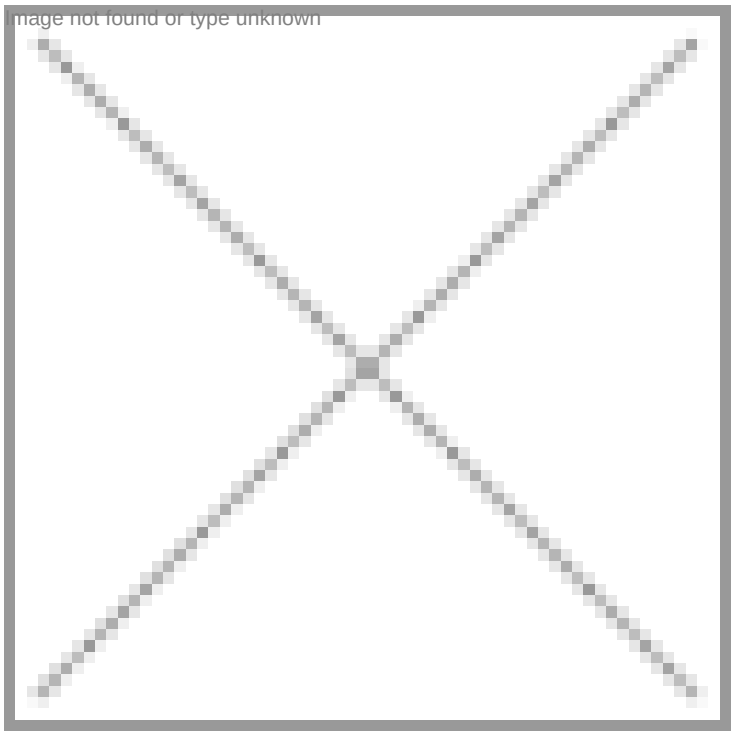
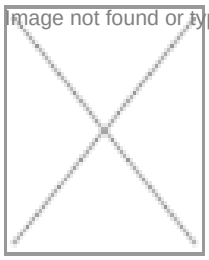
BioSpectrum
the business of Bio & Health Sciences

# "We will launch our first biological product in India"

12 April 2011 | News




**Dr Kamal K Sharma**
managing director, Lupin

Lupin has made significant progress since it first rolled out its biotech program three years ago. In an exclusive interview with BioSpectrum, Dr Kamal K Sharma, managing director of Lupin, gives insights into the company's business strategy in biosimilars and the new biological entities space.

**Q** Can you elaborate on the progress of Lupin's biotech program? What is your strategy for the future?

**Mr Sharma:** Biotech remains an area of strategic focus and a key part of Lupin's road-map for the future. We started our biotechnology program three years ago and we have made rapid progress since then. We have set up our dedicated research and manufacturing facilities in Pashan, Pune. Lupin's strategy and its execution would be very global and in keeping with rigors as demanded by regulators the world over. We plan to make our presence felt in biosimilars, the same way we have emerged as a global generics powerhouse. As is evident from our past behavior, our approach would be dictated by

how frameworks and regulatory pathways pan out in various key markets.

At Lupin, we have always stressed on growing organically and we will continue to follow the same. However, that does not mean we would not look at other modes of growth, be it strategic alliances, partnerships or the inorganic route. All the initiatives will be in tune with our acquisition philosophy and should be in sync with our business road-map. Lupin is now looking forward to launch its first biological in the Indian market by the middle of this fiscal year and going forward, we would like this to contribute about five percent of our global revenue by 2015.

**Q** Can you tell us more about the first biological drug from Lupin?

**Mr Sharma:** The launch of our first biological drug in the Indian market is most likely to happen by the middle of this fiscal year. Lupin currently has seven proteins, all in different stages of development. They consist of both microbial as well as mammalian proteins, focusing on the areas of oncology and diabetes.

**Q** What are the biotech facilities available at Lupin?

**Mr Sharma:** We have state-of-the-art facilities dedicated to R&D in biotechnology outside Lupin Research Park (LRP) in Pune. The vision of the research group is to develop and commercialize biosimilars and new biological entities (NBE) for the company. This R&D facility has already been approved by the Institutional Bio Safety Committee (IBSC) for research on recombinant DNA. Furthermore, this facility has also been accredited as a biotech center by the Bioinformatic Center, University of Pune.

Our biotech program has close to 100 personnel involved in research and support functions. We have invested a lot of resources for recruiting, nurturing and retaining talent in this regard. The team has unmatched domain expertise, and stellar academic qualifications. In fact, we have recently appointed Dr Cyrus Karkaria as the new head for our biotechnology efforts. He is the president of biotech division at Lupin and he comes with 15 years of experience in biotech research.

**Q** Has Lupin entered into in-licensing deals for biologicals products in India? What will be the company's development strategy towards these products?

**Mr Sharma:** According to industry experts, the market share of India in the biosimilars space has so far been negligible. Lupin's biotech endeavors have come a long way since they were initiated three years ago. To optimize production facilities for biotech drugs and considering the time required for developing own drugs, we had in-licensed a few products from overseas players. We have already in-licensed three products for the Indian market and we are now in the process of in-licensing two more products.

**Q** Which are the overseas markets targeted by Lupin for biosimilars and how lucrative is the Indian market for the same?

**Mr Sharma:** The US and EU markets will undoubtedly be the lucrative ones for Lupin in the future but we intend to start by pushing our biosimilar product line into the Indian market and then branching out to the emerging markets. However, our biggest growth will be on the US and EU market, where we are still working on building competencies given the regulatory rigors that are prevalent here. We, nonetheless, believe that these markets will offer tremendous potential, once they fully open up to biosimilars.

Also, in the coming years, oncology, rheumatoid arthritis and diabetes will prove to be lucrative therapeutic segments for Indian biosimilar players, with the rise of these disease levels across the globe. For oncology, growth will be in areas such as colon and breast cancer in the light of the increasing rise of prescriptions in the US.

The global market for biosimilars is worth $120 billion and emerging markets contribute 18 percent of it. The Indian biosimilars market is set to grow at 20 percent by 2015 at par with the global growth rate. In terms of revenues, the Indian biosimilars market is estimated to register $2 billion by 2015 which contribute to 10 percent of the emerging economies. This gives us tremendous scope and opportunities, as far as selling biosimilars in the Indian market is concerned. However, when compared to generic drugs, biosimilars are difficult to develop and the regulatory hurdles are more difficult to clear.

**Q** How will Lupin Research Park augment the company's overall growth in the biotech space?

**Mr Sharma:** Lupin Research Park is the company's global R&D hub. The company now has over 850 scientists as compared to 550 research scientists last fiscal. The increase in the past year has been on the drug discovery side, which we have recently revamped. Lupin's R&D group in Pune supports all our markets working in conjunction with our subsidiaries, strategic business units and business groups, helping them identify lucrative opportunities and put in place a well-differentiated, value-based product pipeline.

Lupin's biosimilar-related R&D work takes place in our Lupin Bioresearch Center (LBC) in Pune which houses two clinicswith

a total of 56 beds, a bioanalytical lab with seven state-of-the-art LC/MS/MS systems and its own clinical chemistry lab amongst several other capabilities. LBC conducts important bioequivalence testing exclusively for Lupin's generic products prior to the filing of abbreviated new drug applications or other regulated market filings. LBC also manages outsourced bioequivalence studies and clinical end-point studies.

**Nayantara Som** in Mumbai