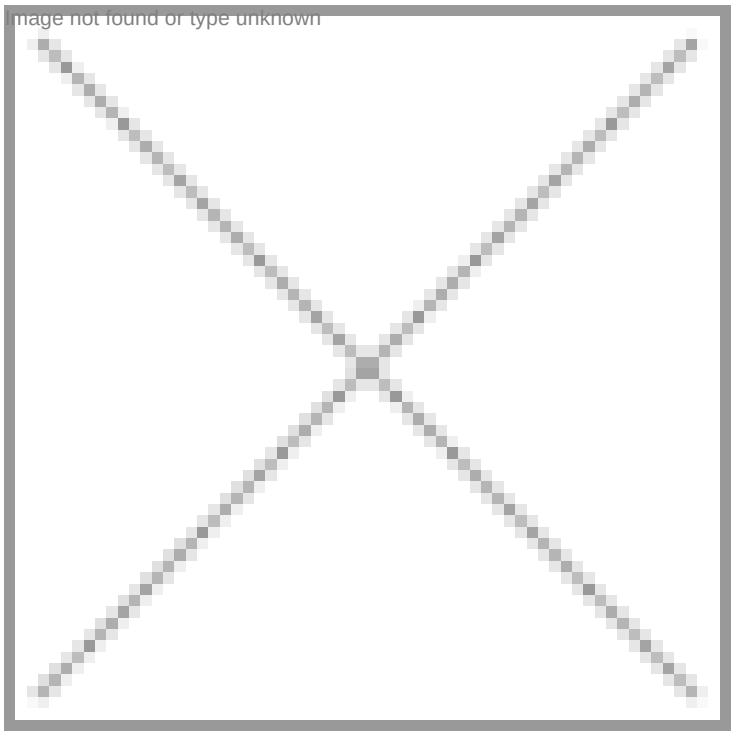
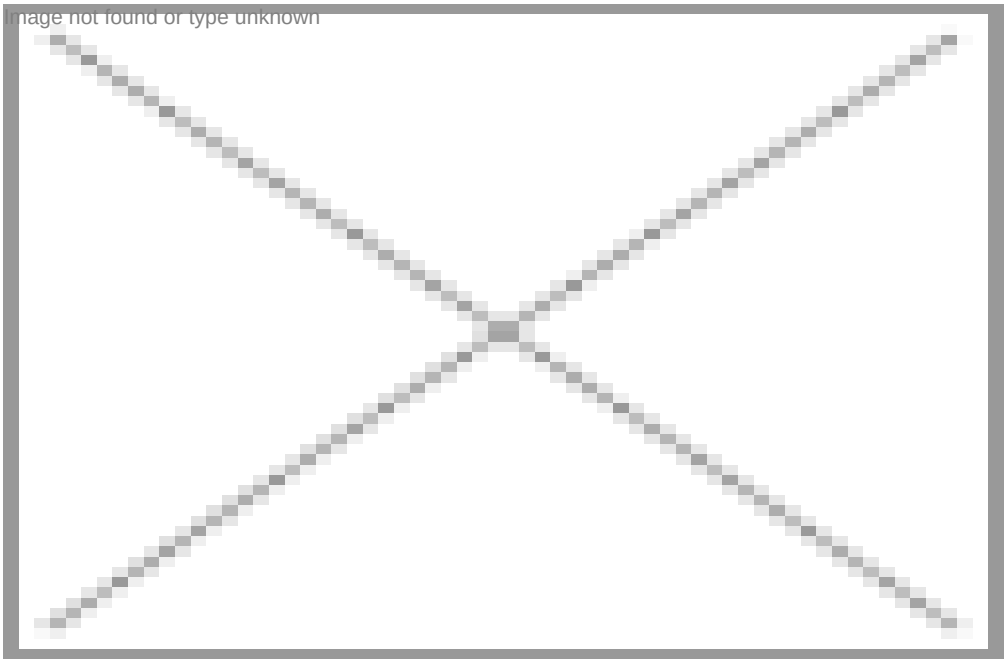
BioSpectrum the business of Bio & Health Sciences

Reditux, an affordable biosimilar monoclonal antibody

05 December 2008 | News



Reditux, an affordable biosimilar monoclonal antibody



With a mission to sell the drugs at one-third, one-fifth or one-tenth of the cost it is being sold today, Dr Reddy's Laboratories has stepped up its efforts in biologics.

Though the use of antibodies for therapy was demonstrated almost a century ago, the real therapeutic use became possible only after the development of monoclonal antibody. However, rejection of these proteins by the human immune system known as Human Anti Mouse Antibody (HAMA) response remained the biggest challenge. This led to the creation of chimeric antibodies, which are derived from the fusion of the mouse variable region with the human constant region. Rituximab is one such chimeric antibody against the human CD20 antigen and has been developed for the treatment of Non-Hodgkin's Lymphoma (NHL) and rheumatoid arthritis.

