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True leadership in healthcare comes from continuously advancing science

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Duane Barnes, President of Sobi North America, outlines how the company has rapidly expanded its presence in the region to become a key player in rare diseases, growing its US business more than twenty-fold over the past decade. He discusses Sobiâ??s strong focus on haematology and immunology, the companyâ??s upcoming pipeline, and the unique challenges of ensuring access and awareness in ultra-rare conditions. Barnes also reflects on Sobiâ??s patient-centred culture, its recognition as the top-ranked company for corporate reputation in rare diseases, and the importance of maintaining an environment that continues to support innovation and patient impact.

Could you begin by giving an overview of Sobiâ??s footprint in North America today and the impact that company has in the US rare diseases market?

Over the years, I have learned that impact can be measured in several ways: by the number of patientsâ?? lives impacted and the revenue generated to fuel future innovation. Using those measures, North America, and particularly the US, has been an area of significant growth for Sobi since our CEO, Guido Oelkers, took on his role about eight years ago. At that time, Sobi had just one product in the US and none in Canada. Guido recognised that in order to expand patient access and deliver on our potential for innovation, we needed a much stronger presence in the region.

Since then, our business in the region has grown roughly eighteen-fold. This growth reflects both the strength of our assets and, more importantly, our ability to meet the needs of patients with rare and

debilitating diseases. Our presence in the US really began to take shape with Synagis, a product we acquired from AstraZeneca that was originally developed by MedImmune. It was used to help protect infants at risk of respiratory syncytial virus. Although Synagis is no longer part of our portfolio, it played a key role in establishing the foundation on which we built both the right culture and the right team.

That initial focus on the US market was a core part of Guidoâ??s strategy back in 2017, and it has clearly paid off. We have evolved from a small regional operation with one product to a robust organisation with five marketed therapies and another expected to launch mid-next year. This trajectory reflects both the strength of our focus and our belief in the long-term potential of the North American market.

Globally, Sobiâ??s portfolio spans the areas of haematology, immunology, and specialty care. How is this therapeutic balance reflected in the region?

Our core therapeutic areas in North America today are immunology and haematology. While Sobi has historically had a strong presence in specialty care, our portfolio has evolved as product life cycles and business priorities have shifted. Because we often acquire products that are already in or near market, rather than developing all assets from the earliest phases, we must continuously plan for the future and refresh our portfolio to meet patient needs.

Today, we have several products in haematology and immunology, including treatments for immune thrombocytopenia, myelofibrosis, and immunotherapeutic cytopenia. Another important asset is a treatment for haemophagocytic lymphohistiocytosis, or HLH, in the ultra-rare disease space. This is a severe, life-threatening condition caused by an overactive immune response. Our therapy helps stabilise the immune system, giving patients the opportunity to safely progress to a bone marrow transplant, which is the ultimate goal of treatment. Earlier this year, we expanded the indication to include macrophage activation syndrome (MAS), which broadened access for more patients with related conditions.

HLH is an incredibly rare and devastating disease, and awareness among physicians has historically been limited. We have made significant progress in building education and understanding across immunology specialists in North America, therefore helping clinicians to identify and diagnose patients sooner. Our product remains the only FDA-approved treatment for HLH, and we are deeply committed to supporting the families affected by this condition.

Beyond HLH, we also market anakinra, an IL-1 receptor antagonist used to treat rheumatoid arthritis and certain autoinflammatory conditions. It has proven especially effective in complex cases where other therapies have failed, making it a vital option for patients with difficult-to-treat diseases.

Across our portfolio our focus is on bringing meaningful therapies to patients who often have few or no alternatives and doing it with urgency. Time is often critical for these individuals and their families, so we aim to work quickly and efficiently to bring them the treatments they need.

Looking at Sobiâ??s upcoming pipeline, what are you most excited to bring to market in terms of patient impact and driving future growth?

One of the products we are most excited about is a therapy for uncontrolled or chronic refractory gout, which we expect to launch in mid-2026. Currently there is only one approved infusion therapy

available for this condition that has been proven effective in lowering serum uric acid (SUA) levels. If approved, our upcoming product will be the second infusion therapy on the market. So far it has shown a significant ability to reduce SUA in patients where an unmet need still exists

While there are a few small-molecule therapies available, these are often used as rescue treatments or are not optimal for patients with a severe, refractory condition. If approved, our new therapy is expected to address that unmet need by targeting the root cause of persistently high SUA, which is what drives reoccurring gout.

