Interview: Brian Canestraro – General Manager, Intercept, Canada

"From the very beginning, it was important to make sure that every decision was made through the lens of what is right for patients."

06.04.2018

Tags: Canada, Intercept, Pharma, PBC, Liver Disease, Strategy

Looking back on three years of operations in Canada and nine months of approval of Ocaliva® for the rare non-viral liver disease PBC, Brian Canestraro, general manager of Intercept, is proud of how far the Canadian affiliate has come. He is confident that the company has established a solid foundation to build upon by focusing on core values, market access capability and keeping a continuous focus on the needs of patients.

How have the beginnings of Intercept in Canada unfolded?

Intercept Pharma Canada Inc. (Intercept) was established in June 2015. Our founder, Mark Pruzanski is Canadian, and opening operations in this country has always been a major goal for the organization.

As we started out, my priority was to build a company that would remain true to Intercept's core values. From the very beginning, it was important to make sure that every decision was made through the lens of what is right for patients.

My other priority was to establish a company that would have the capability to successfully launch multiple indications over the coming years. There is a tendency with start-up companies sometimes to focus on launching a product and waiting to address culture and the necessary governance frameworks to guide decision-making and other organizational processes. I take pride in the fact that we have been able to build a company over three years that has remained true to

its core tenets and has the ability to scale up to support our future potential for growth in other non-viral liver disease indications.

Our focus has been on establishing the company locally and building sustainable partnerships with core stakeholders in the Canadian environment to support the successful Health Canada approval and commercial launch of our lead product Ocaliva® (obeticholic acid) for primary biliary cholangitis (PBC). I am very proud of what our team has accomplished for Canadian PBC patients. We have successfully achieved broad private payer access, in addition to two positive health technology assessment (HTA) recommendations through INESSS (HTA for the province of Québec) and CADTH (HTA for the rest of Canada) within our first few months of approval. We are actively engaged with the PCPA and working to expand reimbursement for PBC patients who depend on public access, which is quite an achievement for such a young company.

Today, Intercept is a full-scale organization with commercial, medical, market access and government affairs functions. We are nine months into our first launch and we continue to see adoption of Ocaliva® accelerate each month. Ocaliva® received a conditional approval from Health Canada in May 2017 for the treatment of PBC patients who have either an inadequate response, or who are intolerant to the current and only available first line treatment for PBC, ursodeoxycholic acid (UDCA). Importantly, Ocaliva® was the first new treatment option approved for PBC in over 20 years in Canada. We are proud to have secured access for so many PBC patients in our early months of launch.

What have been some of the main challenges you have met when establishing the Canadian affiliate of Intercept?

You have to be prepared to manage through many challenges when you are building a company from scratch at the same time that you are preparing for launch in an environment that is constantly evolving. For me, it was important to focus on hiring the right kind of people for Intercept to succeed in Canada and execute against our mission, which is to develop and commercialize innovative treatments that address unmet medical need for patients with progressive non-viral liver disease.

I was facing important questions about how to attract people with a breadth of industry experience who could succeed in the challenging startup environment and most importantly, fit with our core values and customer experience expectations. It was also important for us to attract people who could develop and grow with the company. Looking back on things, I think we were bold to prioritize cultural fit over subject matter expertise in liver disease, but I wouldn’t change anything if

I had to do it all over again.

You are an expert in the field of liver disease, having previously worked with Gilead. What made you the ideal candidate for the job?

[Featured_in]

I was with Gilead for almost 10 years and look back on my time with the organization with fondness. To be honest, I think having the opportunity to take on roles with increasing responsibility over those years was one of the greatest professional gifts I could have asked for. I joined the company during the startup of the Canadian operation as one of the first handful of employees. During my time with Gilead, the affiliate grew from a small team of people and revenue of about CAD 17 million (USD 13 million) to over 100 people with revenues of about CAD one billion (USD 780 million) Through the experience of being involved in Gilead's rapid growth, I learned to appreciate the importance of embedding a strong sense of culture and the value of establishing scalable governance frameworks that I could also apply within Intercept.

Intercept is focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases. What are some of the characteristic in the Canadian market?

According to the Canadian Liver Foundation, liver disease impacts one in four Canadians, which is quite significant. At the same time, general awareness about the liver and liver diseases is fairly low. It is great to see that the medical community has witnessed some major advancement for patients with viral liver diseases. For example, chronic Hepatitis B today, has become a largely controllable disease, and most recently the treatment of HCV has been revolutionized by the introduction of direct acting antivirals.

However, the area of non-viral liver disease still experiences significant unmet medical needs. The May 2017 conditional approval of *Ocaliva*® marked the first innovative drug approval for PBC in over 20 years. PBC is a rare form of autoimmune liver disease that primarily impacts women between the ages of 40 and 60. In fact, PBC represents the number one reason for liver transplant among women in Canada.

Intercept is also exploring research with our lead compound, obeticholic acid, as a potential treatment for nonalcoholic steatohepatitis (NASH), as this disease is expected to become the leading cause for liver transplants within the next few years. As of yet, there is no existing therapeutic option for NASH. At the same time, our company is also exploring the potential of

obeticholic acid to play a role in the treatment of primary sclerosing cholangitis (PSC), another rare autoimmune liver disease that primarily impacts men for which no approved treatment option exists.

