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“We intend to establish excellence centres across India, catering to diverse needs of different regions”

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German firm Miltenyi Biotec is launching operations in India with its first office and investing to set up Miltenyi Innovation and Technology Center as Cell and Gene Therapy (CGT) Centre of Excellence (CoE) at Hyderabad. The company is well poised to enable local development and manufacturing in India to drive affordable and accessible CGT therapies by academia and industry for Indian as well as global patients. BioSpectrum India interacted with Dr Boris Stoffel, CEO and Managing Director of Miltenyi Biotec, at length about the company’s growth plans in the Indian market.

How does Miltenyi Biotec plan to accelerate the adoption of cell and gene therapy technology within the research and translational community in India and what strategies are being employed to foster innovation and support local initiatives?

Our aim is to swiftly introduce this technology to the research and translational community in India to spur new approaches. We are actively seeking additional innovation here and are committed to supporting it. In the realm of cell and gene therapy (CGT) today, much revolves around the MACS Prodigy platform. This instrument, though appearing conventional, serves as a cornerstone in autologous cell therapy. It facilitates end-to-end processing of patient cells, starting from sample collection to final cell product delivery.

The Prodigy platform serves as the foundation for many established procedures, with over 250 different cell types and protocols developed in collaboration with physicians, researchers, biotech companies, and the pharmaceutical industry.

Our platform accommodates a wide range of cell types beyond CAR T's and Chimeric antigen receptor-NK (CAR-NK), including stem cells. We assist individuals and small biotechs in adapting their ideas and protocols to the platform, facilitating faster entry into the market by leveraging our extensive experience.

To expedite market penetration, we have established a team of experts locally. Additionally, we collaborate with physicians who are keen on introducing established therapies and new findings to patients swiftly. We are also open to collaborating with large pharmaceutical companies to develop more closed systems, if desired.

What's your strategy to foster collaborations and partnerships with research institutions and biotech companies? Have you collaborated with any pharmaceutical research institutions in India?

Globally, we have partnered with leading biotech and pharma companies like Novartis, J&J and BMS for delivering cell based products in the market. In India we do not have any notable alliance with any company but we are open to form partnerships and collaborations with biopharmaceutical companies, hospitals and other institutions for sharing our expertise and experience in providing cell and gene therapy.

Each year, more than 10,000 patients are treated with cell products using Miltenyi Biotec's technologies. More than 950 investigational new drug (IND) applications as well as investigational device exemptions (IDE) with the US Food and Drug Administration (FDA) are using our technologies and platforms. In doing so, the company is well poised to enable local development and manufacturing in India to drive affordable and accessible CGT therapies by academia and industry for Indian as well as global patients.

Although we have engaged with renowned institutions and organisations like Biotechnology Industry Research Assistance Council (BIRAC) in India, it is still in the initial stage. We realised the importance of daily presence to foster deeper collaborations. Hence, last year, we established a team in India, to strengthen our presence and engagement in the region.

Despite being operational for only a short period, we've witnessed significant interest from pharmaceuticals and biotech companies in India. Moreover, hospitals and oncologists have also shown keen interest, given the urgent need for effective treatments.

How do you plan to deliver your product to patients in India and monitor effectiveness of treatment?

Cell and gene therapy are cutting-edge medical treatment technologies designed to address complex diseases such as cancer and immunodeficiency disorders. Cell therapy involves the injection, grafting, or implantation of viable cells into patients to produce a medicinal effect, such as transplanting T-cells to combat cancer cells or grafting stem cells for tissue regeneration. On the other hand, gene therapy aims to generate therapeutic effects by manipulating gene expression or altering the biological properties of living cells, addressing genetic problems at their source.

These therapies primarily target diseases like immunodeficiency, haemophilia, thalassaemia, and cystic fibrosis, which are often single-gene disorders suitable for somatic cell therapy. The treatment process involves apheresis, where the patient's blood is collected, processed using necessary reagents and the final product is administered to the patient after quality control checks.

However, the logistical challenge lies in coordinating the treatment process within hospitals due to its precise timing and organisation requirements. To address these challenges and advance therapy development, we collaborate with various stakeholders, including physicians, researchers, and biotech startups. Through workshops, training modules and alliances with academia, we aim to foster innovation and streamline the transition from preclinical to clinical stages. Our collaboration extends beyond providing technological solutions; we aim to support partners throughout their journey, including education and technical training. We are prepared to meet this need by offering a spectrum of support beyond technical assistance, including medical discussions and integration into clinical workflows.

Could you share details of your plan to establish a Centre of Excellence in India?

Hopefully, within a 4-month timeframe, we aim to establish our initial lab infrastructure in Hyderabad to begin training personnel. However, to establish such a setup it requires meticulous planning. We intend to commence this process immediately. In the next phase, as our team has already forged relationships with hospitals and biotech companies possessing GMP facilities, we will take our business forward. We're ready to provide support where needed, including potential facility upgrades. Many of these facilities are poised for operation, and some are already functional. Our focus is on rapid dissemination of knowledge rather than constructing a centralised manufacturing facility.

We intend to establish excellence centres across India to cater to the diverse needs of different regions. Hyderabad has been identified as an initial location, with plans for further expansion in key cities like Bengaluru, Delhi, and Mumbai.

Will you be enhancing your workforce in India in next 12 months?

Currently, our presence in India is relatively small, with 11 employees. However, as we progress, we aim to expand our team, emphasising the importance of talent acquisition to drive our operations forward. Additionally, we leverage strong partnerships to serve customers efficiently, with plans to further expand our workforce as needed to meet growing demand. However, we don't quantify our growth solely in terms of employees; rather, we focus on business development. As we're in the initial stages, we're witnessing significant interest. Currently, our priority is assembling a team capable of swiftly integrating various elements. This process may be influenced by our partnerships and regulatory factors, as everyone involved is continually learning and adapting.

Amguth Raju

(hyderabad@mmactiv.com)