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Paul Newton of Vertex Pharmaceuticals - one of the first biotech firms to use an explicit strategy of rational drug design rather than combinatorial chemistry - outlines the company's footprint in Benelux, how it is looking to take learnings from its success in cystic fibrosis treatment into new therapeutic areas, and gives his take on the pricing and reimbursement scenario in his region.

You have had quite an impressive global career - working with Sanofi in the UK and UCB across the UK, Turkey, Ireland, and CEE. Can you tell us about your professional journey and how you draw on this experience in your current role as Senior Country Manager Benelux at Vertex Pharmaceuticals?

I started my career at French pharma company Sanofi, where I worked in the UK for 12 years. Sanofi was a fantastic place to learn about the pharmaceutical industry from a commercial perspective. I had the opportunity to work across different commercial functions and disease areas such as schizophrenia, bipolar disease, neurology, epilepsy, and diabetes. Working in these disease areas allowed me to see what it's like for people to live with chronic debilitating conditions, and how important it is to bring transformative medicines to these individuals.

After Sanofi, I worked for a Belgian company, UCB, for around 10 years. This was an amazing opportunity for me because I had the chance to work across different geographies, covering

different parts of Europe, and had various assignments in Turkey working in marketing, business excellence, and business development roles for the affiliate. Later, I took on additional responsibility for all the mature products and established brands in Turkey. Working in these different environments gave me the opportunity to develop different skills as well as be agile and responsive to market and economic changes. It also taught me resilience, which is a key value in my opinion.

Working at UCB also allowed me to learn about different cultures and the importance of organizational culture. I came to understand how important it is to have a culture that you identify with and respect.

Since around 2010, I had been following Vertex's journey and the tremendous scientific innovation they have achieved. In 2018 I was approached by Vertex for a market access role with the purpose of leading the commercialization of our portfolio in the emerging markets of Russia and CEE. The past five years with Vertex have been an amazing journey and I am continuously impressed by the emphasis on scientific innovation along with the company's strong culture of inclusion, diversity & equity. The mutual respect that everyone has for one another is the glue that binds us together and this is something I have been drawing on since I became Senior Country Manager of Benelux in 2021. All in all, it's been a very fascinating and rewarding career so far.

Can you offer a brief introduction to Vertex Pharmaceuticals and what the company's areas of focus are?

Vertex is a global biotechnology company that focuses on treating patients with serious diseases that have a high unmet medical need. Our mission is to impact the lives of these patients with transformative medicines by addressing the underlying cause of the disease, rather than just treating symptoms. This is where Vertex's approach to research and development differentiates us from most other companies. Our approach to R&D revolves around understanding causal biology and developing validated targets and biomarkers that are clinically meaningful and translate from bench to bedside.

We do not just focus on one particular therapeutic area, but carefully choose the best strategy to address diseases based on our understanding of their causal biology. This might involve developing small molecules or partnering with other companies for technologies like mRNA or gene editing. We invest 70 percent of our operational expenditure in research and development, and three out of five employees work in R&D, which is almost unparalleled within the industry.

Our approach has been validated through the development of cystic fibrosis treatments that have successfully transformed the lives of patients by addressing the underlying cause of the disease rather than just addressing symptoms.

Vertex's mission to deliver scientific innovation and create transformative therapies drives our entire philosophy, including our differentiated R&D strategy, which involves developing our own technologies, partnering with other companies, and even acquiring other companies when necessary. This approach has allowed us to develop a broad portfolio of platforms and potential treatments in the biotechnology space. With world-leading experts from the lab to the commercial organization, we aim to quickly bring these potentially transformative medicines to patients. The biopharmaceutical industry is currently going through an exciting transformation, as we have gone from identifying mutations causing cystic fibrosis to developing small molecules, and now to having the ability to edit genes. However, this also brings challenges for all stakeholders. At Vertex, we move quickly to stay ahead of the pace of change in the industry.

Vertex Pharma's market capitalization has soared to over USD 80 billion in recent years. However, we often see that even American biotech companies with a global footprint still have a significant portion of their business coming from the US. Has this global success been replicated outside of the US and in your region?

