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Hans Schmid, chairman; and Enrico Magnani, GM, of global cancer supportive care leader Helsinn Pharmaceuticals' operations in China, share the Swiss company's strategy in China, having entered in 2012; the milestone of launching their first product in China in November 2018 for chemotherapy-induced nausea and vomiting (CINV); the importance they place on medical education in a market like China; and their business objectives for Helsinn China for the next few years.



Hans, perhaps you could start by sharing how Helsinn Pharmaceuticals (Beijing) Co., Ltd (Helsinn China) decided to enter the China market back in 2012, considering the fact that Helsinn is a Swiss mid-cap that is only directly present in a few countries?

Hans Schmid (HS): Helsinn is a company that chooses its presence in foreign countries very carefully. Outside Switzerland and Ireland, where Helsinn manufactures finished products, we have a commercial sales and marketing organization in the US. In the rest of the world, we choose to work through trusted partners. China was already a very large pharmaceutical market in 2012, experiencing rapid growth and with expectations that China would become the 2nd largest pharma market globally after the US, which became reality in 2016. With the anticipated importance of the China pharmaceutical market, Helsinn wanted to bring its innovative pipeline of products in cancer and cancer supportive care to China.

In 2012 I moved to Beijing to establish Helsinn's Representative Office in China with the initial objective of hiring a small team of professionals to support Helsinn's clinical and regulatory operations from here. Our first priority was to register our innovative products in China so that Chinese patients can access them. While Helsinn had initially planned (as early as 2007) to select a local Chinese licensing partner through whom we would work, eventually we adjusted our strategy to take greater control of our product registrations by working directly with CROs. It was important to be physically present in China to avail ourselves of the market opportunities. The Representative Office became the beachhead from which we could learn more about the China market and eventually build our own commercial operations on the ground. From the very beginning Helsinn took a very long-term, step-by-step approach when it came to entering the China market.

In 2017, we established Helsinn Pharmaceuticals (Beijing) Co. Ltd and later that year, we added our Shanghai branch. Today, we have consolidated both operations under Helsinn Pharmaceuticals (Beijing) Co. Ltd – or Helsinn China, collectively, with our regulatory and clinical operations continuing to be based in Beijing and our commercial operations based in Shanghai.

In November 2018, our first product was approved in China: palonosetron IV, for Chemotherapy-Induced Nausea and Vomiting (CINV). In December 2018, we successfully concluded our first locally managed clinical registration study for palonosetron IV in postoperative nausea and vomiting. In May 2019, palonosetron IV (CINV) was launched in China. In September 2019, the National Medical Products Administration (NMPA) approved our second product, NEPA (combination netupitant + palonosetron), also for the treatment of CINV. As a final note, in July 2019, Enrico Magnani was appointed GM of Helsinn China and from January 2020 onwards I will continue in my role as Chairman of Helsinn China.

Helsinn is a key global player in cancer supportive care. We know China is a huge oncology market in general but what are the specific needs and therefore commercial potential specifically within the area of cancer supportive care?

Enrico Magnani (EM): Let me briefly highlight some fundamentals about the China cancer market. Certainly, the potential is huge: significant progress has been made in cancer prevention diagnosis and treatment; consequently, more and more patients are diagnosed with cancer; government policy is also increasingly prioritizing this area, resulting in many new and innovative cancer drugs being approved and/or reimbursed. Looking at the number of new drug approvals, oncology dominates.

The question is how a company like Helsinn can play in such a hot market where the top global players as well as strong local companies are both present. Currently, our portfolio targets two areas: cancer supportive care and rare cancers.

The most advanced marketed products we have, including our first two products in China palonosetron and NEPA (combination netupitant + palonosetron), are in the first area, cancer supportive care, specifically CINV. These products target a large population of patients in China because antiemetics are essentially used in most chemotherapy centers. While the chemotherapy market in China is an established market in some sense with many local players, I believe we can differentiate ourselves through both the innovation and quality of our products and through the services we can offer around our products, including medical education, which is a core competence of Helsinn that I will elaborate on later.

We are of course aware of the new immunotherapies that are partially substituting the use of chemotherapy in some cases. We welcome these innovations to cancer care because it is great news for patients, but it is also true that these immunotherapies bring new side effects with them. There may be new opportunities for Helsinn to address these side effects in the future. Nevertheless, currently the majority of cancer patients are still being treated at some points of their journey with chemotherapy. Whether as a standalone therapy or combination therapy with immunotherapies – chemotherapy is still the first-line treatment for most types of cancer in China. In addition, according to our market research, 60 percent of patients receiving chemotherapy in hospitals still report suffering from nausea, and 50 percent report suffering from vomiting[1]. There is a clear need for our products, especially for instance, since NEPA (combination netupitant + palonosetron) has been shown to have a favourable benefit risk profile complete patient response rate of over 90 percent in clinical studies[2].

