Interview: Kurt Stoeckli – Managing Director, Glenmark Pharmaceuticals S.A., Switzerland

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The Chief Scientific Officer and President of Glenmark Pharmaceuticals Swiss R&D Center elaborates on Glenmark's endeavor to venture up the pharmaceutical value chain and discusses the company's R&D strategy. Furthermore, he highlights the significance of strategic partnerships in today's pharmaceutical R&D efforts.

You have spent 23 years working in large innovative pharmaceutical companies. What motivated you to join Glenmark?

Over the course of my career, it became clear to me that large pharmaceutical companies do not differ that much from one another. They share the same challenges, they use highly similar approaches and their organizational mechanics are typically the same. In 2016, when I met Glenn Saldanha, the MD and Chairman of Glenmark Pharmaceuticals, I learned about his story and vision, and it simply fascinated me. His father started the company in a garage in Mumbai in 1977, driven by the vision to build a company providing affordable medicines to patients around the globe. A little more than a decade ago, Glenn made a strategic business decision to enter innovative pharmaceutical drug discovery and development, and he opened this Swiss R&D center to realize that goal.

I found myself at a crossroads, having to decide whether I wanted to remain in big pharma for the rest of my career or join this true visionary and support him in making this journey happen. I was

convinced that I could use the experience and skills I accumulated in translational science and as an immunologist and biochemist, as well as years of experience in late-stage clinical development, licensing and partnerships, to guide the ongoing journey of Glenmark. The opportunity to apply all of this experience to a company on the cusp of important breakthroughs is ultimately why I decided to join.

Today, you are the CSO of Glenmark and based in Switzerland. Glenmark's main markets, however, seem to be India and the US. Could you please introduce your operations here and define its significance for Glenmark?

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Indeed, the global business of Glenmark is mainly driven by the US market, India, other large markets such as Russia and some select emerging markets in Latin America. These are the real revenue-generating markets today; however, Europe is catching up rapidly. We already have a strong presence in the UK and in Germany.

Today, we are not commercially active in Switzerland but purely focused on R&D. Here in Switzerland, we are tasked with discovery research and technical development dedicated to biologics. The entire clinical supply is conducted in Switzerland, and our affiliate is a Swissmedic approved GMP facility. The mid-term plan is to start our commercial operations here as well, because we have strategically invested in our R&D. Our R&D footprint in Switzerland is unique because it is both dedicated to end-to-end preclinical research and clinical studies of our novel biologics candidates, and it also has the capacity to manufacture these assets on a commercial scale.

Why was Switzerland chosen as one of the R&D centers for Glenmark globally?

In fact, Glenmark has three main R&D sites across the globe. One is in India; it focuses on small molecules used in innovative medicines, specialty products or generics—for example, something like a drug-device combination in respiratory that may help patients suffering from chronic obstructive pulmonary disease. The second research center is in the U.S., focusing on the wider clinical journey including, but not limited to, clinical sciences and operations, regulatory affairs, project management, pharmacovigilance and so forth. Switzerland was an obvious choice for Glenmark to house biologics R&D because the country offers high-quality infrastructure, prospering interaction between private and public stakeholders and increased ease of attracting the best talent to the organization.

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Glenmark recently published its strategic blueprint, which entails the focus on innovative new molecular entities (NME), filing as many as nine new drug applications (NDAs)/biologic license applications (BLAs) in the next ten years and targeting 30 percent of total revenues from the specialty and innovation segments over the next decade. In this context, how would you see your mission as Chief Scientific Officer?

My mission is to lead the transformation from generics to innovation and specialty development, including ensuring that we have the right talent, infrastructure, footprint and core strategy. As we orchestrate this significant transition from a generics company to a specialty company to an innovation company—we are literally walking up the value chain! In essence, we will transform the company's business model for one simple reason. We need to diversify to survive and continue thriving.

Why is it important for Glenmark to engage in this transition to become a more innovation led company—clearly it has been highly successful as a generics company…so why change the "winning formula"?