While we are a Boston headquartered company, our success at Vertex Pharmaceuticals is not limited to the United States, where we have our headquarters and R&D facilities on both coasts. We also have a significant presence in Europe, including our international headquarters in London and an R&D facility in Oxford, UK. We have been able to commercialize our products in nearly all European countries as well as the UK, and our international business has become a key growth driver for us. While the US remains the largest pharmaceutical market in the world, our international markets are seeing faster growth. We are now looking to expand further into emerging markets such as Latin America. As a company, we are very matrixed and have a strong leadership team throughout Europe and in London, as well as Boston, and we work together closely to achieve our goals.

As a modestly sized European cluster, what relevance does Benelux have for Vertex more broadly?

Our Benelux affiliate is a sales and marketing organization with a strong medical team, of course, based out of Haarlem (NL), but our presence is continuously evolving and expanding. Vertex incorporated a Belgian legal entity at the start of last year, and we are now looking to expand our team and prepare ourselves for the next phase of our journey. As part of this, we are looking for new office space to accommodate our growing team in Belgium. As a manager, I recognize that our organization is only as good as the people we have, and I am lucky to have inherited a tremendously talented team. However, I always strive to continuously develop our Benelux team to be well-prepared for the future.

In terms of portfolio, we have achieved reimbursements for all our cystic fibrosis therapies in Belgium so far. Currently, we have four products approved for CF, which can treat approximately 85 percent of patients in the country. However, there are still about 2,000 different mutations that cause the disease, with some being untreatable with current small-molecule therapies. Therefore, we continue to work on new therapeutic innovations to bring to patients.

In addition to commercial operations, we also have a strong medical presence in Benelux as this region is considered a biopharmaceutical hub with a history of delivering clinical trials. Our clinical team reports directly to Boston and runs trials locally, having completed 40 clinical trials in Benelux of which 20 are in Belgium alone. These trials cover not only cystic fibrosis but also other disease areas, where we have been working with CRISPR Therapeutics on gene editing technology that could potentially transform the lives of patients with debilitating illnesses. Belgium is therefore a crucial market for Vertex, and we closely follow any developments that happen in the Belgian environment.

As you are looking to grow Vertex's positioning in Benelux, what has been your experience with the local talent?

I've had an extremely positive experience with our local team here in Benelux. One of the challenges in the pharmaceutical industry, and probably all industries, is that we're at near full employment, so recruiting takes time. However, there's an abundance of talent in the biopharmaceutical industry here due to the amount of investment, which is fantastic. I've been fortunate to work with tremendously qualified people, and I've had an opportunity to meet even more through my activities with Pharma.be and various networking events. Meeting the talent here reassures me that the business and the industry are in very safe hands in Benelux. I'm confident that we'll be able to bring on board some great people to our local organization, and we need to

continue to invest in people and the industry to keep the pipeline strong for Belgium and the Benelux area.

CEO Reshma Kewalramani has said that Vertex is at “a new inflexion point today ... we want to replicate what we’ve done in cystic fibrosis and transform, if not cure, multiple additional diseases”. How is this move playing out on a Benelux level as you and your team prepare the ground to move into new therapeutic areas and technologies?

I believe that the move towards transforming and potentially curing multiple additional diseases is playing out very well on a Benelux level. The main driver behind this move is the science and the progress that we have made in cystic fibrosis. We have gone from only being able to address 5 percent of the CF community to now having a portfolio that can address 85 percent of patients. This success has given us the opportunity to explore different disease areas beyond cystic fibrosis, and we are now in five other therapeutic areas where we have gone beyond proof of concept.

However, we know that branching out into new disease areas will require us to reflect on what we’ve learned from our experience in CF and what we can improve upon. As a lifelong learning organization, we are constantly having conversations about what we need to do to get ourselves and our teams ready for this journey. We are also looking at the skills and behaviours that we need to prepare for the introduction of new transformative therapies for patients in the Benelux.

I am confident that we will continue to make progress and hope to see marketing authorization for truly innovative treatments in other serious diseases, in the coming years. Overall, I believe that Vertex is well-positioned to replicate its success in cystic fibrosis and make a significant impact in the treatment of other diseases.

