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My priority leading LEO Pharma Inc. in the US is attracting, developing and retaining members of our team. We have focused on building a company culture and narrative that reflect our mission and direction

26.06.2020

Tags: USA, LEO Pharma, Dermatology, Strategy

Christopher Posner, US head for Danish medical dermatology specialist LEO Pharma, outlines how a mid-sized European company navigates the US market's complex access and affordability issues, the innovations that the company is bringing to the US, and his leadership and HR philosophy.

Chris, could you give us a brief overview of your career highlights prior to joining LEO Pharma in the US?

I joined LEO Pharma nearly three years ago; I was appointed EVP of Region US for LEO Pharma in July 2017. My career started in 1998 with Merck & Co. (MSD outside the US and Canada) after which I moved on to Endo Pharmaceuticals, where I spent four years. Following that, I joined Wyeth, which subsequently became Pfizer. That was when I really moved into the immunology space. After five years with Pfizer, I was briefly with Bristol-Myers Squibb before co-founding a start-up with two colleagues in August 2014.

The main reason I joined LEO Pharma was to spearhead the growth and development of the US business. LEO Pharma’s mission is to help people achieve healthy skin, and our vision is to be the preferred dermatology care partner. We are singularly focused on medical dermatology, and I find that incredibly motivating. As a Danish company founded in 1908, the company’s main markets have centred on Europe, understandably. The US affiliate was established in 2009, so it is just over

10 years old. We are still a rather young organisation.

I was very excited to lead LEO Pharma's charge to become a leader in medical dermatology within the US. Up until now, our presence in the US has been centred around topical treatments for diseases like psoriasis, actinic keratosis and rosacea. As a company, LEO Pharma has continued to develop new and innovative therapies. That will be the growth driver for our company in the US and globally over the next few years.

After ten years in the US market, what is LEO Pharma's current positioning? How does a mid-sized European company like LEO Pharma deal with the complex issues of access and affordability in the world's largest market?

There are over 3,000 skin diseases, and there are hugely significant unmet needs in medical dermatology. LEO Pharma is committed to developing novel medicines that treat these significant unmet needs. We have a rich pipeline and robust R&D activities. Our assets are either first-in-class or best-in-class and they target debilitating dermatologic diseases that can be complex and difficult-to-treat.

Tralokinumab, our investigational biologic in development for adult patients with moderate-to-severe atopic dermatitis (AD), is an excellent case-in-point. We believe biologics will become a mainstay in AD treatment. If approved by regulatory authorities, tralokinumab will become a key growth driver for LEO Pharma in the US and globally.

Access and affordability are critical topics in the US and global markets. Our efforts begin during the R&D process. We focus on significant disease areas within dermatology that do not have solutions. That builds the value proposition of our medicines from the beginning. We are also aware that payers are increasingly becoming an important stakeholder with needs that we have to understand and address. Therefore, we involve payers early in our clinical development process to ensure our investigational medicines, if and when approved, meet the needs of all stakeholders.

At the end of the day, it is not enough to provide innovative medicines. We also need to do our best to ensure that payers are willing to reimburse them, and patients have access to them.

Access and affordability go hand-in-hand. We cannot address one without the other. I am very focused on maintaining the affordability of our medicines for patients in the US We have implemented programs to support access for patients. For instance, the LEO Pharma Connect program helps keep out-of-pocket costs low for commercially insured, eligible patients. We

currently have three marketed medicines in the US, and I am proud that our approach has led to broad commercial access for most patients.

Overall, the US market has certainly been a healthy contributor to LEO Pharma globally and, over the next five to ten years, we will become a major contributor.

Can you tell us more about your upcoming atopic dermatitis (AD) product, tralokinumab?

An investigational therapy under clinical development, tralokinumab is a fully human monoclonal antibody that specifically neutralises the IL-13 cytokine, a key driver of the underlying chronic inflammation in AD.

In its three pivotal Phase 3 trials that involved nearly 2,000 patients, tralokinumab met its primary endpoints at week 16 as assessed by the Investigator Global Assessment score of clear or almost clear skin (IGA 0/1) and at least a 75 percent improvement in the Eczema Area and Severity Index score (EASI-75).

