Interview with James Qun Xue, Managing Director, Genzyme (Shanghai)

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In 2006, Genzyme's global CEO, Henri Termeer, said he is "personally very interested in China" and that he expects the company to build a capable infrastructure in ten years. We're now 30% closer to the deadline. How has this deep commitment to China resulted in developments in the country and is Genzyme on track to establishing a strong operation in time?

The ten-year goal is a big milestone for the company, rather than a hard deadline. Genzyme is looking to achieve milestones in several dimensions within ten years. First and foremost Genzyme wants to be a commercially successful company. There are revenue targets but also therapeutic areas where Genzyme is looking to make a positive impact on the quality of life of Chinese patients. Genzyme has strengths in a number of therapeutic areas, for example genetic metabolic diseases, oncology, hematology, renal disease, and cardiovascular. These are areas where Genzyme is making a tremendous impact globally. The company also has expertise in biotechnology platforms including recombinant proteins, cell therapy, biopolymers, and biomaterials, which will be brought to China in conjunction with product launches in the country. Bringing these product platforms to China will also have regulatory impacts as well as the R&D impact of increasing development on these platforms. In January 2006, Genzyme established its first wholly owned subsidiary in China called Genzyme (Shanghai) Biopharmaceutical that is primarily responsible for sales and marketing promotion of Genzyme products. In parallel, we want to be a company that has a comprehensive presence as a healthcare company. In April 2008 in

Beijing, Genzyme announced that it is establishing another presence called Genzyme Beijing Biotechnology Co. Ltd., which will be the primary entity for the R&D activities in China. The facility is focused on R&D as well as laboratory scale manufacturing, specifically a clean lab focused on cell therapies. This facility will produce the first commercial cell therapy products in China. This is the only product based R&D facility outside the US, which represents a US$ 90 million investment for the building alone. The global CEO will lay the corner stone in September of this year. Genzyme would also like to be a true partner in developing the biotechnology industry in China. We are also trying to move our participation in the market to the regulatory front, working with the SFDA and MOH in introducing novo Genzyme products both in the therapeutic sense but also in the regulatory and product platform sense. Platforms such as cell therapy, gene therapy, biomaterials, and biopolymers are quite new to Chinese stakeholders and we are quite happy to be working with the Chinese regulatory authority to identify pathways to get these products to obtain regulatory approval in a timely fashion. Genzyme is also heavily involved in collaboration with Chinese institutions and companies for the purposes of advancing product development and improving standards of care in disease areas where Genzyme has expertise. One excellent example is the partnership that Genzyme established in 2006 with Shanghai Jiao Tong University, where the company now offers a yearly postdoctoral scholarship to key labs that have a strong overlap with Genzyme’s global R&D initiatives. Thus Genzyme is creating synergies between the Chinese research community and the company’s global research network. Another partnership is with the Chinese Charity Federation that allows Genzyme to provide Cerezyme to over 130 Chinese patients suffering from the rare but highly debilitating genetic disease called Gaucher’s Disease. Genzyme has been giving away this product in over 30 countries where the local healthcare system does not allow patients to have access to this drug. Genzyme distribute these life-saving drugs in part to raise the profile of the need of these patients in terms of market access to life-saving medications.On a worldwide level, Genzyme distributes Cerezyme to any patient in need, regardless of whether they are covered by a healthcare system that includes the drug on a reimbursement list or not. However, in China, giveaways of this product may reach US$ 180 million per year.

How does this business model really worldwide and is it actually translatable to the unique Chinese market?

This is where Genzyme differentiates itself from other companies. We don’t define the end goal as getting a product approved and launched in the market. The goal is whether the patients’ quality of life was fundamentally changed, which requires Genzyme work with local governments, physicians and patient groups to establish an avenue for sustainable access to a drug or treatment. Genzyme

has done this in each market the company has entered, including the United States, where company has worked with insurance companies and also by testifying before Congress as to why the treatment has such a high cost per patient. In countries like Brazil Russia and Australia, funds covering treatments are provided by the government. China's economic development status has not allowed the government to make it a priority to fund orphan drug products. This situation has required Genzyme to work even harder together with the government, medical establishment, Chinese regulatory authority, and the Social and Labor Security Authority to identify a more feasible way to, overtime, have a sustainable funding system. This could start in the coastal areas encompassing Beijing, and Shanghai and gradually moving to the inner provinces.