Secondly, while the market here is established in some sense when it comes to local competition, it is still at an earlier stage when you look at product innovation. In terms of CINV, for instance, there are a couple pathways targeted by existing drugs. One pathway is targeted by 5-HT_3 receptor antagonists, of which palonosetron hydrochloride represents the second and best in class generation, and it is a well-established market. However, the second pathway targeted by NK_1 receptor antagonists represents a market at a much earlier stage compared to overseas as there is only one product available in China at the moment. Our second product approved, NEPA (combination netupitant + palonosetron), targets both pathways and therefore represents a great opportunity for us to expand the market and improve the quality of life of cancer patients.

As you mentioned, cancer is a very crowded space globally, and even more so in China. How can Helsinn position itself best within this space?

EM: In addition to our innovative products in cancer supportive care as I discussed, the second part of our global portfolio is in rare cancers. This is an area where a company like us can certainly have more of a play. Taken collectively, rare cancers represent around 20 percent of cancer cases globally[3]. We do not have thorough statistics on this in China yet but taking even a conservative figure of 10 percent out of the four to five million cancer diagnoses a year, we still have a large number of patients with rare cancers. Most of them are still being treated with non-specific therapies.

We already have one product under registration in China for a rare form of skin cancer. This product is already marketed in the US and Europe, and the new regulatory policies in China have benefited us because we have been able to obtain a clinical trial waiver (an exemption from conducting a clinical study for registration) from the NMPA for this product.

We also have a product for a rare form of leukemia in the pipeline, and we have recently included China in our global Phase III trial; as well as an earlier-stage product for a rare mutation in lung cancer. This pipeline certainly gives us exciting opportunities in the future to address a market of significant size like China in a way that plays to our strengths.

If I could also offer a preview of our overall China strategy, after we have consolidated our commercial operations for our first products on the market, the next phase is to start exploring other product opportunities, both internally and externally. Internally, we are leveraging the rare cancer products in our pipeline and exploring how we can have a broader geographic footprint in China, either with a partner or alone.

Externally, as a company, Helsinn is always looking for new product opportunities. We have a very active business development team scouting for new and interesting assets. Traditionally, the focus has been to look for assets from mature markets to bring to China but now it is also time to look more closely at innovations coming from China that could be interesting for global markets. We have already begun to monitor the local market and we attend the relevant partnering and business conferences in China.

Could you share more about your decision to find a commercial partner in China?

EM: Generally speaking, partnership is at the heart of Helsinn, and our organization has really grown by being centered on the concept of partnership. Around the world, we have over 80 trusted partners covering more than 190 countries, so part of our organization has been specifically designed to collaborate with and support our partners. This is true also in China. Given the relatively small size of Helsinn in China compared to established players, partnership is absolutely the way forward. Through these partnerships, we hope to complement our strengths and capabilities while lowering potential risks.

As Hans mentioned, in the past few years, we partnered with service providers to develop and register our products here. As our products were coming closer to approval, we started to look for commercial partners.

Our cancer supportive care products have a broad patient base, so a large organization is needed to promote and detail them. It is not feasible or strategic for us to build a large salesforce immediately, so we wanted to have a partner that already has an extensive presence in China. Within our commercial partnership, we have also carved out an opportunity for us to co-detail some of our drugs in the Shanghai municipality, which allows us to start establishing a small commercial base from which we can expand our presence in the future, perhaps with new products.

Enrico, you mentioned that a core competence of Helsinn is in medical education. How important is that in a market like China?

EM: This is really integral to our brand and a critical differentiating factor that we want to bring to China. Due to our business model, we have focused intensively on building product knowledge and sharing that product knowledge to our global partners in terms of medical education and marketing support. Helsinn has always abided by high standards when it came to marketing and promotion,

and we believe in the importance of strong medical education. That is what we offer as part of our brand and we see this also as a competitive advantage within this market.

In fact, one of the first positions we filled in China was the Head of Medical Affairs so we could start transferring the global product knowledge to our local operations and our partner. In addition, we have already begun to engage with key experts and scientific organizations in our fields. For instance, we have started to work with the Chinese Society of Clinical Oncology (CSCO) to provide support and training for young and talented oncologists. We want to contribute to the scientific and academic communities in China as well as increase the medical resources at patients' disposal, and in doing so, we will also be to communicate the strengths of Helsinn's brand more clearly in this market.

