



Press Release

Biocon Gets its First Generic Formulation Approval in EU; On Track to Launch Rosuvastatin Tablets in FY 17

Bengaluru, India, February 15, 2016

Biocon Ltd. (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced today that it has received European approvals for its Rosuvastatin Calcium 5 mg, 10 mg, 20 mg and 40 mg tablets, a generic equivalent of Crestor® tablets, indicated for hyperlipidemia or mixed dyslipidemia.

This first generic formulations approval in the regulated markets marks an important milestone in Biocon's small molecules strategy of forward integration from APIs to finished dosages.

The approval for Rosuvastatin Calcium, through decentralized procedure will open the doors for Biocon to over 15 European countries and will enable the company to address US\$ 1.2 billion opportunity, starting FY17.

Biocon was the first generic company to receive a Certificate of Suitability (CEP) for Rosuvastatin Calcium API from the European Directorate for the Quality of Medicines (EDQM). CEP certification indicates that an API is suitable for use in medicinal products in the EU.

Biocon Chairperson & Managing Director Kiran Mazumdar-Shaw said: *"This is indeed a proud moment for Biocon's Small Molecules business. This approval paves the way for Biocon to launch Rosuvastatin Calcium tablets in several European countries. We plan to collaborate with regional partners in the near term to provide access to this affordable generic and thus help patients and governments to bring down their healthcare spends."*

Dr. Arun Chandavarkar, CEO and Joint Managing Director, Biocon said: *"The European approval for Biocon's generic version of Rosuvastatin Calcium underscores Biocon's unique strengths in the chronic therapies space and our compliance with global standards that enable us to achieve the highest quality standards for all our products. It augurs well for this nascent business, which will be one of our growth drivers in the coming years."*



Biocon aims to rev up its generic formulations business with a target of 20-25 filings over the next few years. Its new potent oral solid dosage formulations facility coming up in Bengaluru will enable this business expansion.

The company is also working on dossiers to introduce these formulations in emerging markets where regulatory clearances are primarily based on approvals given by regulators in the US / EU.

Biocon is a partner of choice for pharma companies globally that rely on the company's differentiated portfolio of APIs spanning complex molecules ranging from cardiovascular and anti-obesity agents to immunosuppressants and narrow spectrum antibiotics. Biocon has built on this core expertise in APIs to develop value-added generic formulations for both emerging and developed markets. It had filed an initial set of Marketing Authorization Applications (MAAs) in the EU and Abbreviated New Drug Applications (ANDAs) in the US in FY15.

* Crestor® is a registered trademark of the AstraZeneca group of companies.

About Biocon Ltd

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and fully-integrated, innovation-led biopharmaceutical company. As an emerging global biopharmaceutical enterprise serving customers in over 100 countries, it is committed to reduce therapy costs of chronic diseases like autoimmune, diabetes, and cancer. Through innovative products and research services it is enabling access to affordable healthcare for patients, partners and healthcare systems across the globe. It has successfully developed and taken a range of novel biologics, Biosimilars, differentiated small molecules and affordable recombinant human insulin and analogs from 'Lab to Market'. Some of its key brands are INSUGEN®(rh-insulin), BASALOG® (Glargine), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab) and ALZUMAb™ (Itoлизumab), a 'first in class' anti-CD6 monoclonal antibody. It has a rich pipeline of Biosimilars and novel biologics at various stages of development including Insulin Tregopil, a high potential oral insulin analog.

Visit: www.biocon.com

| | |
|--|---|
| Contacts: | |
| For Media Relations | |
| Seema Ahuja VP & Global Head of Communications 080 2808 2222; +91 99723 17792 seema.ahuja@biocon.com | Rumman Ahmed Sr Manager, Corporate Communications 080 2808 2223; +91 98451 04173 rumman.ahmed@biocon.com |
| Investor Relations | |
| Saurabh Paliwal Head, Investor Relations 080 2808 2040; +91 95383 80801 saurabh.paliwal@biocon.com | |