Given China's current healthcare system, with the disparity in urban and rural areas, and a patchwork of regional systems, its fair to ask, will it ever be a government priority to address such niche conditions as Gaucher's Disease?

In the context of purely an expense, funding for this treatment can be difficult to justify. But, when the context is broadened, one sees that this is a win-win for every party involved. The treatment should be put in the context of a company like Genzyme making important and strategic investments in China that allow the country to have a global biotechnology leader make a permanent presence in the country. This presence allows Chinese patients and physicians to have access to state of the art products and technologies, which are revolutionizing therapies for a number of diseases. This is a win for the Chinese industry, which will help the country eventually be a leader in global life sciences and biotechnology. The third win is for the Chinese government itself. As the economy develops, Chinese society is also developing and the government's guidance through the Olympics and World Expo indicates that China is looking to bring its civil society up to par with the developed world. Part of this increased development involves a healthcare upgrade that improves the health of its citizens. In Shanghai, Beijing, and Jiangsu province, it is our understanding that the healthcare fund has an annual surplus. The government has no interest in keeping this money, but they also have the fear that if the money isn't allocated properly, the funds could run deficits, which would be a serious problem. The good news for Genzyme and the Chinese government is that even though the individual cost of treatment is extremely high, this disease is so rare that the total cost as a percentage of healthcare expenditure will be very limited.Pharmaceutical companies haven't always had the best press and have sometimes been demonized in China. The government wants flexibility on price in the short term while the market develops but most multinationals haven't been very open to this concept.

Do you see an evolution in the state of mind of multinational companies? Do you think they are starting to understand what the Chinese government and people are telling them?

They key concept is innovation. Pharmaceutical, biotech, and innovative life sciences companies need revenues today to continue investing in innovative products for the future. The Chinese government started to realize these needs and we are seeing the beginning of a shift as occurred in the IT industry. There we saw that companies cannot rely on selling inexpensive products and also become competitive in the global economy. Over the past five years, the Chinese government has sent a delegation to the Biotechnology Industry Organization (BIO) annual conference in the United States. The Chinese government wants to see how the US has successfully developed this industry and thus see how China can develop this sector as well. The government clearly recognizes the benefit of developing the life science sector, of course for intellectual properties. Genzyme is a biotechnology company producing innovative products that fit true medical needs that have no available treatment. Therefore, any product we bring to the market makes a life or death difference to our patients, including of course, our Chinese patients. Thus, in addressing this area we are sensitive to the Chinese government's concerns that multinational companies are here only to extract revenue and profit. That's not what Genzyme is about; Genzyme is here to partner and develop a win-win model, as in every country, developing the biotech industry whose eventual beneficiaries will be patients and the entire society.On the one hand, the government has a made a declaration of expanding R&D activity, pushing for a shift from a manufacturing to an innovative society. Genzyme is not alone in setting up R&D facilities in China, but on the other hand, R&D return on investment is still unproven in China. Many companies are setting up clinical research operations, but drug development isn't nearly as widespread.

What convinced Genzyme that now is the right time to build its first research center outside Europe and the US, here in China?

Mr Henri Termeer is of course the best person to answer this question. But as I was also intimately involved in this process, my answer is that it has been a very carefully thought out and deliberate decision. This decision was made over quite a few years, involving three personal visits by Mr. Termeer and other senior executives over the past three years. It is important to recognize that among major life science players, Genzyme has made a relatively late entry into the Chinese market. Genzyme itself is a young company – only 28 years old. Thus it has not been until recently that Genzyme has had the ability to set up a presence in China or India or Russia. In that context, Genzyme's board and senior management were convinced that China, along with India, Brazil, and Russia would be the fastest growing markets in the industry. Thus investing in China at this

moment, where most multinationals have a 15-20 years old presence is not too early. Investing in R&D fits the company's goal of building a comprehensive presence over the next 10 years, as well as becoming the leader in life sciences and biotech in China. Genzyme has had a number of discussions with the Chinese government, which has indicated that over the next decade life sciences and biotech will be one of the most strategic industries. This is also represented in the availability of emerging partnerships in the sector.It seems that these partnerships are a big part of the strategy in working with Chinese companies and institutions. However, a recent trend has emerged for multinational firms to buy out local joint venture partners and move to 100% foreign-owned entities. At the same time, Genzyme has entered a partnership with Sunway Biotech to not only manufacture but also co-develop experimental gene therapies.