How has Ocaliva® been received in Canada?

I joined Intercept at a time when our worldwide headcount was just under 200 and we were at the cusp of making the transition from an R&D organization to a full scale commercial organization with a presence in many markets around the world. I have been proud of how the organization has supported the build of the Canadian affiliate and impressed with how Canadian stakeholders have responded to Intercept, and Ocaliva®**.** While still early days, we are very encouraged with the positive response Ocaliva® has received from hepatologists and gastroenterologists.

In addition, we have seen a tremendous amount of support and excitement from patient and stakeholder groups for this innovation, which they have been waiting for, for over 20 years.

How would you characterize the Canadian healthcare landscape?

I like to refer to Canada as a "global petri dish", and while it is often characterized as complicated, it is really an interesting mix of US managed–market, and European HTA-centric landscapes. It is important to recognize this and tailor your strategy accordingly. Organizations that build strong market access and medical affairs capabilities are often able to succeed in Canada. And while Canada may be considered small compared to other markets, it remains an important market that allows companies to pilot initiatives that can be exported to US and European markets.

[related_story]

Canada also enjoys a positive regulatory environment with rates of new drug approvals and time to approval via Health Canada aligning closely with the FDA and EMA. Importantly, Canada also has a robust research eco-system and has made a lot of progress in recent years to lower barriers for doing R&D in Canada. I was pleasantly surprised by the amount of Canadian clinical trial sites who have and continue to participate in our phase 2 and 3 clinical development programs. Canada has the opportunity to continue being a strategic location in life sciences, both today and into the future.

Pricing is an important issue when it comes to highly innovative treatment options like *Ocaliva*®. How do you demonstrate the value of your product to the regulatory bodies?

It is very important to be able to articulate your value proposition to the authorities. You need to be able to explain to a payer why a drug is priced at a certain level, the value it is bringing not only to a patient's life but also what it means for the broader healthcare system overall. If you can create a tight connection between the clinical value of your drug and its impact on the healthcare system, payers will more often recognize the value that has been attached to innovation. Historically, I have found that payers want to provide access for patients. Our job is to make sure we generate the evidence that predictably guides payer investment and that we collaborate closely to make that happen for as many patients as possible.

How was your market access experience with *Ocaliva®?*

Very positive. We were able to secure rapid access with private payers and have been pleased with their receptivity, willingness to engage early with us, and appreciation of the unmet medical need for PBC patients. Moving forward, we want to ensure that patients who depend on the public formulary system for reimbursement are able to access *Ocaliva®* as quickly as possible. With this in mind, we have also found our engagement with the PCPA who negotiates on behalf of Canadian provinces and territories to be equally encouraging, and productive thus far.

Intercept has benefitted from Canada's excellent R&D infrastructure and has conducted clinical trials for PBC across multiple sites in the country. How will you leverage these capabilities in the future?

We have been fortunate, as Canada has a large number of opinion leaders in liver disease. I was actually impressed by the number of Canadian sites that are part of our clinical programs. We had number of sites participating in early PBC research; as well as a significant number of sites in long-term extension studies as part of our post approval commitments. We also have a number of sites participating in our NASH registration studies and are very optimistic that this will continue to be the case as we explore potential further research in PSC. All this speaks to the quality of Canadian research and the leadership in this space here.

In addition to a favorable R&D environment and strong opinion leadership, Canada also has a very diverse population; it is very inclusive, multicultural and provides the opportunity to generate additional insights in the context of R&D.

Overall, I have found that there are sometimes limitations in relying solely on translating data from abroad into the Canadian environment in a way that is meaningful. This underscores the importance of incorporating Canadian-specific epidemiology and disease outcomes data into planning, which ultimately supports stakeholders and healthcare professionals to make better

decisions. The more you can help characterize the progression of the disease and what the local patient population looks like, the more you can help quantify the magnitude of unmet need and guide budget predictability.

How do you advocate for investment in research at your headquarters?

Our organization, like most, has the benefit of making R&D investments in many markets across the world. We are always hoping that decisions are made to partner with Canadian researchers and sites. We have benefited from a number of advantages that exist in Canada to attract organizational R&D investment. Canada offers an environment that provides access to high quality researchers and infrastructure where research can be done quickly. Furthermore, we have a wealth of internationally-recognized opinion leaders and a diverse patient population, that add value to research conducted in Canada.

What are your key priorities over the coming years?

Our key priorities will continue to focus on making a meaningful difference in the lives of patients with progressive non-viral liver disease. In the near term we will work towards finalizing public payer access to Ocaliva® and continue to find ways to improve our cross-functional efforts to reach as many treatment-eligible PBC patients as possible with the desire to improve health outcomes.

In the longer term, we will continue to improve our core capabilities, support people development, and refine our governance model to ensure that we are ready to scale-up and have the talent necessary to execute against potential future launches and realize growth opportunities that we hope will present. Regardless of our future state, we will continue to keep the patient at the center of everything we do.

See more interviews