Gout often presents as sudden, painful flares, but itâ??s also a systemic immunological disease that can lead to chronic inflammation and the formation of tophi, which are large uric acid deposits that can be visibly disfiguring. Beyond the physical discomfort, it can be deeply debilitating and have a profound impact on quality of life. By hopefully bringing a new and effective treatment option to this patient population, we are excited about the potential to make a meaningful difference in symptom control and long-term disease management.

The US rare disease landscape presents a very distinct set of challenges compared to most European systems that have a single payer. What are the unique characteristics and the key considerations you must keep in mind when working to ensure patient access to these therapies?

Access here depends heavily on understanding which patient populations are being addressed and which payers are in charge of their care, whether that be government-funded programmes such as Medicare, Medicaid, and the Veteranâ??s Affairs, or commercial insurance. For example, in gout, most patients fall into the older populations, so we are often working within government-managed programmes.

Every new product launch requires us to look carefully at who the patients are, where they are treated, and what reimbursement landscape applies. We also have to consider whether a product falls under Part B or Part D, meaning whether itâ??s physician-administered or a small-molecule drug dispensed through a pharmacy. Those differences may have an impact on access and availability.

Diagnosing patients in rare and ultra-rare diseases is one of the most difficult tasks in this segment. Many physicians may not have the right tests in place or do not immediately think of a rare disease as the underlying cause of health challenges, which can lead to delays in diagnosis. In some of these cases, that delay can be life-threatening, or it can mean a significant decline in a patientâ??s health before they finally get the right treatment.

It all comes down to connecting the dots and making sure the testing exists, that doctors know when to use it, and that there are clear referral pathways to specialists who can treat these conditions. On top of that, you have to navigate reimbursement, treatment settings, and payer requirements. Itâ??s a very complex environment, but that is also what makes it so rewarding when we are able to remove some of those barriers and see a patient finally get the care they need.

How does Sobi address the challenges of raising patient awareness, improving diagnostic pathways, and ensuring access to specialist careâ??all of which are critical in the rare disease space?

Raising awareness and improving diagnosis in rare diseases is always a challenge, and HLH is a good example of that. When we first brought emapalumab into the Sobi portfolio several years ago, it was only approved in the US and targeted 5,000-7,000 HLH patients a year, though not all are ever identified. Primary HLH is genetic, while secondary HLH is not, which makes it even more complicated to recognise. When a physician sees a patient presenting with these symptoms, HLH is rarely the first thing that comes to mind, simply because itâ??s so rare. Meanwhile, the patientâ??s condition can deteriorate rapidly while doctors try to determine what is actually happening.

At that time, there were only a handful of centres of excellence in the US that could reliably diagnose and treat HLH. These include Cincinnati Childrenâ??s Hospital and the Childrenâ??s Hospital of Philadelphia. Outside of those few institutions, awareness was very limited. We have worked hard to change that by building broader understanding of the disease across the physician community and expanding access to diagnostic tools such as the CXCL9 test, which helps identify HLH. That test was once only available in a few hospitals, but today, is far more widely used thanks to ongoing collaboration with clinicians and hospital systems.

Each rare disease comes with its own unique challenges, but there are a few common priorities that guide our work: increasing awareness among patient and advocacy groups, helping physicians recognise early symptoms, ensuring that testing and diagnostic tools are available, and making sure patients can access the right treatment at the right time. Itâ??s a complex process, and it looks different for every therapy, but ultimately it all comes back to the same goal of shortening the time between symptom onset and diagnosis so patients can get the care they need as quickly as possible.

The recently passed One Big Beautiful Bill Act included provisions expanding the orphan drug exclusion under the Inflation Reduction Act. However, how do you see any risk for the overarching policy ambitions around pricing influencing the rare disease sector and patient access in the US?

The idea of implementing Most Favoured Nation (MFN) pricing in the US has come up under several administrations over the past decade. However, it has always proven difficult to move forward because of just how complex the execution is. If the system is ever introduced, policymakers would likely begin with the big-ticket products that offer the greatest government-sponsored healthcare savings potential. Even then, there would still be significant legal and operational questions about its validity, and litigation will likely determine whether and how MFN pricing gets implemented. The policy would also primarily apply to government-funded programmes rather than commercial markets.

