ViiV Healthcare and the Medicines Patent Pool sign new voluntary licensing agreement to expand access to innovative long-acting HIV prevention medicine

PUBLISHED JUL 28, 2022
BY GSK

For media and investors only

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, and the Medicines Patent Pool (MPP) today announced the signing of a new voluntary licensing agreement for patents relating to cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP) to help enable access in least developed, low-income, lower middle-income and Sub-Saharan African countries 1, 2.

Through this agreement, selected generic manufacturers will have the opportunity to develop, manufacture and supply generic versions of cabotegravir LA for PrEP, the first long-acting HIV prevention medicine, in 90 countries, subject to required regulatory approvals being obtained. It is expected that this agreement will help to enable at-scale access to generic cabotegravir LA for PrEP. This announcement comes just seven months after the first regulatory approval of cabotegravir LA for PrEP in the world, by the US Food and Drug Administration (US FDA).

Each year, there are approximately 1.5 million new cases of HIV worldwide 3, most of which occur in resource-limited countries, with women and adolescent girls disproportionately impacted. While oral PrEP options are available in many countries, challenges with adherence and stigma have limited their impact in some populations. Access to an effective long-acting HIV prevention option could significantly contribute towards the goal of ending the epidemic.

The new voluntary licence announced today builds on a long-standing partnership between ViiV Healthcare and MPP, which has been highly successful in facilitating the manufacture and sale of generic versions of oral ViiV Healthcare medicines in countries most affected by HIV and least able to pay for treatment and care. In particular, voluntary licensing has enabled access to generic products containing another of ViiV Healthcare's innovative medicines, dolutegravir, for at least 20 million people living with HIV in low- and middle-income countries, as of December 2021 4.

Deborah Waterhouse, CEO at ViiV Healthcare said,

> Today's announcement represents a potentially game-changing moment in HIV prevention. Enabling at-scale access to generic cabotegravir LA for PrEP could play a significant role in averting the transmission of HIV, particularly amongst women and adolescent girls and help end the HIV epidemic. I am proud that through our long-standing partnership with MPP, we continue to play our part in widening access for people in resource-limited countries to new innovative medicines.

Charles Gore, MPP Executive Director said,

> We are delighted to sign this voluntary licence with ViiV for cabotegravir LA for PrEP. Long-acting technologies open up a whole new dimension that facilitates medicine uptake, and this product brings a much-needed option for those at risk. This licence was negotiated in double-quick time and is another example of MPP's continued commitment to making innovation available and affordable in low- and lower middle-income countries in the shortest possible time. Rapid access to new technologies is our only hope of hitting the Sustainable Development Goal targets.

This voluntary licence forms part of a holistic approach to enable at-scale access to cabotegravir LA for PrEP in least developed, low-income, lower middle-income and Sub-Saharan African countries 1. There are complexities and considerations that need to be managed to support the manufacturing and roll out of a generic long-acting injectable. Compared to oral PrEP options, cabotegravir LA for PrEP is more complex to manufacture and there is an evolving and less well-defined demand for the product. These are challenges not only

for ViiV but also for any potential generic partners. ViiV Healthcare and MPP will now work closely with stakeholders and generic manufacturers selected through MPP's expression of interest to enable access to generic cabotegravir LA for PrEP as soon as possible.

Cabotegravir LA for PrEP is a long-acting injectable which has recently gained its first regulatory approval for use in HIV prevention in the USA for at risk adults and adolescents weighing at least 35kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to receiving it. It is not currently approved for use in HIV prevention anywhere outside of the USA. ViiV Healthcare has submitted marketing applications in a number of countries including the majority of countries where the clinical trials were conducted, with further registrations planned. ViiV Healthcare is also working with stakeholders including global health agencies, non-governmental organisations (NGOs), governments and community partners to understand country-specific contexts and is supporting implementation science projects that will provide critical information on the feasibility, acceptability and scalability to deliver successful introduction of cabotegravir LA for PrEP into national programmes.

> Long-acting PrEP has the potential to transform HIV prevention efforts, but only if it is made widely available at affordable prices. Unitaid welcomes the news of this voluntary licence, agreed in record time, which gives people at risk of infection additional options so they can choose the HIV prevention method that works for them. Developing solutions that respond to different needs and preferences is critical to averting new infections globally.

