

Interview: Ross Glover - General Manager, Taiho Pharma Canada



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Taiho Pharma

ceutical Co., Ltd. (TPC), Japan, part of Otsuka Holdings, established its Canadian affiliate in 2017. Ross Glover, general manager for Taiho Pharma Canada, has spent the past year tackling the mammoth task of establishing the foundations for the operations, including preparing a new drug for market approval and navigating the complex healthcare landscape in Canada.

Could you outline the rationale behind why 2017 was the right time to introduce Taiho Pharma to Canada?

The establishment of the Canadian affiliate had always been part of our global expansion plan, whereby the intention was to establish a strong presence in the US first, before venturing across the border. An internal evolution at TPC Japan, Taiho's parent company, and New Jersey's Taiho Oncology Incorporated built upon the already budding interest in the US and Canadian markets; hence why we started preparations for the Canadian affiliate over three years ago. Canada has always been of keen interest to Taiho, especially given that our now departing North American CEO, Eric C. Benn, is Canadian.

Since our arrival in Canada (with head offices in Ontario), the global company has continued to understand the importance and potential of the Canadian market and we are now collaborating strongly across all frontiers.

What priorities did you set upon establishing the affiliate here?

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First and foremost, we set about managing our drug submission for LONSURF® in an urgent and critical fashion by emphasizing the serious unmet needs of Canadian cancer patients in combatting late-stage colorectal cancer. We wanted to make sure that this first product launch to Canada and its importance to Canadian patients was clear. We worked closely with Health Canada and eventually LONSURF® received a priority review based on its importance and benefit to patients with late-stage colorectal cancer. Ultimately, we were successful and LONSURF® was granted marketing authorization through a Notice of Compliance (NOC) on January 25th, 2018, following an expedited review at Health Canada. It was encouraging to observe the regulatory agency agrees that LONSURF® is a unique treatment with high value for patients in need and we look forward to introducing it to patients and their caregivers.

Secondly, we prioritized establishing a strong team with a sense of dedication and passion for creating a strong Canadian affiliate at its core. In a small rapidly-growing operation like Taiho Pharma Canada, creating a positive culture from the get-go is of utmost importance. We sought to develop a company culture from day one, which encompasses resilience, passion for what we do and a trusting reliance on one another. We asked employees what they want their culture to be and we are working to identify how we will grow within those principles. Assembling the team was enjoyable, and we try to inject a little fun and a lot of passion into everything we do. Given how challenging work can be on a daily basis in such a complex market, where we engage with medical, regulatory, legal and governmental bodies regularly, it is vital to keep a positive spirit.

The third priority was to establish a solid base to run our operations. We found an office location in December 2017 and are excited for the growth prospects that being in Ontario offers. Of course, drug submission and hiring come first, but a well-located, modern office is a crucial component in creating a positive work environment and to a business' success.

How would you evaluate your first year leading Taiho Pharma Canada?

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We have been very successful in hitting our objectives. We hired a fantastic team, secured a professional office, and achieved our NOC. Further, we received a priority review from the pan-Canadian Oncology Drug Review (pCODR)—our health technology assessment agency—that evaluates oncology drugs in Canada and subsequently issues a recommendation for public

reimbursement. Finally, we are preparing our plans for the next five years so that we can be better organized and make our inevitable growth a strong opportunity for our young company.

What will be the go-to-market strategy for LONSURF®?

First, we will work with health care providers and share experience from our clinical trials and from other countries to help them understand who will benefit from the drug, ensuring the drug's value is understood across the healthcare spectrum. Second, we will work with patient groups to set about making expectations and details surrounding the drug clear. Finally, through partnerships with academic institutions, we will develop more Canadian based studies in late stage colorectal cancer, further building upon LONSURF®'s utility in cancer.

We will soon submit LONSURF® for a second indication in gastric cancer. Following LONSURF®, we intend to introduce similar DNA targeted drugs, one of which is currently in phase 2 trials. In total, we have close to six products in the development pipeline and are very excited about the future, both for Taiho and Canadian patients

Pricing is a sensitive subject, particularly in oncology. How will you communicate the value of your product and the potential for value-based pricing models?

Our desire is to make the drugs accessible to patients. We work and will work closely with the pCODR and the pan-Canadian Pharmaceutical Alliance (pCPA) to communicate the value proposition of our therapies and how best to enter the market. Price is but one dimension of the value that our products offer to patients and the health care system. Our pricing strategy considers the comparative value offered through our Patient Support Program, our collaboration with prescribers and our thoughtful understanding of the challenges that private insurers and government payers face in the Canadian context. In short, we are on track to make affordable pricing achievable by taking a system-wide approach.