There are multiple dimensions to the rationale for this decision. The global generics business faces a number of challenges like the decline in small molecule generics opportunities in the U.S., the increasingly competitive landscape with the entry of multiple new players and price erosion. Depending on the region, erosion is about ten percent each year, which results in intense pricing pressure to all companies in this segment. Moreover, the logistics and distribution sector of generics is currently in a consolidation phase, bundling the power within a limited number of suppliers, which poses diminishing returns in our supplier-customer relationship. As highly competitive and demanding as the generics business already is, trajectories indicate that this will intensify further. Moreover, we are currently enjoying an average of 20-percent growth across the different markets we operate in, and we recognize that this level of growth is unlikely to be sustainable.

Another dimension of this strategic decision is that the true breakthroughs and revenue drivers today are typically based on novel biologics. Of course if you think about lifecycle management of biologics, you can develop a biosimilar strategy, which Glenmark is in a position to consider. However, many people assume that biosimilars are simply the equivalent of a generic to a biologic drug. Frankly speaking, it's not quite that simple. The complexity of biologic drugs means that biosimilar development demands far greater resources than generics development. Therefore, I

recommended against making biosimilars a short-term priority until we are able to apply the necessary resources to integrate it as a core part of our business. Instead, I believe that developing new molecular entities (NME) is a more compelling case. The transition toward such a mixed generics-NME business model offers us more options regarding the management of risks and capital expenditures while potentially generating higher margins.

Looking at these targets and your role to meet those, what are Glenmark's R&D efforts focused on and why?

Because we decided to become an innovative biopharmaceutical company, we have to focus on developing breakthroughs that leverage our internal areas of expertise and complement our existing development programs. Obviously, we need to focus on therapeutic areas that complement our generic and specialty assets, particularly in respiratory, dermatology and oncology. Dermatology is already our main revenue-generating segment in generics, and in oncology, we have nine different injectable products. This allows us to leverage existing strengths and key relationships and helps us define Glenmark's strategic blueprint. Right now our furthest pipeline candidate is a potential treatment for atopic dermatitis, which also has potential in other immunological disorders. In oncology, this is an exciting year for Glenmark because we plan to file a number of investigational new drug (IND) applications in both solid tumors and blood cancers.

What will be the role of generics for Glenmark in this transition phase?

Generics will always be a pillar for Glenmark. They are the backbone of the company and fundamental to the core mission, which is to provide affordable medicines to patients around the globe. Our strategy is to live the values of the company and adapt them to accommodate all three pillars: generics, specialty products and innovative products. Of course, the innovative field is already and will continue to become more competitive; however, it is also evolving. It will be important for us to evolve as well, to equip ourselves to take on new challenges, new ideas and positive change.

How important are partnerships with other pharmaceutical companies, universities and healthcare stakeholders within Glenmark's R&D efforts?

This is tremendously important and increasingly essential! In fact, strategic partnerships are part of my mission, because I am convinced that the concept of research being handled independently by any one company is no longer a reality. Today, even the likes of Novartis and Roche opt for open innovation concepts; it is very clear to any pharmaceutical company in the world that it cannot innovate by keeping its perspectives closed to the public. Today's scientific breakthroughs are

undoubtedly exciting, but it is imperative that we consider the potential of discovery through the lens of its real-world impact. We need to ask ourselves hard questions about how an innovation will translate into value for patients, and define the unmet medical gap it will fill, well before we initiate the innovation process.

In a similar vein to open innovation, we are aggressively exploring public sector partnerships. Collaborative efforts with nearby public centers of excellence offer the potential to share resources and risks, learn from each other and exchange expertise and know-how.

What is the added value that Glenmark can bring to potential partners?

The pipeline products I am most excited about are from our oncology pipeline and based on bispecific antibody technology, which only eight to ten other companies in the world can compete with and which may offer significant differentiation from existing treatments with similar molecular targets. Preclinical studies have demonstrated superiority to these current care standards, and our bispecific antibodies may also fill unmet needs for millions of patients who will become resistant to their current treatments. I am convinced that our three main selling points are treatment superiority, an increased therapeutic window of safety and technical feasibility due to our ability to scale up to full commercialization. Moreover, we understand the complete process of a product’s lifecycle from start to finish and have state-of-the-art technology ready to accommodate each individual step. With so much attention paid to biotech IPOs and life-science companies that have the highest market capitalizations, I believe Glenmark is truly unique—it has all the potential of a major biotech and has achieved that potential by transforming organically and evolving internally.

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