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Patrik Zachar, Vice President Central Europe of Ipsen, shares how the company has built a strong presence in oncology and neuroscience in the CE region and the Czech Republic, quickly establishing market-leading positions in the indications they compete in. Whilst in neuroscience, Zachar still sees significant growth potential for its botulinum toxin for the treatment of spasticity, Ipsen also invests in the area of rare diseases, for which Zachar rejoices about proposed legislation to create a regular market access pathway for orphan drugs, but also cautions authorities about overemphasizing low prices which can slow down access to innovative medicines.

Patrik, you became Vice President Central Europe of Ipsen five years ago. During that time, Ipsen has undergone immense changes such as a new CEO, incredible growth and moving into new therapeutic areas. What have been some of your key milestones and achievements during this time?

I agree, Ipsen has undergone incredible changes since I joined in 2015. We are progressing in our mission to become a leading biotech company focused on innovation in specialty care, building a strong presence in three key therapeutic areas: oncology, neuroscience, and rare diseases. We have transformed the organization to be able to help bring medicines to patients as quickly as possible, as our medicines address significant unmet medical needs and patients do not have time to wait, so every single day counts. Our products are not just “nice to have” but they save patients’ lives and significantly improve their quality of life. As a result, in oncology and neuroscience, our

medicines are well-positioned on the market in the areas we compete in. In rare diseases, patients are in serious conditions and often do not have any alternative treatment options, so we need to make sure we accelerate their access to our medicines. This is the reason we exist as a pharma company. Additionally, Ipsen also has a consumer healthcare business which represents roughly 20 percent of revenues and delivers solid performance.

How have you implemented the company's European strategy in the CE markets?

The CE region is completely in line with the global strategy, and, in some respects, I would say we are one step ahead of the broader organization in its implementation. My mission started back in 2015 with the task of building a cluster of the four Central European markets (Czech Republic, Slovakia, Romania and Hungary), and creating an organization dedicated to accelerating access to our innovative medicines by implementing best practices. Our ambitions in Central Europe are very much aligned with the strategic vision introduced by our CEO David Meek in 2016. We walk in the same direction, focusing on innovation and specialty care, and growing at the same pace or even faster than the global organization. We continuously build our strong presence in oncology and we are market leaders in our neuroscience niche. Definitely, we walk the talk in Central Europe.

At the global level, Somatuline grew substantially in 2018 and achieved sales of over USD 1 billion, making it Ipsen's first-ever blockbuster. This success is also reflected in the Czech Republic where between 2015 and 2019, sales have increased by 90 percent and market share has grown from 39 percent to 57 percent. What were the key factors behind this incredible performance?

Somatuline is our most important brand and the first blockbuster in Ipsen's history. This product is a testament to Ipsen's commitment to bring solutions for diseases which are hard to diagnose and treat. Somatuline is one of a handful of drugs which have changed the standard of care from symptomatic treatment to addressing the actual cause of the disease.

The success of Somatuline stands on a combination of three factors. The first is the people, both our incredible research teams who discovered and developed the treatment, and the people bringing it to patients.

The second factor is our dedication to support patients and their caregivers by listening to their needs and proposing solutions to address them. For instance, in September, we launched new pre-

filled syringe of Somatuline Autogel, which is much easier to use and safer, not only for caregivers but also for patients as it offers the possibility of self-injection. Although it has only been available for about 3 months, the feedback we have received is extremely positive, and we have not heard any complaints. This means that Ipsen integrated the feedback on the design of the device and that we were successful in explaining how it should be used and what its benefits are. As a result, the new device has been embraced by both healthcare professionals (HCPs) and patients, and we have smoothly shifted all patients to use this innovative form of Somatuline Autogel.

The last element of Somatuline success is our close collaboration with key opinion leaders (KOLs), HCPs, caregivers, health authorities, and payers to ensure we bring the product as quickly as possible to patients.

Over a short period of time – I still feel like the launch was yesterday – we have positioned Somatuline as the clear market leader in the Czech Republic, overtaking competitor product. Most patients diagnosed with neuroendocrine tumours are treated with Somatuline as HCPs and KOLs are convinced it is simply the best solution available, combining an exceptional efficacy and safety profile with a delivery mechanism which maximizes patients' treatment experience. The fact that Somatuline has reached blockbuster status is not a surprise. Our ambition is to further strengthen our market-leading position in the Czech Republic by offering it to more patients, and thus contribute to the success of Somatuline at the global level.

Somatuline is indicated for neuroendocrine tumours and acromegaly, a rare hormonal disorder, which are both difficult to diagnose leading to late diagnosis. How are you raising awareness across the medical community about this issue?

Most patients are treated for neuroendocrine tumours, which, as you correctly point out, are difficult to diagnose because they can manifest in different ways. We try to increase the awareness of this disease by bringing together physicians from different specialties to discuss how we can improve the referral of patients from general practitioners to experts, what can be done for patients, and how Ipsen can become a partner along the patient journey.

In 2018, Cabometyx received two new indications at the EU level, bringing the total to three in advanced renal cell carcinoma and hepatocellular carcinoma. How successful has been the launch of Cabometyx in the CE region?

Cabometyx further strengthens our presence in oncology and has been a key driver of Ipsen's growth in the last few years, helping us to become one of the fastest-growing oncology companies in the world. In 2018, Ipsen entered among the top 14 oncology companies globally, and, at the end of this year, we should be closer to the tenth spot.

Although the reasons remain unclear, the Czech Republic has one of the highest incidences of renal cell carcinoma (RCC) in Europe, which makes the country one of the most important markets for Cabometyx. We first launched the product in April 2018 for the second-line treatment of RCC where Cabometyx has shown excellent efficacy, adding many months to the lives of seriously ill patients. As a result, we were able to establish a market-leading position very quickly in this indication.

