Press Release

Biocon Introduces CIMIVIR-L™ for Hepatitis-C in India

A Convenient, Affordable, Once-a-Day, Combination Therapy for Patients

Bengaluru, India: Dec 24, 2015

Biocon Ltd, Asia's premier biotechnology company, today announced the introduction of an advanced novel therapy CIMIVIR-L™ for the treatment of Hepatitis C in India. CIMIVIR-L™ is a fixed dose combination of Ledipasvir 90 mg and Sofosbuvir 400 mg, which is an equivalent of the innovator product commercialized by Gilead Sciences in the US.

The Drugs Controller General of India (DCGI) recently approved the sale of Sofosbuvir-Ledipasvir combination, which is being manufactured in India under a license from Gilead.

CIMIVIR-L™, a once-a-day oral therapy, will offer a convenient, effective and safe alternative to people infected with the Hepatitis-C virus (HCV). It is estimated that nearly one lakh people die annually in India from HCV infection and co-morbidities. CIMIVIR-L™ is indicated for Hepatitis-C Genotype 1 patients who account for ~25% of the total estimated HCV patient population of 18 million in the country.

CIMIVIR-L™ will be made available to patients in India at a fraction of the global cost of the innovator brand. The cost of a 12-week course of this combination therapy in the US is $94,500, *(~ Rs 63 lakhs).*

In keeping with its commitment to introduce innovative therapies at an affordable price to patients, Biocon had entered into a licensing agreement last year with US-based Gilead to manufacture and commercialize its chronic Hepatitis-C blockbuster product range, Sofosbuvir and Sofosbuvir-Ledipasvir combination in India and in select emerging markets. These territories account for more than 50% of the global Hepatitis C prevalence.

Commenting on the launch, Ravi Limaye, President - Marketing, Biocon said: *"The introduction of CIMIVIR-L™ will strengthen Biocon's current portfolio of Virology products. It furthers our commitment to offer affordable therapy for unmet patient needs in debilitating and life-threatening conditions. Through our patient support program we aim to create awareness on HCV to improve diagnosis and ensure better therapy compliance through patient education."*

Hepatitis C is a viral disease that causes liver inflammation leading to diminished liver function or liver failure. It is referred to as a "silent epidemic" as most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take decades. Chronic HCV infection could lead to scarring and poor liver function (cirrhosis) over many years, resulting in complications such as bleeding, jaundice, fluid accumulation in the abdomen, infections and liver cancer.

Hepatitis C is a global public health concern and lack of disease awareness and unavailability of treatment options are the main factors limiting disease management in developing economies like India.

Previous treatment regimens for Hepatitis-C Genotype 1 often involved multiple separate medicines and complicated dosing, which were largely difficult to tolerate.

A once-a-day pill treatment, CIMIVIR-L™ not only offers convenience but also better cure rates and patient tolerance compared to existing therapies. Clinical studies by the innovator on a wide range of chronic HCV patients have shown that the Sofosbuvir - Ledipasvir combination therapy resulted in very high cure rates ranging from 94% - 99%*. *(see notes to the editor)*

Biocon, which had launched CIMIVIR™ (Sofosbuvir) earlier in 2015, has been working towards raising awareness about HCV in India and improving diagnosis of the disease in the country.

***Notes to the Editor:**

About Ledipasvir & Sofosbuvir Molecule:

Ledipasvir is a potent inhibitor of HCV NS5A, a viral phosphoprotein that plays an important role in viral replication, assembly and secretion. Sofosbuvir is a nucleotide analog inhibitor of Hepatitis C virus NS5B polymerase—the key enzyme mediating HCV RNA replication. The triphosphate form of sofosbuvir (GS-461203) mimics the natural cellular uridine nucleotide and is incorporated by the HCV RNA polymerase into the elongating RNA primer strand, resulting in chain termination.

***US FDA Approval**: On October 10, 2014, the fixed-dose combination Ledipasvir-Sofosbuvir (#* Harvoni®*) was approved by the US FDA for the treatment of chronic Hepatitis C Genotype 1 infection in adults. On November 12, 2015 the FDA expanded the approval of Ledipasvir-Sofosbuvir to include (a) treatment of chronic Hepatitis C genotypes 4, 5, and 6 and (b) patients co—infected with HIV.*

***Indications**: The fixed dose combination Ledipasvir-Sofosbuvir (90 mg/400 mg) is approved by the US FDA for the treatment of chronic Hepatitis C genotypes 1, 4, 5, and 6 in both treatment-naïve and treatment-experienced patients.*

***Clinical Study:** In a study of 647 patients with Genotype 1 Hepatitis C, with no prior Hepatitis C treatment and without cirrhosis, 96% (208 out of 216) of those patients who received Harvoni® once daily for 12 weeks were cured. And of those patients with lower levels of virus (less than 6 million IU/mL) who received Harvoni® once daily for 8 weeks, 97% (119 out of 123) were cured.*

In a study of 865 patients with Genotype 1 Hep C, with no prior Hep C treatment and with or without cirrhosis, 99% (176 out of 177) of those patients without cirrhosis, and 94% (32 out of 34) of those patients with cirrhosis who received Harvoni® once daily for 12 weeks were cured.

In a study of 440 patients with Genotype 1 Hep C who had failed prior Hep C therapy, 95% (83 out of 87) of patients without cirrhosis who received Harvoni® once daily for 12 weeks and 100% (22 out of 22) of those with cirrhosis who received Harvoni® once daily for 24 weeks were cured.

 # Harvoni ® is the innovator brand of Gilead Sciences. **Source: www.harvoni.com & hepatitis C online*

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 ™(Itolizumab), 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.

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