For companies like us, the level of exposure to such policies depends heavily on whether products are reimbursed through government channels or commercial insurance. Products with a high proportion of Medicare or Medicaid patients would of course carry more risk. Still, one of the fundamental challenges is determining which countries would be used as reference points for pricing.

When you look at the rare disease space, the scale is completely different from other therapeutic areas. We are not dealing with multi-billion-dollar markets like those for GLP-1s, for example. Our therapies are targeted to small, severely ill patient groups, and the revenues are much more conservative by comparison. Implementing reference pricing or similar mechanisms across such specialised products would be complicated and have a much lower saving potential.

That said, there is no explicit protection for rare disease products, so the risk canâ??t be entirely ignored. Still, the reality is that pricing reforms are cyclical. Each administration brings a new set of policy priorities, and the landscape can change quickly. For now, we are focusing on the practical realities like tariffs, which have always been placed on APIs for example.

Sobi was recently ranked first by PatientView for corporate reputation within the rare disease space. How do the companyâ??s values shape this approach to acting as a trusted and patient-centred healthcare partner?

Sobiâ??s culture is deeply rooted in our core values of Care, Ownership, Urgency, Partnership, and Ambition. Care sits at the heart of everything we do. We are driven by a genuine passion to understand and respond to patient needs, recognising that every disease area and every individualâ??s experience is different. Urgency is equally important because in the rare disease community, time matters. Many of the patients we serve are seriously ill, and delays in diagnosis or treatment can have major consequences. That sense of urgency defines how we approach our work and how we make decisions.

Partnership is another key value because collaboration is essential to making progress in rare diseases. We work closely with hospitals, payers, advocacy groups, and other institutions to build awareness, improve disease understanding, and ensure access to treatment. These partnerships help build a stronger ecosystem of support for patients and their families.

Finally, we are all driven by a sense of ownership and ambition. We see it as our responsibility to make a meaningful impact, and we encourage an entrepreneurial spirit among our teams. Across all our therapeutic areas, from myelofibrosis and immune thrombocytopenia to Stillâ??s disease and HLH, we show a relentless commitment to helping people in need.

Sobiâ??s CEO, Guido Oelkers, has stated that the companyâ??s growth journey will continue through advancing innovative treatments in rare diseases. How is this global growth vision being translated into strategy and action within North America?

Our focus in North America is fully aligned with Guidoâ??s growth ambition. In the region, we are strengthening our impact in haematology and immunology, successfully launching our new gout product next year, and expanding our presence in oncology. Over the past four years, we have grown by more than 50 percent in the US alone. We will continue to grow our business to enable an innovative and healthy environment for the entire global organization.

Equally important is our commitment to culture. We take great pride in fostering a collaborative and entrepreneurial environment where people feel empowered to share ideas and challenge the status quo. Our recognition by PatientView reflects this culture of trust, integrity, and partnership.

Looking ahead, we aim to further strengthen our leadership in haematology, where we currently have two products on the market. Although one of these will reach the end of its lifecycle in 2027, it has shown exceptional growth, and we intend to build on that momentum.

Overall, North America is a critical growth engine for Sobi. This is not only because of the marketâ??s size and maturity, but also because of its ability to generate innovation and meaningful impact for patients. I am fortunate to work with a global leadership team that understands the importance of this region and fully supports our strategy to drive innovation, expand access, and

deliver long-term value for patients and the company.

What final message would you like to share to the US and global healthcare and life sciences community?

When we talk about the US as an enduring global powerhouse of life science, itâ??s not just about scale, but also innovation. True leadership in healthcare comes from continuously advancing science. This is a mindset we need to be maintaining in the US. Our continued leadership in healthcare depends on creating an environment that supports discovery, investment, and patient access.

My hope is that, as an industry, we remain focused on enabling innovation rather than constraining it. Policies and market factors should not impede the progress and innovation needed to help patients worldwide. And within Sobi, I am grateful for the strong support we have from our CEO, our board, and the wider organisation to keep driving growth and patient impact in North America.

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