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“We anticipate India will adopt decentralised models for managing CGTs, ensuring closer proximity between patients and treatment facilities”

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Cell and gene therapy (CGT) expert from Germany, Miltenyi Biotec has recently announced its entry into the Indian market to provide researchers, scientists and clinicians easier access to expertise, research, and manufacturing solutions. The company is well poised to enable local development and manufacturing in India to drive affordable and accessible CGTs by academia and industry for Indian as well as global patients. In conversation with BioSpectrum Asia, Dr Boris Stoffel, Chief Executive Officer and Managing Director of Miltenyi Biotec, talks about the real challenges associated with the use of CGT, and the way forward.

Could you elaborate on the narrative behind Miltenyi Biotec’s invention of the groundbreaking technology that has led to the development of new procedures for treating diseases through Cell and Gene Therapy? How was this achieved?

Miltenyi Biotec, being a private entity, stands as the pioneer in next-generation technology within the field of Cell and Gene Therapy (CGT). The significance of this technology persists even after 35 years, as it emerged in 1989 at a time when the concept of disruptive technology was still nascent. Looking back 35 years, it's evident that our innovation was disruptive because, at that time, only a handful of labs worldwide utilised large-scale cell sorters. Specialised operators were required to sort immune cells from blood, making it a cumbersome process.

The invention of MACS technology revolutionised this landscape by enabling every researcher to utilise a simple column and antibodies coupled with small microbeads in a magnetic field to separate cells within a short timeframe. This democratisation of technology meant that researchers were no longer reliant on expensive, specialised equipment available only in select labs. At that time, Germany, for instance, had only two such sorters, one of which was located at the Institute of Genetics of Immunology, where Stefan Miltenyi, the founder, was a student.

In the realm of 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.

Could you provide an overview of cell manufacturing for personalised medicine with the CliniMACS Prodigy?

The core of this platform, reminiscent of our innovation 35 years ago, lies in the isolation of specific immune cells, crucial for therapies such as Chimeric Antigen Receptor (CAR) T cells. These cells are then transferred into a cultivation chamber, forming a closed system. Within this chamber, cells can be manipulated and expanded for weeks, culminating in the final product packaged in a culture bag ready for re-implantation.

However, as a global community by facility operations by streamlining processes and leveraging advanced analytics, we can collectively enhance the efficacy of cell manufacturing technologies like the CliniMACS.

How did you translate the new technology into pharmaceutical settings for distribution in patient treatment, and what are the associated costs? Do you believe that cell and gene therapy treatment is affordable for the Indian population, and what is your philosophy in introducing this new technology to India?

As we observe the pricing trends in the US and Europe, where these treatments are offered at substantial costs ranging from $300,000 to 400,000, it raises questions about accessibility, particularly in regions like the APEC where efforts seem minimal.

We believe that these transformative therapies should be accessible to all, regardless of geographic location or socioeconomic status. Traditionally, high-tech innovations tend to first benefit countries with advanced infrastructure, with others reaping the benefits later. However, we challenge this notion. Miltenyi Biotec has had a presence in India for nearly two decades, initially through distribution channels. However, a strategic shift occurred about a year and a half ago. Recognising the global demand for equitable access to therapies, we decided to overhaul our approach. With the support of our network of physicians worldwide, our goal is to make these therapies available to every hospital in India at affordable and reasonable costs, for this we are talking to government agencies, research institutions and other funding agencies that can make it happen.

With your direct entry into the India market, how do you plan to tackle the existing infrastructure, regulatory, and quality control challenges in India?

Miltenyi Biotec has always prioritised quality control, leveraging flow cytometry for product validation. We have developed Benchtop flow cytometry and curated one of the largest collections of recombinant antibodies, ensuring precise and repeatable analyses.

To simplify quality control procedures, we developed MACS-Quant software with express modes, streamlining flow cytometry analyses. This user-friendly approach ensures that even individuals without extensive laboratory experience can conduct quality control assessments effectively. Our aim is to integrate these components seamlessly, enabling individual hospitals to establish units for providing these therapies to patients with ease.

What factors have led to India's unique approach in advancing technology and bringing it to market, particularly in the context of regulatory standards and the emergence of autologous cell and gene therapies like CAR-T treatments?

We believe that India has chosen a unique path in terms of advancing technology and bringing it to market. Historically, India has aligned itself with regulatory standards set by entities such as the US FDA and EMEA. However, the emergence of autologous cell and gene therapies, particularly CAR-T treatments, is altering traditional paradigms.

Moving forward, we anticipate India will adopt decentralised models for managing these therapies, ensuring closer proximity between patients and treatment facilities. Our aim is to facilitate progress in oncology hospital infrastructure by leveraging state-of-the-art CAR-T therapies.

Furthermore, we offer comprehensive training and support to hospitals and research institutions. Our approach encompasses education on manufacturing processes, quality control, and medical discussions. Additionally, 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 Bangalore, Delhi, and Mumbai.

Could you please provide an overview of your global operations?

Our global headquarters is near Cologne, Germany, under the ownership of our founder and innovator, Stefan Miltenyi. Currently, our workforce totals approximately 5,000 employees worldwide, with around 900 based in the United States, which serves as our largest business hub for several reasons.

Primarily, the United States remains a hotbed for research and innovation, making it crucial for us to have a presence there. Additionally, significant investments, particularly in CAR-T cell therapy, have originated from the US, with Novartis being a notable example. While our manufacturing primarily takes place in Germany, we've also established facilities in California and on the East Coast to meet market demands, largely through acquisitions of smaller companies.

In Europe, we have marketing, sales, and support organisations spread across various countries. However, all manufacturing operations are centralised in Germany, emphasising the "Made in Germany" quality standard. Looking ahead, we anticipate a shift in the importance of regions like India and China for biotech manufacturing due to geopolitical factors and population size. Consequently, we may explore manufacturing solutions in these regions in the future.

Overall, our approach in the APAC region differs slightly from other areas, as we adopt a more focused and strategic approach in defining markets and partnering with specific entities to serve our objectives. As we continue to expand globally, we will remain adaptable to market dynamics and explore opportunities for further growth and collaboration.

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