Why did you decide go develop these products with a local partner, and not a multinational or simply go it alone?

Genzyme did a lot of due diligence from 2004 through 2006, at which point I was relocated to Shanghai. I made almost monthly trips over the three years before I was relocated, when I met with many executives in China. Historically, multinationals entered joint ventures because it was the only vehicle for them to establish operations in the country. These companies found a number of pros and cons in the joint ventures over ten to fifteen years. The joint ventures were also primarily focused on manufacturing, chemical products and distribution of those products in China. Now, these joint venture requirements have been removed and there is no need for multinational companies to set up a permanent presence in the country. On the other hand, there are other areas that make more sense for partnerships. One example is distribution, which is not one of Genzyme's focus areas in China. Genzyme's R&D partnerships are especially focused on development. Genzyme can provide expertise in the laboratory but also across the entire development process. In particular, the company is working with regulatory authorities to manage trials and data, areas in which Chinese companies lack experience. The truly innovative Chinese companies want to expand internationally, and that's where Genzyme's expertise really comes into play. For example, Genzyme has extremely extensive experience working with US and EU authorities on GMP issues, particularly in biotech platforms. In China, as with other countries, Genzyme's strength is in accelerating late stage product development, and that focus is applied to partnerships including Sunway. The company's goal is to use the Beijing research center as a platform. There will be a team that will support these kinds of partnerships by training Chinese physicians and scientists both at the Beijing center and also in the US. Rather than developing new technology, the goal is to utilize Genzyme's technology to accelerate product development. To my knowledge, Genzyme is second only to J&J in having the most comprehensive development

platforms in the world.We have talked about working with the government to get on reimbursement lists, launching new products in the Chinese market and setting up new partnerships.

How far along are you and when do you think you will start building up the sales presence in China?

Over the past three and a half years, Genzyme has been building the promotion and marketing infrastructure very rapidly. On the physical distribution side we are primarily relying on multiple partnerships. Promotion has focused on hematology and oncology, with a product called Thymoglobulin, a polyclonal product for the treatment of bone marrow and solid organ transplantation rejections as well as severe aplastic anemia and other immune diseases. Genzyme has recently announced the closing of a transaction with Bayer, acquiring three oncology products. One of these products is called Fludara and is now being transitioned from Bayer China to Genzyme China. Thus we have established a reasonable presence in the Chinese hematology and oncology community and Genzyme's products save the lives of Chinese patients on a daily basis. Conservatively speaking, sales in 2009 have doubled 2008 numbers. These numbers will only go up, with an average of two new product launches annually over the next five years. You must have learned a lot going through the process of expanding your operations here.

What would you advise to another country manager looking to build out their company's Chinese presence?

I think Genzyme's senior executives would agree with my advice, which is to be local. We have found that the fact that we allowed Genzyme to become a local company in each market has been driving the firm's success in many countries. We have achieved this in France, Japan, the UK, the Netherlands, and places like Taiwan, Brazil and Mexico. The local nature of these operations is manifested in partnerships but also in employees. We are investing in Chinese talent including management, the sales force, and researchers, which are of course Chinese nationals. In most countries Genzyme hires the staff locally including the general manager and management team. I think this is a great strength. The other piece of advice is to stay open minded. We can't expect China to reach the level of the US or EU overnight, its an evolution. But, if you examine how far China has come in the past 10, and even 5 years, one can have confidence that sooner rather than later China will be one of the most attractive markets for all life science companies. One excellent analogy is the auto industry, which began with Volkswagen's joint venture in 1983. From that time, China has become the largest market for Volkswagen and also the largest profit contributor for the German auto company. Other car manufacturers have had a similar experience in China. It is only a matter of time for China to contribute to the pharmaceutical sector in a similar fashion.

Do you have a final message for Pharmaceutical Executive’s international readers?

I hope that you will come back and follow up on Genzyme’s development in China. It is important to focus on Genzyme’s positive impact on patients’ quality of life. That is our only purpose in China. Our CEO reminds us that the reason so many Genzyme employees are tirelessly working at the company, after 20 years service, is our shared mission to bring innovative, breakthrough therapies as rapidly as possible to those who rely on them for their survival.

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