Press release

For media and investors only

Issued:14 July 2025, London UK

ViiV Healthcare extends voluntary licensing agreement with Medicines Patent Pool to enable access to innovative long-acting injectable HIV treatment

- Agreement allows manufacturers to develop, manufacture and supply generic long-acting injectable cabotegravir (CAB LA) for treatment in 133 countries
- Builds on the voluntary licence for CAB LA for HIV pre-exposure prophylaxis (PrEP), enabling increased access to innovative long-acting injectables for HIV treatment

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GSK plc (LSE/NYSE: GSK) announced ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today shared an update to their voluntary licensing agreement with the Medicines Patent Pool (MPP) for cabotegravir to include patents relating to its use in a long-acting HIV treatment regimen. The announcement follows updated guidance from WHO recommending long-acting injectable cabotegravir + rilpivirine as an HIV treatment option.

Existing generic licensees for prevention will be able to develop, manufacture and supply generic CAB LA, for use in combination with long-acting rilpivirine, subject to required regulatory approvals being obtained, to help enable access to the long-acting treatment in 133 countries worldwide. This includes all least-developed, low-income, lower middle-income and Sub-Saharan African countries, as well as countries where ViiV does not have patent rights for cabotegravir.

Deborah Waterhouse, CEO at ViiV Healthcare said: “As leaders in long-acting innovation we’re proud to be expanding our voluntary licence with the MPP to now include treatment of HIV in addition to prevention. Long-acting injectables have the potential to transform HIV treatment and we welcome the latest recommendations from WHO to expand treatment options. In line with our mission to ensure no one living with HIV is left behind, we’re committed to working with partners like MPP to continue to increase access and reach those most impacted by HIV.”

Charles Gore, Executive Director at MPP said: “We’re delighted to extend the CAB LA licence to cover HIV treatment, reflecting the latest WHO recommendations. Our previous agreement with ViiV for dolutegravir has already enabled the supply of generic DTG-based HIV treatments in 129 countries and we hope that over time a similar coverage can be achieved for CAB LA. CAB LA is a vital addition to the HIV treatment toolbox — especially for people facing adherence challenges with oral regimens. Expanding access to long-acting options like this supports a more person-centred, choice- and needs-driven approach, which is exactly what an equitable and effective HIV response requires.”

Dr Meg Doherty, Director Global HIV, Hepatitis and STI Programmes at World Health Organisation said: "The World Health Organization welcomes the expansion of the voluntary licence agreement for long-acting cabotegravir to include HIV treatment. This step is closely aligned with WHO’s new recommendation of long-acting injectable antiretrovirals as an alternative for people who are virologically suppressed but face adherence challenges with daily oral regimens. It reflects our commitment to expanding access to innovative, person-centered treatment options that improve outcomes — particularly in underserved regions. This agreement aligns with our global goals to ensure equitable access to essential medicines and improve health outcomes for all. We are committed to supporting countries in implementing these new guidelines and ensuring that no one is left behind.”

The updated MPP-ViiV agreement is an extension of the voluntary license for cabotegravir for HIV PrEP. ViiV Healthcare has been supporting the generic manufacturers with technical know-how to enable development and access to CAB LA as soon as possible.

Through the agreement, the existing licensees, Aurobindo, Cipla and Viatris, will be able to develop, manufacture and supply generic versions of CAB LA, for use in combination with long-acting rilpivirine, for the treatment of HIV-1 infection in adults and adolescents weighing at least 35kg, subject to required regulatory approvals being obtained.

About *Apretude* (cabotegravir long-acting)
Apretude is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35kg who are at high risk of being infected. 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. It should be used in combination with safer sex practices, such as using condoms. *Apretude* contains the active substance cabotegravir.

Please consult the full EU Summary of Product Characteristics for all the safety information: *Apretude* 600 mg prolonged-release suspension for injection

About *Vocabria* (cabotegravir)
Vocabria injection is indicated - in combination with rilpivirine injection - for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents (at least 12 years of age and weighing at least 35kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitors (NNRTI) and integrase inhibitor (INI) class.

Vocabria tablets are indicated - in combination with rilpivirine tablets - for the short-term treatment of HIV-1 infection in adults and adolescents (at least 12 years of age and weighing at least 35kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class for:

- oral lead in to assess tolerability of *Vocabria* and rilpivirine prior to administration of long acting *Vocabria* injection plus long acting rilpivirine injection.
- oral therapy for adults who will miss planned dosing with *Vocabria* injection plus rilpivirine injection.

Vocabria tablets are only indicated for treatment of HIV-1 in combination with rilpivirine tablets, therefore, the prescribing information for *Edurant* (rilpivirine) tablets should also be consulted for recommended dosing.

Please consult the full EU Summary of Product Characteristics for all the safety information: *Vocabria* 400mg/600 mg prolonged-release suspension for injection and *Vocabria* 30 mg film-coated tablets

About *Rekambys (rilpivirine)*
Rekambys is indicated - in combination with cabotegravir injection - for the treatment of HIV-1 infection in adults and adolescents (at least 12 years of age and weighing at least 35kg) who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with, agents of the NNRTI and INI class.

Rekambys should always be co-administered with a cabotegravir injection. The prescribing information for cabotegravir injection should be consulted for recommended dosing. *Rekambys* may be initiated with oral lead-in or without (direct to injection).

Please consult the full EU Summary of Product Characteristics for all the safety information: *Rekambys* 600mg/900 mg prolonged-release suspension for injection

About ViiV Healthcare
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 could benefit from HIV prevention. Shionogi became a ViiV 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 viivhealthcare.com.

About GSK
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.

About MPP
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 22 patent holders for 13 HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a cancer treatment, four long-acting technologies, a post-partum haemorrhage medicine, three oral antiviral treatments for COVID-19 and 16 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), Government of Canada, the World Intellectual Property Organization (WIPO) and the Government of Flanders. MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government, the French Ministry for Europe and Foreign Affairs, the German Agency for International Cooperation, and SDC.

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