How will Canada's plan to revise the reference basket for international reference pricing impact your pricing strategy?

Pharmaceutical pricing reforms are impacting markets around the globe as payers come to grips with balancing the introduction of new technologies with the need for affordability. In Canada, the creation of the pCPA was an impactful event that changed the pricing landscape. Our view at Taiho is that the proposed new reforms will have a negative and deleterious effect on patients and on new companies considering establishing operations in Canada. While Taiho has considered current pricing reforms in its plans to launch in Canada, price uncertainties in a market such as

those proposed by the Patented Medicines Pricing Review Board (PMPRB) are cause for concern. The plan to revise the basket of reference countries is the tip of the iceberg of the proposed reforms and Taiho, along with our industry has voiced concern and we have sought a delay and more thoughtful dialogue on these important issues. Overall, patient access to new medicines from current and potentially new companies to Canada may be delayed and/or even denied which is an issue that impacts all Canadians.

How does Taiho Pharma Canada intend to tap into the R&D potential here in Canada?

Certain R&D sites are already operational in Canada, and we intend to further capitalize on the rich R&D landscape here. When I came on board at Taiho Pharma Canada, I noticed that we lacked research activity in Canada, and there was tremendous scope to ramp up and expand operations. Following meetings with top academics in the country to foster partnerships with their institutions, we shared ideas on how we could develop and work on new molecules to bring them to market. To cite an example, I am excited that we have started a new level of colorectal research and cholangiocarcinoma research in Canada.

Indeed, Canada should not be overlooked for R&D operations due to its global connectivity. We offer a more affordable environment than other major countries like Germany, the US or the UK. We have excellent facilities and the best academic minds in the world. With Japan's help, I would like to see early Phase 1 research undertaken in our country.

How do you go about advocating that level of investment into Canada?

We advocate with facts: we show what the potential costs are, we use academics' past achievements in Canada, and we show how advances and progress made here are communicated and accepted globally.

Masayuki Kobayashi's message (President of TPC) in opening the Canadian affiliate explained his intent to attract the best talent and establish a great team. To what extent have you accomplished this task?

We are all fortunate in that we have an incredibly skilled talent pool in Canada. We were excited to see that some very talented individuals with distinguished career records were interested to come and work at a new operation like Taiho Pharma. We leveraged the resources available to us to build our vision, and have since assembled a great team. Employees relish being part of something long-term and purpose based, and Taiho Pharma Canada's vision is undoubtedly long-term oriented. Taiho Pharma Canada is fresh, it has a viable drug with great potential coming to market, and we

are in an exciting, dynamic field: oncology. Consequently, we received fantastic applications and have been successful in putting together a high caliber team.

What is the importance of operating a Canadian affiliate to pharmaceutical operations globally?

Being present in Canada is beneficial for global expansion due to its status as a Top Ten pharmaceutical market. However, it is important to understand our unique environment; whereby with a good product and a good strategy success is possible, but failing to execute the strategy with a strong local guidance may mean losing out.

Considering our neighbor, the Canada-USA comparison is interesting in that partnerships are made possible due to the US's huge resource pool and that the two countries, in fact, complement one another. For Taiho Pharma Canada, LONSURF was released three years prior to the US, and so we were able to learn from their experience and we are now in a position to share some of our insights gained throughout our launch.

How does the Japanese company culture transcend working life in Canada?

The Japanese company influence is centered around working together as one company globally, to which Taiho Pharma Canada commits itself wholly. Personally, I appreciate the Japanese approach of a unified Taiho, with overarching company themes that cover global operations. Beyond that, I cannot emphasize how helpful Taiho Oncology Inc. in the US and TPC in Japan were to help form our beginnings, and how objective and open Taiho Japan has been in eagerly learning about the Canadian pharmaceutical environment. We engage in thoughtful and deliberate conversations about what is needed to make Canada successful.

The Japanese long-term perspective is useful in communication and understanding of our product launches, particularly when an affiliate first gets off the ground. For example, they can see that we have the approval but understand that we will not have a rush of sales for a long time because LONSURF® will initially only be available in the private market in the short term.

What advice would you like to share on establishing an affiliate here?

The critical learning experiencers have to be aware that you need to make efficient, effective, long-term decisions at speed: you cannot shy away and must learn to live with decisions made. The decisions made in the first 12 months will set the trajectory of Taiho Pharma Canada over the next ten years.

We have made the right decisions across our first year because we have worked as a team covering all the bases. I would recommend that when attempting a project as large as opening an affiliate, seek assistance from peers; assemble a strong team and strike up an atmosphere of trust and teamwork. Asking questions and being curious is crucial while reaching out to other parts of the company where global operations are based is essential. Tapping into the Taiho network was effective given the wealth of experience available.

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