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â€œWe intend to make India our base for clinical development, manufacturingâ€?

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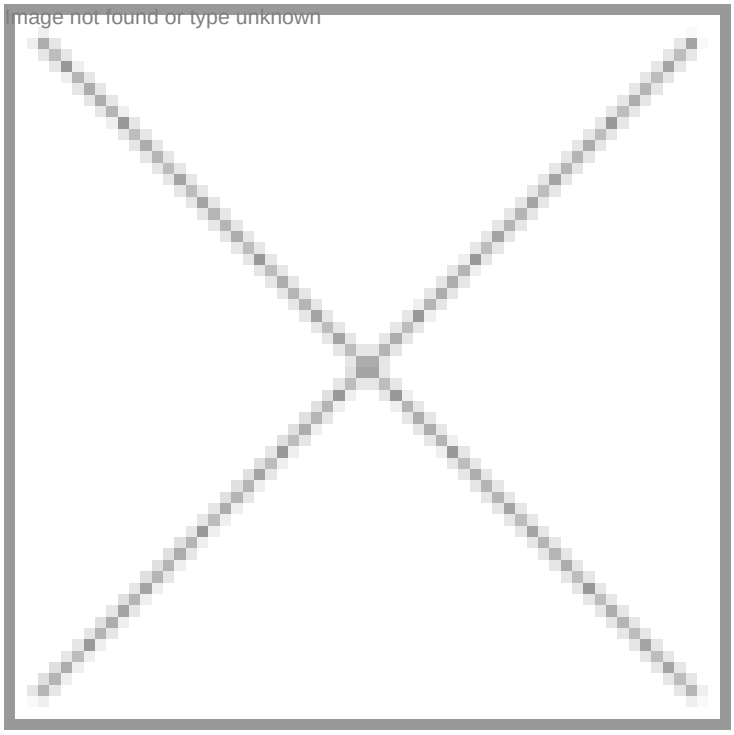

- Sandeep Sahney, managing director, Genzyme India, Gurgaon

Genzyme, one of the leaders in developing advanced technologies for the life sciences industry, has ambitious plans for India. These include launching their entire global portfolio of niche drugs in the next three to four years, rolling out a number of research initiatives, inking collaborative deals and in the future make India their base for clinical development and manufacturing. In a free-wheeling interview to BioSpectrum, Sandeep Sahney, managing director of Genzyme India, shares various initiatives and strategic plans of Genzyme for India.

Q What have been some of the achievements of Genzyme India since its inception in 2007?

Within 25 months of our existence in India, we have been able to bring five novel treatments to the market. All of these meet specific demands of clinicians in the areas of transplant medicine, osteoarthritis, renal disease and hematology/ oncology. Besides this, we have created an access mechanism on a compassionate basis, for our enzyme replacement therapies (ERTs) that are the only approved and available treatments for some of the genetic disorders. Because of our investment in the area of clinical development, we have several ongoing programs in India. While some of these are global trials, we are also supporting many studies to create indigenous data on various diseases and their progression-for the very first time in many cases.

In November 2008, Genzyme entered into research collaboration with the International Center for Genetic Engineering and Biotechnology (ICGEB) for the development of new, improved treatments for malaria under our Humanitarian Assistance for Neglected Diseases (HAND) program. This collaboration includes an innovative approach to intellectual property rights, providing ICGEB the rights to commercially use the neglected disease portfolio on a royalty-free basis. We have also instituted two Genzyme India Fellowships for Excellence in Biotechnology at the National Institute of Pharmaceutical

Education and Research (NIPER) that comes under the aegis of the Department of Pharmaceuticals, Government of India.

Q In terms of investments, is Genzyme looking at India as one of its prime growth destinations?

India will be one of the major markets in the coming years and we are taking initiatives to establish our presence in the country. In two of our most recent global launches, India has been among the first five countries on our priority. In addition, we see India as a key player in our global development of newer therapeutic agents and cutting-edge therapiesâ€"be these in the areas of basic research or clinical development or even manufacturing at a later stage. Few months back, we have also begun work on a $100 million (Rs 464 crore) facility in China after about five years of establishing our entity.

