PRESS RELEASE

The Medicines Patent Pool Signs First Sub-licences for Hepatitis C Medicine Daclatasvir

~ Four companies to help speed access to curative direct-acting antiviral in 112 low- and middle-income countries

Geneva, and Mumbai, India, 20 January 2016: The Medicines Patent Pool (MPP) announced its first round of sub-licences for the generic production of Bristol-Myers Squibb's daclatasvir, a novel direct-acting antiviral that is proven to help cure multiple genotypes of the hepatitis C virus. Generic companies Cipla, Emcure, Hetero and Natco have signed non-exclusive, royalty free agreements with Bristol-Myers Squibb and the MPP to produce and sell daclatasvir in 112 low- and middle-income countries.

The sub-licences follow MPP's announcement of its first hepatitis C licensing agreement, signed with Bristol-Myers Squibb in November 2015, and mark the first time that generic manufacturers have worked through a non-profit, public health organisation to increase access to new hepatitis C medicines for developing world patients. Between 130 and 150 million people worldwide are estimated to have hepatitis C. The vast majority lives in low- and middle-income countries.

"Given the burden of hepatitis C, MPP worked quickly to forge agreements with generic companies," said Greg Perry, Executive Director of the MPP. "Cipla, Hetero and Emcure are long-term partners working with us to develop generic HIV antiretrovirals. We welcome Natco, a new collaborator, to the MPP and hope to have other companies on board as well."
MPP is assessing applications from several other companies and expects to grant further sub-licences soon.

The MPP licence allows generic manufacturers to develop fixed-dose combinations that offer the potential to treat all of the six major genotypes of hepatitis C (HCV). Daclatasvir, in combination with sofosbuvir, for example, produces high cure rates after 12 weeks of treatment, with recent Phase III studies demonstrating that the regimen could cure up to 100% of HCV patients depending on genotype and stage of liver disease.

Natco is an India-based pharmaceutical company with five manufacturing facilities throughout the country and is one of the first generic companies to have India's Drug Controller General's approval to market the hepatitis C drug in the country. "Natco is committed to making affordable drugs available in developing countries. Daclatasvir combinations offer valuable treatment choices, including

a potential pan-genotypic option. We look forward to collaborating with MPP to improve access to these medicines in India and elsewhere," said Rajeev Nannapaneni, Vice Chairman & CEO.

Cipla is a global pharmaceutical company with more than 1,500 products across various therapeutic areas. With a strong presence in HIV, the company holds several MPP sub-licences for key antiretrovirals, including dolutegravir and tenofovir alafenamide. "We are pleased to once again work with the MPP to bring new classes of drugs to people who need them the most in developing countries," said Dr. Jaideep Gogtay, Chief Medical Officer of Cipla. "Pan-genotypic daclatasvir regimens are crucial in resource-limited countries where access to genotype testing is limited."

"It has been a pleasure working with the Medicines Patent Pool that has recently included hepatitis C into its focus areas. This licence will help us distribute daclatasvir to low- and middle-income countries at affordable prices," said Vik Thapar, Head of Strategy, Emcure, one of the first generic companies to sign a licence with MPP for HIV antiretrovirals in 2012.

Hetero, one of India's leading generic pharmaceutical companies, also signed an MPP licence agreement to produce daclatasvir. "Hetero is pleased to enter in the licensing agreement with MPP to produce daclatasvir for low- and middle-income countries," said Bhavesh Shah, Director, International Marketing for the company. "The MPP has been a valued partner in our work to develop MPP-licensed HIV medicines and we welcome the opportunity to work on improving the standard of care and treatment for hepatitis C."

Daclatasvir, discovered and developed by Bristol-Myers Squibb, is the first-in-class NS5A inhibitor used in combination with sofosbuvir for the treatment of patients with chronic hepatitis C virus (HCV) genotype 3 infection. Compared to other treatment options, this combination not only increases the cure rate, but is also regarded as a valuable treatment option in some of the difficult-to-treat HCV patient subsets.

About the Medicines Patent Pool

The Medicines Patent Pool is a United Nations-backed public health organisation working to increase access to HIV, viral hepatitis C and tuberculosis treatments in low- and middle-income countries. Through its innovative business model, the MPP partners with industry, civil society, international organisations, patient groups and other stakeholders to prioritise, forecast and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, the MPP has signed agreements with six patent holders for twelve HIV antiretrovirals and for one hepatitis C direct-acting antiviral. Its generic partners have distributed more than three billion doses of low-cost medicines to 117 countries. The MPP was founded and remains fully funded by UNITAID.

About Cipla

Cipla is a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients. For 80 years, Cipla has emerged as one of the most respected pharmaceutical names in India as well as across more than 150 countries. Our portfolio includes 1,500 plus products across therapeutic categories with one quality standard globally.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla's emphasis on access for patients was recognized globally for the pioneering role played in HIV/AIDS treatment as the first pharmaceutical company to provide a triple combination anti-retroviral (ARV) in Africa at less than one dollar a day and thereby treating many millions of patients since 2001.

Cipla's research and development focuses on developing innovative products and drug delivery systems.

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