How important is cystic fibrosis in Belgium in terms of relevance, stakeholder prioritization, and the patient journey?

Although CF is categorized as a rare disease, it is absolutely an important disease in Belgium and the most prevalent of rare diseases. In Belgium alone, it affects around about 1300 people and its impact on patients and their families is considerable. Thankfully, the healthcare system in Belgium prioritizes the treatment and care of CF patients, and there is a strong focus on further R&D for this disease. Additionally, patient advocacy groups and support organizations play an important role in raising awareness about the disease and advocating for better treatment and care for CF patients.

In terms of the patient journey, cystic fibrosis is a very challenging disease. Patients require multiple therapies and treatments, including physiotherapy, and often have to spend significant amounts of time in hospital. This disease also puts a lot of pressure on families and caregivers, who have to provide constant support and care for the patient. However, with the availability of transformative therapies, there has been significant improvement for patients and their caregivers. These new therapies offer the potential to transform the lives of CF patients, allowing them to live a more normal life and have a brighter future.

Many of your industry colleagues have expressed frustration in the reimbursement process which is often quite challenging and slow. What are the specificities of pricing negotiations in the Belgian market and are your arguments well received by the relevant government stakeholders?

From my perspective, as a biotechnology company, it's crucial that Vertex brings transformative medicines to patients in countries like Belgium. Therefore, I believe it's the responsibility of governments to have efficient processes in place to ensure these medicines can be made available to patients as quickly as possible.

I'm proud to say that we've reached an agreement with the relevant Belgian authorities so that all of our medicines are available to all patients in line with the EMA label. Of course, pricing negotiations are always necessary, and the willingness to pay must be considered. However, I believe that the transformative nature of treatments must be recognized, and if it is, then a proper discussion on the value should follow. Through collaboration and active listening with the authorities, locally driven solutions for access can be achieved, as has been the case for us.

I hope that governments will always find a way to reward true innovation and pay for the transformation when it's justified, as the benefits to patients are clear.

As an industry, we have a responsibility to collect information on reported outcomes and work with health authorities to ensure our products are doing what we said they would. I'm pleased to hear about new policy initiatives that focus on capturing real-world evidence to ensure that our products perform as expected.

Uncertainties and clinical questions must also be managed, and we periodically present data to resolve these uncertainties. It's important to have good policies in place that ensure sustainable reimbursement, as the changes we make now will affect not only the pharmaceutical industry but

also patients for generations. It's our duty to think carefully about what we do and have a good dialogue with all stakeholders, including patient organizations, healthcare professionals, and academia, and to listen to each other. I believe this is key to making positive changes in the industry and ultimately benefiting patients and society.

Do you feel that the Belgian authorities are open to these conversations and sitting down at the table to collaborate with the industry?

Yes, I do believe that the Belgian authorities are open to having these conversations with us. I have seen signals that they are listening to our concerns, and I hope that this continues. Our industry representatives at pharma.be are doing a great job of representing the views of its members and patients in discussions with various stakeholder groups, including the government. I believe that if we listen to each other, we can work together to create a sustainable healthcare system that benefits patients, healthcare systems, and society as a whole.

What would you highlight as your ambitions for the Benelux affiliate at this exciting moment in the company's development?

It is absolutely an exciting moment in the company's development and my ambition for the Benelux affiliate is to create a strong and healthy team that not only embodies our culture but is also prepared for the future.

One of my main goals is to foster a culture of inclusion, diversity, equity, and respect within the team. I believe that this is crucial for building a solid team that can engage in dialogue with different stakeholders, listen to their views, and represent our company and patients with a strong and consistent voice. And this is something that I would like to see happening not just now, but also in the future. If I can achieve this ambition, then I would consider myself to have been very successful and lucky to do so.

Speaking about Vertex, I think we are true to our mission, and our scientific innovation is almost unparalleled. What excites me every day is the combination of our amazing culture with our mission to develop innovative treatments to transform the lives of patients living with serious diseases, in Belgium and beyond. I feel proud to be a part of this company and it truly feels like home.

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