Dr Philippe Duneton, Executive Director, Unitaid

Unitaid created the MPP to facilitate access conditions for critical medicines in 2010 and continues to be MPP's principal funder. A new coalition to accelerate access to long-acting PrEP, convened by Unitaid and partners, is working to develop and implement coordinated strategies to overcome access challenges to new PrEP options.

> This is really welcome news and a next important step along the road to ensuring the promising innovation of injectable

> cabotegravir LA for PrEP is made accessible to all who would benefit from it even those from the least well-resourced regions. We know primary prevention is key to controlling HIV globally but to get the most from innovation we need access and scale up.

Linda-Gail Bekker, Director of the Desmond Tutu HIV Centre at the University of Cape Town

Indication and Important Safety Information for Apretude (cabotegravir extended-release injectable suspensions)

APRETUDE is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED EARLY HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

- Do not use APRETUDE in individuals:

- with unknown or positive HIV-1 status

- with previous hypersensitivity reaction to cabotegravir

- receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine

Comprehensive Management to Reduce the Risk of HIV-1 Infection:

- Use APRETUDE as part of a comprehensive prevention strategy, including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. Risk for HIV-1 acquisition includes, but is not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Inform, counsel, and support individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner[s] HIV-1 status, including viral suppression status; regular testing for STIs)

- Use APRETUDE only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment. Prior to initiating APRETUDE, ask seronegative individuals about recent (in past month) potential exposure events and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (

- When using APRETUDE, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs

- Additional HIV testing to determine HIV status is needed if an HIV-1 test indicates possible HIV-1 infection or if symptoms consistent with acute HIV-1 infection develop following an exposure event. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment

- Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE

Potential Risk of Resistance with APRETUDE:

- There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before, while taking, or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1–negative status. Individuals who are confirmed to have HIV-1 infection must transition to a

complete HIV-1 treatment. If individuals at continuing risk of HIV-1 acquisition discontinue APRETUDE, alternative forms of PrEP should be considered and initiated within 2 months of the final injection of APRETUDE

Long-Acting Properties and Potential Associated Risks with APRETUDE:

- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Take the prolonged-release characteristics of cabotegravir into consideration and carefully select individuals who agree to the required every-2-month injection dosing schedule because non-adherence or missed doses could lead to HIV-1 acquisition and development of resistance

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE

- Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated

- Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors

- Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated

- Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicidal ideation or attempt) have been reported with APRETUDE

- Promptly evaluate patients with depressive symptoms

Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions:

- The concomitant use of APRETUDE and other drugs may result in

reduced drug concentration of APRETUDE

- Refer to the full Prescribing Information for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE

The most common adverse reactions (incidence ≥1%, all grades) with APRETUDE were injection site reactions, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection.

- Refer to the full Prescribing Information for important drug interactions with APRETUDE

- Drugs that induce UGT1A1 may significantly decrease the plasma concentrations of cabotegravir

USE IN SPECIFIC POPULATIONS

- Lactation: Assess the benefit-risk of using APRETUDE to the infant while breastfeeding due to the potential for adverse reactions and residual concentrations in the systemic circulation for up to 12 months or longer after discontinuation

- Pediatrics: Not recommended in individuals weighing less than 35 kg

About the Medicines Patent Pool

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups, and other stakeholders to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with 15 patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, two long-acting

technologies, two oral antiviral treatments for COVID-19 and 12 COVID-19 technologies. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government, the French Ministry for Europe and Foreign Affairs and SDC.

ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of becoming infected with HIV. Shionogi joined as a shareholder in October 2012. The company's aims are to take a deeper and broader interest in HIV and AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV.

For more information on the company, its management, portfolio, pipeline, and commitment, please visit www.viivhealthcare.com.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company

Country classifications as defined by the World Bank: https://data.worldbank.org/country Country classifications as defined by the United Nations: LDCs at a Glance | Department of Economic and Social Affairs (un.org) https://www.unaids.org/en/resources/fact-sheet Medicines Patent Pool 'Access to Medicines tracker'. Data as of December 2021. https://medicinespatentpool.org/progress-achievements/access-t...

Press release distributed by Wire Association on behalf of GSK, on Jul 28, 2022. For more information subscribe and follow us.

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