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The Medicines Patent Pool Announces First World Health Organization Prequalification Submissions for Generic Dolutegravir

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Geneva, 10 November 2016 — The Medicines Patent Pool (MPP) announced today that two of its generic manufacturing partners are the first companies to apply for prequalification of generic dolutegravir (DTG), a new antiretroviral that the MPP licensed from ViiV Healthcare in 2014. Cipla and Mylan have applied to WHO for prequalification of generic versions of the 50 mg tablet of DTG, a necessary step in allowing international procurers such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNICEF and UNITAID to purchase and distribute the treatment in developing countries.

"We congratulate our generic partners on achieving this milestone so quickly after signing agreements with the MPP," said Greg Perry, MPP's Executive Director. "We have worked closely with our partners on rapid product development to ensure the availability of generic DTG in low- and middle-income countries shortly after its rollout in high-income nations."

Recently recommended as an alternative first-line treatment by the WHO, DTG is considered a significant improvement in antiretroviral therapy. The treatment does not require boosting and has a good barrier to resistance, as well as high efficacy and tolerability at a relatively low dose. As part of a daily regimen, the 50 mg tablet is currently prescribed for patients that have never taken HIV therapy, as well as for the many that have developed resistance to current treatment.

"Dolutegravir is an important innovative antiretroviral drug with great ability to reduce viral loads quickly, as well as effectiveness in preventing resistance of the virus," said Sharadd Jain, Head of Cipla Global Access. "This kind of alternative treatment is imperative if we hope to meet international treatment scale-up targets and progress towards the elimination of HIV."

"We recognize the critical importance of growing our ARV portfolio, because 50% of people living with HIV/AIDS worldwide who are receiving treatment depend on a Mylan product," commented Mylan President Rajiv Malik. "Our submission of dolutegravir for WHO prequalification is another way we're demonstrating Mylan's commitment to providing the world's seven billion people access to high quality medicine."

ViiV Healthcare granted MPP two non-exclusive licences for the generic manufacture of DTG: one for the production of the medicine for adults and another for children. Both licences permit generic pharmaceutical companies based anywhere in the world to manufacture DTG and to combine the treatment with other drugs to develop fixed-dose combinations of regimens recommended by the WHO. In the spring of 2016, the two parties extended the adult licence to all lower middle-income countries, allowing sale of generic DTG in more than 130 countries.

ViiV Healthcare is facilitating applications for Tentative Approval by the US Food and Drug Administration (US FDA) of DTG products manufactured by MPP generic partners by waiving its right to a five-year new chemical entity (NCE) exclusivity for DTG, solely for the purpose of allowing the US FDA to review these applications.

Currently, nine MPP licensees are developing DTG as an active pharmaceutical ingredient and in formulations and will be submitting dossiers to the WHO PQ programme and/or the US FDA, some of them very soon.

"Robust competition among MPP licensees will improve access for this key medicine," concluded Perry.

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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 119 countries. The MPP was founded and remains fully funded by UNITAID.

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