Press release

For media and investors only

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European Commission authorises ViiV Healthcare's long-acting injectable *Vocabria* + *Rekambys* for HIV treatment in adolescents

- *Vocabria* + *Rekambys* (cabotegravir + rilpivirine) is the first and only complete long-acting injectable for the treatment of HIV
- Ninety-nine percent of adolescents living with HIV preferred the long-acting injectable to a daily oral regimen when given the option due to convenience and pill burden reduction
- This Marketing Authorisation builds on company legacy of expanding access to medicines for children and young people

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GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, has today announced that the European Commission has authorised *Vocabria* (cabotegravir long-acting injections) in combination with Johnson & Johnson's *Rekambys* (rilpivirine long-acting injections) for the treatment of HIV-1 infection in adolescents 12 years of age and older and weighing at least 35 kg who are virologically suppressed.

As of 2023, there were 1.55 million people aged 10 to 19 around the world living with HIV; people in this age bracket typically have lower reported treatment coverage, adherence to treatment and viral suppression rates than older age groups.[1] Cabotegravir and rilpivirine long-acting reduces the number of doses needed for effective HIV treatment from 365 daily pills to as few as six injectable treatments per year and helps alleviate challenges with daily oral treatments, including stigma and adherence-related stress, in clinical trials and observed in real-world studies.[2,3]

Harmony P. Garges, M.D., Chief Medical Officer at ViiV Healthcare, said: "This authorisation for *Vocabria* + *Rekambys* is an important milestone for adolescents living with HIV across Europe who may prefer a long-acting HIV treatment that could address challenges with taking daily oral regimens and could better suit their individual needs. As the only global pharmaceutical company 100% dedicated to HIV, we are committed to ensuring no person living with HIV – regardless of their age – is left behind, and today's announcement is one more step towards realising this mission."

The Marketing Authorisations are supported by week 24 data from the MOCHA study, (IMPAACT 2017, Study 208580), an ongoing Phase I/II multicentre, open-label, non-comparative study of the safety, tolerability and pharmacokinetics of cabotegravir and rilpivirine long-acting. Based on data from the study in 144 adolescents (aged at least 12 years and weighing 35kg or more), no new safety concerns were identified and 139 of 144 participants (96.5%) remained virologically suppressed (plasma HIV-1 RNA value <50 c/mL).[4]

Ninety-nine percent of the MOCHA study participants (139/141) stated that they preferred injectable long-acting medicines over daily orals, mainly for the convenience and pill burden reduction; the most prominent components of pill burden reduction were decrease in adherence-related stress and increased privacy.[5]

Cabotegravir and rilpivirine long-acting, under the brand name *Vocabria* + *Rekambys*, was approved by the EMA for the treatment of HIV-1 in adults who are virologically suppressed in December 2020.

About *Vocabria*

Vocabria (cabotegravir) 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 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*
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 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 are at risk of acquiring HIV. 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.

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Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

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