

Companies Eyeing EPO Market in India

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Shantha Biotechnics, a pioneer in modern biotech products launched its Shanpoietin - recombinant DNA Erythropoietin (EPO) in prefilled syringes at the 2nd Asian Chapter Meeting of International Society of Peritoneal Dialysis in Hyderabad in January 2005 in the presence of over 1000 eminent nephrologists from India and abroad. With this, it became the second Indian company to develop and market indigenous EPO after Wockhardt. Wockhardt has developed its own recombinant human Erythropoietin (r-EPO), and launched it under the brand EPOX in April 2001.

The Hyderabad-based Shantha Biotechnics has spent over Rs 20 crore on five years of research and development for the development of the EPO product. Development of indigenous products like Shanpoietin will give an impetus to the biotech industry in terms of domain expertise and mastery over the technology and processes and also helps the country in forex savings to the tune of Rs 50 crore a year. Stating that the Indian EPO market is currently estimated at around Rs 75 crore with 70 per cent of imported drugs, Varaprasad Reddy, managing director, Shantha Biotechnics said, "the company expects to record sales of Rs 10 crore a year on the product."

Players

Besides Shantha Biotechnics, the other major players in the Indian EPO market include LG Life Sciences India, Ranbaxy, Johnson & Johnson, Emcure Pharma, Wockhardt, Zydus Cadila, Hindustan Antibiotics. Except Wockhardt all the companies have entered into agreements with different multinationals for marketing and licensing rights to offer recombinant EPO to Indian patients.

Hindustan Antibiotics, the first drug manufacturing company to be set up in the public sector by the Indian government is selling Recombinant Human Erythropoietin Omega under the brand name HEMAX. It has entered into an agreement with the

US-based Elanex Pharmaceuticals to manufacture and market Hemax in India.

Emcure Pharmaceuticals, Ltd. a Pune-based pharmaceutical company has been in this market since 2002 after entering into a marketing and licensing agreement with Dragon Pharmaceuticals Inc, Canada for the distribution of its EPO in India in November 2001. The agreement provides Emcure with rights to distribute EPO in India and throughout the entire South Asian subcontinent as well as in select markets in sub-Saharan Africa where Emcure has an established presence and sales

force. Ranbaxy, the leading pharmaceutical company in India too has been selling Erythropoietin under the brand name Ceriton since June 2003.

Although r-EPO is a life-saving drug for patients, because they were hitherto only imported from sources in Europe and elsewhere, they prove to be extremely expensive and usage in India is highly restricted. Wockhardt is marketing EPOX at Rs 798/2000 iu/ml lowest against its near competitors. At the launch of EPOX, Habil Khorakiwala, chairman, Wockhardt Ltd noted, "By pricing it at this level, we have made EPOX therapy significantly more affordable to cancer and kidney failure patients in India. This will increase the usage of this drug in India and will be within the reach of many more patients."

Wockhardt is also a market leader for its consumer healthcare products like baby cream and prickly heat powder is a market leader. Janssen-Cilag CRF, a business division of Johnson & Johnson and a franchise was amongst the first to launch a successful biotech drug in India namely Eprex. Eprex in a short span of five years has become the largest selling brand of Janssen-Cilag India. Its efforts in the areas of customer service, direct to patient contacts, nurse education and scientific marketing has set several benchmarks in the industry and to a large extent responsible for developing the EPO market in the country.

LG Life Sciences India Pvt Ltd (LGLSI) is another multinational company marketing EPO in India. LGLSI, a 100 percent subsidiary of the Korea based LG Life Sciences Ltd, and a group company of LG Group, has introduced nine biopharmaceutical products including EPO under the brand LG Espogen Inj and two diagnostic kits in India in 2002. It is looking at setting up its own production and R&D units in India so as not only to innovate, manufacture and sell in India but also build export business to other SAARC, Middle East and African countries.

Potential

According to India Renal Foundation, an NGO working towards creating awareness about Chronic Renal Failure (CRF) and methods of prevention, it is estimated that one out of every 10,000 people (100 per million) suffer from kidney failure in India. The frequency of kidney failure may be more in states like Gujarat, Rajasthan as well as western Madhya Pradesh where the quality of water is harder than normal. It is also estimated that there are between 5 to 6 lakh CRF patients of whom only 10-12,000 receive treatment. India has over 1,50,000 new cases of CRF each year. Half of the number of these patients require dialysis or kidney transplantation. That is a huge financial burden as a one-time dialysis treatment costs anywhere between Rs 1,500 and 2,500 and it has to be done twice or thrice a week. Even then the mortality is 18-20 percent.

Looking at the trends and increase in the number of reported cases of CRF in India, the market for erythropoietin in India has been rising. The EPO market was estimated at Rs 35.2 crore in 2001. Last year it increased to Rs 60 crore and this year it was estimated at about Rs 75 crore.

In the pipeline

Considering the opportunity with few serious players, Ahmedabad-based Intas Pharmaceuticals is launching its indigenously developed EPO product in April this year.

R Chandrasekaran, vice-president marketing, biotech/oncology, Intas Pharmaceuticals Ltd said, "We are launching the EPO product in April. The product will be made available in 4-5 strengths. Although the market is very small, it is a niche market and there are few players in this market."

Commenting on the possibility of price war, Chandrasekaran said, "We don't initiate any price war in this niche market. Our focus will be to provide good service and better quality product to the customers. Companies like Johnson & Johnson and Ranbaxy with their well established names are doing well in the market. Intas will have an edge in this niche market as its products are targeted at oncology and nephrology."

"For the EPO product we see Johnson & Johnson as the market leader in India. At the same time Wockhardt and Emcure are equally competitive in this space. Other key players in this field are Ranbaxy, LG Life Sciences," he said.

Hyderabad-based Hindustan Bio Sciences Ltd (HBSL) and New Delhi-based Kee Pharma Limited are also looking at entering this niche market where the competition is not much.

Last year HBSL announced that it had obtained approvals from the GEAC for importing and marketing EPO. According to reports, HBSL will import erythropoietin manufactured in China by Shandong Kexing Bio Products Company Ltd for marketing in India. HBSL proposes to launch the EPO in the Indian market under the brand Eposino targeting mainly the middle and lower income group patients unlike similar drugs in the market, such as Eprex of Johnson & Johnson, Hemax of Hindustan Anti Biotech and Zyrop of Zydus Biogen, which, HBSL says, are expensive.

Kee Pharma Ltd is also planning to launch recombinant erythropoietin besides other rDNA products. According to reports, with a view to strengthen its brand portfolio, Kee Biogenetics (a specialty Biotechnology Division of Kee Pharma Ltd) has signed agreements with some of the world-renowned biotech companies.

The potential opportunity and increase in the number of reported cases of CRF has made the Indian companies enter this niche market. Although eight companies are marketing different brands of EPO in India, the product is still not reaching the entire patient community. It is mainly because of the cost factor as the different brands of EPO are priced in the range of Rs 550 - 998.91 per 2000 iu/ml. It is to be seen how the price will vary with the entry of new players in this niche market following the 2004 expiry of key EPO patents in major developed world markets.

Narayan Kulkarni in Mumbai