Press release

For media and investors only

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ViiV Healthcare announces CHMP positive opinion for *Vocabria* + *Rekambys*, the first and only complete long-acting HIV treatment, for adolescents in Europe

- *Vocabria* + *Rekambys* (cabotegravir + rilpivirine) is the first and only complete long-acting regimen for the treatment of HIV, reducing dosing days from 365 to 6 per year
- At just 65% globally, treatment coverage for 10 – 19-year-olds living with HIV is lagging behind UNAIDS's target, demonstrating need to improve HIV care options for 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 Committee for Medicinal Products for Human Use (CHMP) of the Europe Medicines Agency (EMA) has issued a positive opinion recommending marketing authorisation for *Vocabria* (cabotegravir long-acting injections) in combination with Johnson & Johnson Innovative Medicine'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 young people aged 10 to 19 around the world living with HIV.[1] Advances in treatment mean HIV can be a manageable condition, but some people face challenges with taking daily oral regimens, including adherence, the daily reminder of HIV, and a fear of disclosure and associated stigma.[2]

This expanded indication for cabotegravir and rilpivirine long-acting, if approved, will mark the first time a complete, long-acting regimen is available for adolescents living with HIV, who have lower reported treatment coverage, adherence to treatment and viral suppression rates than older age groups.[1]

Harmony P. Garges, M.D., MPH, Chief Medical Officer at ViiV Healthcare, said: "Today's positive CHMP opinion is an important step towards bringing the first long-acting injectable regimen to adolescents living with HIV. Long-acting regimens have potential to provide effective HIV therapy and help address the challenges many people face taking daily oral regimens. This progress underscores our ongoing commitment to bringing more therapeutic options to young people as part of our mission to leave no person living with HIV behind."

The positive opinion is 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) at week 24.[3] Furthermore, 99% of participants asked at week 24 (139/141) stated that they preferred injectable long-acting medicines over daily orals, mainly for the convenience and burden reduction; the most prominent components of burden reduction were decrease in adherence-related stress and increased privacy.[4]

Marketing Authorisation from the European Commission is anticipated in the coming months. 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 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 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 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 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.

GSK enquiries:

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Annabel Brownrigg-Gleeson	+44 (0) 7901 101944	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)

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Camilla Campbell	+44 (0) 7803 050238	(London)
Steph Mountifield	+44 (0) 7796 707505	(London)
Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
Frannie DeFranco	+1 215 751 4855	(Philadelphia)

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.

Registered in England & Wales:
GSK plc
No. 3888792

ViiV Healthcare Limited
No. 06876960

Registered Office:
79 New Oxford Street
London
WC1A 1DG

ViiV Healthcare Limited
GSK Medicines Research Centre
Gunnels Wood Road, Stevenage
United Kingdom
SG1 2NY

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