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Medicines Patent Pool and Roche Sign HIV Medicines Agreement: Focus on Preventing Blindness in People Living with HIV

The Medicines Patent Pool and Roche today announce an agreement to increase access in developing countries to valganciclovir, a key easy-to-take oral medicine to treat cytomegalovirus (CMV), a viral infection that can cause blindness in people living with HIV.

The agreement will significantly improve access to Roche's valganciclovir for people living with HIV in 138 developing countries by making it up to 90% cheaper than current prices. As a second step, the Medicines Patent Pool and Roche will also enter into licensing and technology transfer negotiations to encourage the development of internationally approved quality generic versions of valganciclovir.

The most widely used treatment for CMV in developing countries requires injections directly to the eye, which can be painful and also difficult to administer on a large scale.

"The agreement announced today will make a more affordable oral treatment for CMV available immediately and also catalyse the creation of a sustainable generic market," said Greg Perry, Executive Director of the Medicines Patent Pool.

"There is a vicious cycle with CMV: since the current treatment options are either unaffordable or inconvenient, HIV clinics rarely screen for the disease. Because clinics rarely screen for CMV, there is little demand for treatment and therefore little demand for easier to administer, affordable solutions. As a result, preventable blindness continues to occur in people living with HIV, especially in Asia," said Dr David Heiden, a CMV expert working with Seva and Pacific Vision Foundations.

"CMV infection occurs when people have severely weakened immune systems. With timely initiation of antiretroviral therapy, HIV-related CMV has almost disappeared in developed countries, but in resource-limited settings still many people are not getting treated or start treatment late. CMV retinitis has not gone away and the availability of simpler, more affordable CMV treatment to prevent blindness from this disease is welcome news," said Dr Nathan Ford, of the World Health Organization (WHO) HIV/AIDS department.

The Medicines Patent Pool will also work with other key stakeholders to develop long-term treatment strategies for scaling up the use of valganciclovir for treatment of HIV-related CMV in developing countries.

In addition, the Medicines Patent Pool and Roche have agreed on the licensing of the antiretroviral, saquinavir, if a significant medical need is identified. The WHO recommends saquinavir as an alternative ARV in special situations and where other preferred treatments are not available.

NOTES TO THE EDITOR

CMV: Cytomegalovirus (CMV) is an opportunistic infection, which, in its most common form, attacks the retina of the eye in patients with suppressed immune systems, such as those with advanced HIV infection. Vision loss from CMV retinitis can be prevented through early diagnosis and treatment. HIV-related CMV disease is no longer a problem in developed countries, but still affects at-risk people living with HIV in low- and middle-income countries especially in Asia, and to a lesser extent in Latin America and Africa. According to new research that systematically reviewed 65 studies conducted in these regions. The new research was presented at this year's International AIDS Society Conference in Kuala Lumpur 30 June – 3 July and was published in *Clinical Infectious Diseases* (Ford N, Shubber Z, Saranchuk P et al. Burden of HIV-related CMV retinitis in resource-limited settings: a systematic review. Advanced Access published 29 July 2013, doi:10.1093/cid/cit494. See: <http://cid.oxfordjournals.org/content/early/recent>).

By region, the prevalence of patients diagnosed with CMV retinitis was 14.0% (11.8-16.2%), 12.0% (4.2-19.9%) and 2.2% (1.3-3.1%) in Asia, Latin America and Africa respectively. Traditionally, the treatment of CMV is difficult to administer, requiring several injections to the eye. This requires hospitalisation of patients and highly trained staff, which may not always be available in resource-limited settings. An alternative is the oral treatment valganciclovir.

Valganciclovir: Valganciclovir is indicated for the treatment of CMV. Currently, the main use of valganciclovir is for organ transplant patients. Due to access issues, the current use in HIV-related CMV is extremely small, thus there is insufficient demand to generate generic competition through licensing agreements. This differs substantially from other HIV medicines, which the Medicines Patent Pool has identified for immediate in-licensing. For this reason, the agreement with Roche is the first agreement that the Medicines Patent Pool has concluded that includes both a pricing and a licensing element. The agreement presently covers 138 countries but may be expanded further if there is an unmet treatment need in other countries.

The Medicines Patent Pool (MPP): The MPP is a United Nations backed organisation that offers a public-health driven business model that aims to lower the prices of HIV medicines and facilitate the development of better-adapted HIV medicines – such as simplified “fixed-dose combinations” and special formulations for children – in developing countries. It was founded in 2010 at the request of the international community through the WHO-based financing mechanism UNITAID. The MPP has been endorsed by the WHO, the 2011 UN High Level Meeting on AIDS, and the Group of 8 as a promising innovative approach to improve access to HIV medicines.

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