been more about buying innovations by acquiring biotech companies and at the same time, it is increasingly expensive for biotechs to research and develop products through to commercialization stage. Are we at a point now where we will not see biotechs growing into pharma giants?

Hopefully we are not at that point, as our plan at Aquinox Pharmaceutical is to become a large biotech player. Aquinox Pharmaceuticals' entire strategy is to take our own products through commercialization and launch them ourselves, at least in the North America region. Nevertheless, not every product is suitable for a small company to take all the way to commercialization. Products in very large markets managed mostly by primary care physicians are more difficult to effectively target by small companies. In a very well-defined market such as urology, a small company can build a commercial infrastructure.

Moving forward, what are your main areas of focus in the development of Aquinox Pharmaceuticals?

Our number one priority is to complete our on-going phase III trial for rosiptor, and then, given the expectation it may be positive, to continue to work towards completing the requirements for

approval of this product. At the same time, we are increasing our efforts to advance the products in our pipeline. As previously mentioned, capital access has never been a major concern of ours, and we have confidence that when further development of our products is justified we will have great support from our investors.

On another note, we are interested in finding partners in urology and women's health for markets outside of North America and for earlier stage programs in oncology. In urology and women's health we plan to commercialize our own products in Canada and the USA, but in oncology we have gathered less expertise and are looking for partners with a strong presence in that field for earlier stage research.

Urology is to us an area that is truly underinvested in, underserved by most big pharmaceutical companies that have abandoned research in this area. Still, it is a field with millions of patients, and we believe we have the potential to become a global player in this area.

And while I applaud the regulatory stance to develop drugs for rare diseases, thus developing treatments for people whose need for treatment has long been ignored, I think that, as an industry, we should not forget to focus on the very prevalent diseases. In the end, this is where the cost of healthcare comes from.

As CEO and co-founder of the company, what is the most exciting for you at the moment?

It is most exciting to be part of a company that is making the transition from being in the development stage to envisioning the commercial stage; although much work still lies ahead. Not many companies are able to experience this, and it is thrilling to see that we are progressively inching closer to commercialization.

See more interviews