In 1993, IDEC Pharmaceuticals (now Biogen-Idec) began phase-I clinical trials with Rituximab. It was launched in the US for the treatment of relapsed or refractory, low grade or follicular, B cell NHL in 1997. In March 2001 the Drug Controller General (India) approved Rituximab for marketing in India by Roche Holding.

In 2003, Dr Reddy's Laboratories, the Indian pharma major came out with the novel concept of producing the biosimilar version of Rituximab, a version of Roche Holding's cancer therapy, which could allow a greater access to the drug at half the price of the original.

US based Genentech and Biogen Idec market the drug as Rituxan in the United States, and Roche sells it in Europe and other markets under the name Mabthera.

Comments from patients:

Miranda, Mumbai
I noticed a lump appearing below my cheek and it was as hard as a stone. I went to a consultant in Leelavati hospital; he analyzed and told me to do a biopsy and it turned out to be non-Hodgkin's Lymphoma. The doctor informed us about this new drug Reditux from Reddy's Laboratories which when used together with regular chemotherapy is very effective. With Reditux given on the first day itself I felt as if I was getting some energy, which I neither understand nor know the source. The next day they started with chemo and told me to go home. And when I came home I found the lump had disappeared. Now that the trauma is over, I feel I am on top of the world.

Veerampati Prasad, Kakinada
I am 56 years old. I was working as a Licensed Surveyor in the Kakinada Municipality and I was overseeing building plans and estimates. I started feeling severe pain in the ball and socket joint of my right leg. I noticed a change in my gait and wondered why the pain was not going away. I consulted a doctor. The Doctor suggested that we go for a biopsy test for better diagnosis. When the doctor confirmed that it was cancer. After completing the tests at NIMS and based on the suggestion of one of the NIMS doctors to go for Dr. Reddy's Reditux combined with chemotherapy, I have opted for this treatment. After completing six cycles, there was a lot of change and people who have seen me before the treatment wonder how there was such a positive change and how I recovered so fast.

Creating a niche

The pace of growth in the development and manufacturing of biologics in India has been slow primarily because of the relative lack of maturity in the key capabilities needed for these activities. Several of the older molecules were first introduced into India based on technology transfer from more developed countries or have been imported as finished dosages. However with the more complex molecules like monoclonal antibodies, Dr Reddy's believes that the preferred strategy is to systematically develop the entire spectrum of development and manufacturing capabilities. The complexity of the molecules and the processes means a close integration of all the relevant skills within one organization with direct links between the manufacturing groups and the process, analytical, pre-clinical and clinical development groups.

World class facilities and laboratories of Dr Reddy's, the scientific depth of its team, the robustness of the development strategy and the focus on quality issues were some of the key factors that contributed to the successful development of a complex molecule like Reditux.

Reditux is the second product from Dr Reddy's Biologics Division, which is developing treatments for cancer and autoimmune diseases. The company has also launched the generic version of Amgen's Neupogen, and named it Grafeel. The company has spent more than $10 million in developing Reditux and within a year of its launch the products has successfully gained 30-35 percent share of the market.

Dr Reddy's Reditux is priced at Rs 39,996 for a vial and is almost half the price of Roche's Mabthera. This product is now approved for marketing in India. Product availability is planned at company's C&F agents and at all major hospitals in the country. The company's marketing niche is to re-engineer biologic therapies and produce them at a cheaper price. There are several other products in development primarily in the areas of oncology and autoimmune diseases.

"Within a year of its launch, the number of patients taking Reditux has increased by 2.5 times. This within itself is a good achievement. But that is still less than 5 percent who actually need the treatment," said, Dinkar Sindhu, director, business development, Dr Reddy's Laboratories. Earlier the drug was being sold at approx. Rs 1 lakh per vial of 500mg. However Dr Reddy's launched 500mg at exactly at Rs 39,996, so it is 40 percent of the original price. A patient has to take 6-8 vials during the course of treatment plus there are other costs associated. It would have cost Rs 8-9 lakh including all charges without the generic version. Now it has come down to Rs 4-5 lakh.

Since the launch of the biosimilar, Roche has officially brought down their MRP to Rs 80,000 and have been promoting it

heavily with the best schemes thus reducing the effective price difference between the original product Mabthera and the biosimilar Reditux.

Commenting on the safety aspect of Reditux Dr Cartikeya Reddy, senior vice president and head, biologics, Dr Reddy's Laboratories, said, "The market as well as the number of people treated has grown significantly thus showing the efficacy and safety of the product. We are sure that we are in the right trajectory and I certainly feel that the Indian regulatory system is pragmatic and thus helping the companies to bring such products to the market. However, this requires a certain diligence both from the company and the regulator."