In January 2019, we submitted our application for first-line treatment to Czech authorities. In the Czech market, we need to go through a difficult price and reimbursement approval process. We received a positive evaluation report from the State Institute of Drug Control (SUKL) and we are now completing negotiations with payers. We hope to be able to launch in April 2020. Our ambition is to make Cabometyx the standard of care for first-line RCC as well.

When it comes to hepatocellular carcinoma (HCC), the situation is more complex. We will conduct conversations with authorities to determine the position of Cabometyx in the second-line treatment of HCC, and potentially in the first-line treatment.

Cabometyx has been investigated for different indications across many other tumour types, either in monotherapy or in combination with other drugs. As we have seen quite significant benefits for RCC in the last three to four years, I am optimistic that Cabometyx will be able to demonstrate similar results in other tumour types for the benefit of patients.

Ipsen also commercializes Dysport, a botulinum toxin indicated for both therapeutic indications in neuroscience and aesthetic indications. In the Czech Republic, which segment drives the growth?

Dysport is the market leader in both therapeutic and aesthetic indications. However, in neuroscience, Dysport still has significant growth potential as there is a considerable pool of patients suffering from muscle spasticity who could benefit from the treatment. While patients receive excellent care in the acute phase, patients who develop chronic spasticity, after suffering from a stroke, for instance, somehow get lost in the system. Together with HCPs and key healthcare centres, we are designing programs aiming to provide patients and their families with

information about treatment options, how to prevent spasticity, and how to minimize the severity of the condition. Many patients are simply not aware that botulinum toxins can dramatically improve their symptoms. Moreover, HCPs are also not accustomed or comfortable with injecting the toxin as a treatment to spasticity. Therefore, we work on two fronts in parallel by educating healthcare providers, KOLs and specialists on one hand, and increasing the awareness of patients and their families of existing treatment options on the other. In addition, although Dysport is reimbursed in therapeutic indications, the budget allocated to the treatment is limited. From the perspective of healthcare providers, it is not easy to start with new ways of treatment if their budget is linked to the past. We negotiate with payers for them to give more space to this treatment in their healthcare plans in order to address this unmet need as patients deserve to be properly treated.

Although there is a long journey ahead of us, we have already seen significant improvements. The number of patients is increasing, and we are growing much faster in the therapeutic indications than in the aesthetic business.

As you mentioned, in the Czech Republic, patients' access to innovative drugs is a complicated and lengthy process. What are your thoughts on the progress made and rooms for improvement in this regard?

We have seen quite a significant improvement over the last couple of years. As individual companies, but also through the Association of Innovative Pharmaceutical Industry (AIFP), we have had fruitful discussions with the Ministry of Health (MoH) and SUKL which have led to an improved, more predictable overall process with fewer bottlenecks. The MoH and SUKL are aware of other limitations in the current system, and new legislation should improve access. In particular, there is currently no standard pathway for orphan drugs to be assessed, priced and reimbursed. However, the MoH is drafting an amendment to the Act on Public Health Insurance which aims to change the situation. Despite the challenges and uncertainties, Ipsen is investing in the rare diseases field. As a result, we are extremely interested to see how we can improve access to new therapies for ultra-rare, complex and difficult-to-treat diseases for which there are no alternatives for patients. I am glad that the Minister of Health and other authorities are aware of the situation and that new legislation is being discussed to improve access to those orphan drugs.

The Ministers of Health of the Czech Republic, Poland, Slovakia, Hungary and Lithuania recently agreed to share information and jointly negotiate innovative drug prices. If this mechanism sees the light of day, what challenges and opportunities could it bring to your overall CE operations?

This is an interesting question which does not have an easy answer. While governments and payers are trying to increase price transparency, it also comes at a risk. Simply comparing prices between various countries does not necessarily reflect the differences and nuances between their respective systems. If price becomes the main measure to grant access, then these countries run the risk of further delay of access to innovation to their population. Even nowadays, the Czech Republic, Hungary, and Poland are the countries with later access to innovative medicines, in part because prices are set through a reference system based on the lowest prices available in Europe. If getting the lowest price in Europe continues to be the focal point, I am afraid that access to innovation will worsen. Moreover, in Europe where there is free movement of goods, low prices encourage parallel exports, decreasing the availability of drugs for Czech patients, a problem which the Minister of Health is trying to address. We try to explain these issues to authorities by engaging in regular dialogue.

In Consumer Healthcare, Ipsen significantly grew its presence in the Czech Republic and Central Europe with the acquisition of five OTC products from Sanofi in 2017, many of which had already been marketed in the region before. How have you continued to increase your presence of the Consumer Healthcare segment?

Consumer Healthcare in the CE region represents a growing opportunity. The strong awareness of the SMECTA umbrella brand has paved the way to build a strong portfolio of products in the area of gastroenterology. We do not only offer new ways of delivering SMECTA, but we have also launched completely new combinations of SMECTA with different brands, providing more complex solutions than in the past. The second pillar, still in the area of gastroenterology, is made up of our colon-cleansing solutions where Ipsen is the market leader, with our FORTRANS and EZICLEN/IZINOVA brands. We will continue to strengthen our portfolio in those two pillars and to look at other growth opportunities.

When we met with CEO David Meek, he talked about the One Ipsen mindset whereby the entire organization “needs to start every day with the patients’ best interests in

mind” because “after all, Ipsen’s best interests are the patients’ best interests”. How are you bringing this patient-centric mindset to the Central European region?

Patients are at the heart of everything we do. We have recently adjusted the organization in order to focus completely on patients. We have designed an organization focused on establishing a regular dialogue with patient groups as well as with experts in the areas of oncology, neuroscience, and rare diseases, and other stakeholders, so that patients can have access to our new products or new indications faster.

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