HS: Another important collaboration I would like to highlight is our work with the CEO Roundtable on Cancer, a global organization based in the US focusing on making progress towards the elimination of cancer through various initiatives, including the promotion of a healthy work environment within companies. In 2014, Helsinn became one of three global founding companies to support this initiative and adopt a tobacco free work place in China. The CEO Roundtable includes commercial enterprises, hospitals and other institutions and the workplace wellness it promotes are very much in line with the Healthy China 2030 plan.

Most recently, for instance, we supported an event in Shanghai hosted by the CEO Roundtable on Cancer to celebrate '70 Years of Cancer Care in China'. The event gathered representatives from government, medical, industry and public sectors to review the progress in cancer treatment over the last 70 years in China and looked at what the future might hold for oncology prevention and control to contribute to a healthier Chinese population.

What would you like the Helsinn brand to be associated with in China?

HS: As a Swiss family-owned company, our vision is to help people with cancer get the most out of their everyday lives. In every aspect of our work, we remain committed to our vision and mission to bring respect, integrity and quality to whatever we do, whether it is the products we manufacture or the services we offer. As a Swiss company too, we are expected to, and we do adhere to the highest standards in providing innovative solutions that improve the health and quality of live for everyone affected by cancer.

We have also strived to position Helsinn as an honest, ethical and trustworthy company with the goal of becoming the cancer care partner of choice to the entire Chinese ecosystem. With our company focus on partnerships, we treat our partners as we would like to be treated. This philosophy has resulted in the formation of longstanding and strong relationships with over 80 valued partners across more than 190 countries. Our mission, vision and commitments are key components of how Helsinn has always worked across the globe and how we will continue to work in China.

This value system is rock solid even in a changing and complex environment like China. Over the past few years, we have followed through on our principles, and as a result, Helsinn China is respected for what we stand for by our customers, partners and employees. Though we are still a small company, we have developed a good corporate image and are respected and known for the quality and care we bring to cancer patients.

To start wrapping up, Hans, what have been your key learnings having established Helsinn's presence in China?

HS: I have three to highlight. First, as a small organization, one of the key challenges is how to bring capable, talented individuals to work together to create an efficient and effective organization in pursuit of common objectives and goals. As a new affiliate, far smaller than established MNC operations, it is important to find the right people. Our values of respect, integrity and quality, along with our collaborative and nurturing culture in combination with a good overall compensation package, have helped us build the right organization: small, professional and focused.

Second, the environment in China is changing all the time. This may be true of many countries, but the pace of change is perhaps more rapid in China than elsewhere. A company has to learn to adjust quickly to these changes and challenges. This is not always easy but it is important that one does not lose sight of the goal – which, in Helsinn's case over the past seven years, was to obtain marketing approvals for our products and bring these to the commercial market for the benefits of cancer patients.

Finally, you have to believe in what you are doing. We believe that our products can help patients lead better lives. To stay focused on that ultimate mission gives us the strength to persist in the face of challenges. We believe we have navigated through this challenging period quite well. Now it is time for Helsinn to move on to the next step of the strategic plan and make a success of our

products in the commercial market in China!

Looking forward then, Enrico, what are the top one or two priorities for you in your first year as GM of Helsinn China?

EM: Our business objectives for the next few years are very clear. We are looking to build up Helsinn's commercial footprint in China. I also want to see Helsinn recognized as an excellent partner in China – as we are in other parts of the world. We want to ensure that we consolidate and strengthen existing partnerships for the success of our products and to benefit patients in China.

Therefore, firstly, I want to assemble a strong team with a shared vision. At the end of the day, the success of a company comes from its people. Talented individuals need to be brought together to work towards the same goal.

Secondly, at this stage, it is very important that we continue to consolidate Helsinn's brand and reputation in China. We must always have patients in mind, and we will continue to organize our medical education and promotion activities in conjunction with key cancer stakeholders within China's healthcare ecosystem.

[1] IQVIA Market Research, 2018

[2] PJ Hesketh, G Rossi, G Rizzi, M Palmas, A Alyasova, I Bondarenko, A Lisyanskaya, R Gralla. Efficacy and safety of NEPA, an oral combination of netupitant and palonosetron, for prevention of chemotherapy-induced nausea and vomiting following highly emetogenic chemotherapy: a randomized dose-ranging pivotal study. Ann Oncol 2014;25:1340-6

[3] Eur J Cancer, 2011 Nov;47(17):2493-511

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