Q What is the strategy behind free distribution of couple of your products and how supportive is the Indian government towards this initiative?

We are currently providing free access of ERTs to numerous children affected by Lysosomal Storage Disorders (LSDs) that include Gaucher, Pompe, MPS 1 and Fabry's disease. A specially created program-India Compassionate Access Program (INCAP)-reflects our commitment to create awareness, helping diagnosis and facilitating proper management of these patients. The mission of INCAP is to provide these therapies and offer the chance of well-being to these patients as a bridge until sustainable funding mechanisms emerge in the country. The program has the oversight of some of the best known medical geneticists from India as well as across the world. Of course, we look forward to both center and state governments support to help more such needy patients.

Q How well has this strategy worked in other geographies and how supportive have those governments been?

In many societies across the world, Genzyme has started its operations by providing free drugs to LSD patients through various charitable access programs to give the patients a chance to lead normal lives. However, the visible impact of these therapies on the affected children has provided motivation for governments across the world to collaborate with Genzyme and workout sustainable funding mechanisms. Other than the US and western Europe, these therapies are funded by the state even in emerging markets like Brazil, Russia, Mexico and South Africa as well as in countries like Chile, Bulgaria and Malaysia.

Q How encouraging is the Indian market when it comes to product launches?

Our experience has been an extremely positive one and this is due to the product mix that we bring to the global market. We do work in the areas of unmet medical needs and hence our therapies really offer significant benefits to the patients in need. In these areas, we have found a very welcoming attitude from both the Indian doctors as well as patients who look for the best treatment options.

Q Which disease areas are you looking at in India?

We plan to bring in our entire portfolio of products and services to India in the next three to four years as each of them does offer substantial benefits. And unfortunately, we do have patients in India for practically the entire spectrum of diseases including those afflicting developed as well as underdeveloped societies. Hence, there is a visible need for effective management in all the disease areas that we are working on presently. The major therapeutic areas of interest include transplant medicine, renal, hemato-oncology, orthopedics and genetic disorders. The relatively newer areas of interest and development include multiple sclerosis (MS) and cardiovascular diseases.

Q What kind of partnerships Genzyme looks forward to in the future?

As a company we are extremely focused on enhancing patient outcomes and that forms the basis for all that we do. Hence, besides the requisite domain experience-research or commercial areas-we look for the two qualities of patient focus and ethics in our prospective partners.

We are actively looking at partnering in both research as well as commercial areas and that is one of the mandates that Genzyme India has from the corporation. We are in active exploration stage on both counts.

Q There is no independent regulatory structure for biologic drugs in India? Is that an issue for Genzyme?

This is certainly an area of concern as we work on some of the most cutting-edge therapies including cell and genetherapies. There is a definite need for right-skilling regulatory professionals besides creating a distinct pathway for the biologics. We do realize that this is a newer area for the regulators and we are open to sharing with them all that we have learnt in our journey of nearly 30 years.

Q Has the global meltdown affected Genzyme India's operations?

Not really, and in fact it has brought out the salience of building operations in India at a faster pace.

Q What are the achievements of Genzyme India as compared to its counterpart in China?

India and China are two different markets and the scope for fast growth is their common feature. Genzyme is operating in China for a longer period and hence has its own set of achievements. As far as India is concerned, all I can say is that we are moving as per plan and as a company, we do focus on long-term growth more than some of our counterparts.

Q What is your take on the Indian biotech industry?

Biotech industry in India is still at a nascent stage, but, it offers tremendous opportunity for the simple reason that the global biotech industry is less than 40-year-old. On the commercial side, the market is becoming more sophisticated and both doctors and patients are looking for more customized and innovative solutions to address medical needs. In the area of research and development, there is a great chance for us to 'catch-up' and lead, probably much more than the conventional pharmaceuticals.

At present the indigenous efforts are directed more at the development of biosimilars, we do see the government takingsteps to foster and support the path to innovation. From our perspective, we will be happy to participate in some of these plans to develop newer therapies in India and hence assist in capability and capacity building for the country.

Nayantara Som in Mumbai