Sparsh, a noble initiative

In May 2006, Dr Reddy's launched an initiative called Sparsh, meant to reach out to economically challenged cancer patients. This program operates by routing expensive cancer medicines to needy patients through their Sparsh patrons-oncologists across the country. Today, under the aegis of Sparsh, all oncology brands of Dr Reddy's are being given free to patients suffering from cancer. The company has made available medicines worth approximately Rs 6.2 crore as part of the Sparsh program to deserving patients in the year 2007-08, offering 3,000 cycles of treatment using most of the major brands of Dr Reddy's oncology.

The program continues to improve the accessibility to oncology drugs to patients in need. Over the past year, Sparsh has provided quality and affordable anti-cancer drugs to over 500 patients, through their doctors. Of this number, 200 patients suffering from Non-Hodgkin's Lymphoma benefited from the new drug Reditux.

Sparsh can be accessed on http://www.drreddys-chaitanya.com/sparsh/login.asp by the country's oncologists. Doctors are given access to the website by the company wherein they refer needy patients for treatment of Reditux. Dr Reddy's thus ensures that the patients identified by the doctors through Sparsh are provided the recommended therapy free of cost.

Rituximab, since its launch in 1997 as the first monoclonal antibody approved for cancer therapy, has been at the forefront of MAb therapies that have dramatically altered the therapeutic landscape. The company hopes that Reditux will be the first in a series of biosimilar products that will revolutionize the affordability of these products to patients in India. "As an organization, over the past few years we have focused all our efforts on affordability and we hope that some of this will be evident in our subsequent products," said Dr Cartikeya Reddy.

"Our mission is to sell drugs at one-third the price of what is being sold today"

"Our mission is to sell drugs at one-third the price of what is being sold today"

-Dr Cartikeya Reddy, senior vice president and head, biologics, Dr. Reddy's Laboratories

Who conceived the idea of working with this molecule? Who all formed the team?
It is not in a sense a novel idea and a specific entrepreneurial intent as much as a systematic follow-through on very simple decision that the company made that this is a class of molecule, which should be seriously pursued. However, it was very much an entrepreneurial kind of a dynamic within a larger company. At one level it is not discovery but development. So it is not a scientist's idea, it's just a group of peple doing something where the target is already clear.

It was not a contribution made by one person. It was headed by Abhijit Mukherjee (president, pharma services and active ingredients) when I joined. I was in a way handling the operation part but he was more into strategy and planning. Subsequently it moved to executive vice chairman and CEO, GV Prasad. So it is hard to draw a clean line about the effort. In the early phase of 2003, Raghu Cidambi, advisor, legal and strategy played a big role in developing this idea.

What are some of the challenges that you faced during the process?
The only challenge was to assemble the skills. Apart from that fundamental challenge, I don't think there were any other specific challenges that were so important to us. The key challenge for anybody in this stream is to bring together a team, assembling the skills and essentially being able to do something that very few companies in the world have the opportunity to do, especially in an environment that is very nascent and growing.

Will you be marketing this product in other regions as well?

Yes, certainly but it all relates to the patent situation in those countries. So wherever there is no patent we are certainly keen. We have launched it in India and we will be looking at launching it in the regulated markets as well.

What is the price variation?

The treatment cost for a patient using Mabthera would be around Rs 8 lakh. Reditux is a very important drug, which gives significant freedom from the burden of the disease at a price almost 40 percent of the original cost. Dr. Reddy's is a leader in this space as there is no generic antibody anywhere. We are increasing the access to the drug. We are working with a class of molecules that have the ability to create a huge impact. We want to make sure that people at least in the middle class are able to afford the treatment for the disease.

With pharma drugs, a person can afford the drugs but worries about the doctor's and hospitalization fees. That success does not translate to biotechnology. The number of patients getting treated by Reditux has increased by two-and-half times. We expect this to double in the coming year.

What is your production capacity?

We commissioned an entire new area for the production of Reditux. Today we are operating at 200 liter scale which is enough for a market like India. But now that has to be increased. We will be investing $30 million in the next phase of infrastructure building.

Are there any other molecules in the pipeline?

We have eight molecules in various stages of development. They are all different class of molecules. Some are simple and some are very complicated like Reditux and some are even more complicated. in a oncology portfolio we have two biologics products-Reditux and Grafeel. Otherwise, in total we have 14 anticancer drugs, which are not biotech products. Dr. Reddy's is the second largest player in oncology in India after Roche. Again, our biotech products are not only focused on oncology and monoclonal antibodies but also in nephrology and autoimmune diseases.

Jahanara Parveen