Tralokinumab also demonstrated significant improvements in secondary endpoints, including the extent and severity of skin lesions, pruritus (itch) and health-related quality of life measures at week 16, when administered once every two weeks with or without concomitant TCS use. Secondary endpoints assessing AD signs and symptoms were measured by changes in the following scores: SCORing Atopic Dermatitis (SCORAD), Pruritus Numeric Rating Scale (NRS) and Dermatology Life Quality Index (DLQI).

The most commonly reported adverse events in the Phase 3 trials that were higher with tralokinumab than placebo included viral upper respiratory tract infections, upper respiratory tract infections, conjunctivitis, headache, and injection site reactions.

AD is a chronic, inflammatory, heterogeneous skin disease characterised by intense itch and eczematous lesions. It is the most common inflammatory skin disease in the developed world, affecting up to five percent of adults across the US, Canada, Europe and Japan.[1],[2] The burden is higher with greater AD severity, which has been patient reported as moderate in 20–37 percent and severe in 10–34 percent of patients. Severity varied by scale and region.[2] AD can really be a debilitating disease with a severe and significantly negative impact on the lives of patients.

Tralokinumab is an important step in our ambitious growth journey and the transformation of LEO Pharma.

What other innovations can we expect from LEO Pharma in the US market?

An important pillar of our 10-year strategy moving forward is rare dermatologic diseases. In 2018, LEO Pharma established a strategic development and commercialisation collaboration with PellePharm, based in San Francisco, for an investigational medicine in Phase 3 clinical research and development for Gorlin Syndrome.

Gorlin Syndrome is a rare, genetic disease characterised by constitutional, heritable mutations in one allele of the tumour suppressor gene encoding PATCHED1 (PTCH1), which acts as the primary inhibitor of the hedgehog signalling pathway. This leads to the formation of multiple basal cell carcinomas, often on the face.

Can you share a few words on your leadership and HR philosophy?

My priority leading LEO Pharma Inc. in the US is attracting, developing and retaining members of our team. We have focused on building a company culture and narrative that reflect our mission and direction. The keyword I use when I speak to potential candidates is ‘growth’. If someone wants to be part of an exciting growth story, LEO Pharma is the place to be. We are looking for people with the right combination of ability and experience. At LEO Pharma, we firmly believe that we are “One Team. One Mission.” and we want to have entrepreneurial people that are keen to be part of something bigger. This is a very compelling and attractive opportunity.

The COVID-19 pandemic has heightened our efforts in culture-building. Since stay-at-home orders and quarantines began in mid-March, we had to adapt to what we expect will be a new normal. LEO Pharma has always focused on empathy, trust and connection. During this difficult period, we have doubled down to really listen to the concerns, priorities and needs of our employees. This has allowed us to continue to manage our operations in a safe and effective manner for both internal and external stakeholders. For instance, my leadership team and I conduct weekly town hall meetings with all US employees to help stay on the same page.

A great example of this successful culture is in the relaunch of our product for rosacea in April. This product had been out-of-stock for about a year. Given the pandemic, we decided to launch the

product virtually. A number of ideas that made the launch possible came from the field as we listened to people on the ground who are closest to our customers. It was great to see the energy and creativity behind this virtual launch. I am also proud of my leadership team for being able to pivot and make decisions quickly. After two months, the launch has exceeded our expectations and patients once again are able to receive our medicine.

A final message to our international audience?

2020 has been a very disruptive year, particularly in the US In times like these, it is really important to focus on the fundamentals – my mandate as a leader and our mission in the US

Our “North Star” is the patient. Our job is to deliver medicines that matter to patients who need them. My job is to ensure the safety of my team and colleagues while keeping the business going strong. We need to remain agile and committed to our mission while incorporating new tools and technologies to continue engaging with our stakeholders.

References

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[2] Barbarot S et al. Epidemiology of atopic dermatitis in adults: Results from an international survey. Allergy. 2018;73(6):1284-1293.

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