PRESS RELEASE

For media and investors only

ViiV Healthcare announces FDA approval of Cabenuva (cabotegravir, rilpivirine), the first and only complete long-acting regimen for HIV treatment

Cabenuva allows virologically suppressed adults living with HIV without prior treatment failure or resistance to cabotegravir or rilpivirine to maintain viral suppression with 12 dosing days per year

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London, 21 January 2021 – ViiV Healthcare, the global specialist HIV company majority owned by GlaxoSmithKline plc ("GSK"), with Pfizer Inc. and Shionogi Limited as shareholders, today announced that the US Food and Drug Administration (FDA) approved Cabenuva, the first and only complete long-acting regimen for the treatment of HIV-1 infection in adults. Cabenuva is provided as a co-pack with two injectable medicines — ViiV Healthcare's cabotegravir and Janssen's rilpivirine — dosed once monthly, as an option to replace the current antiretroviral (ARV) regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per milliliter [mL]) on a stable regimen, with no history of treatment failure, and with no known or suspected resistance to either cabotegravir or rilpivirine. Prior to initiating treatment of Cabenuva, oral dosing of cabotegravir and rilpivirine should be administered for approximately one month to assess the tolerability of each therapy.[1]

Lynn Baxter, Head of North America, ViiV Healthcare, said: "Today's FDA approval of Cabenuva represents a shift in the way HIV is treated, offering people living with HIV a completely new approach to care. Cabenuva reduces the treatment dosing days from 365 days to 12 days per year. At ViiV Healthcare, we are dedicated to ensuring no one living with HIV is left behind, and adding this first-of-its-kind regimen to our industry-leading portfolio of innovative medicines reinforces our mission."

The approval of Cabenuva is based on the pivotal phase III ATLAS (Antiretroviral Therapy as Long-Acting Suppression) and FLAIR (First Long-Acting Injectable Regimen) studies that included more than 1,100 patients from 16 countries. Prior to initiating treatment with Cabenuva, oral dosing of cabotegravir and rilpivirine (lead-in) was administered for approximately one month to assess the tolerability of each

therapy. In these studies, Cabenuva was as effective in maintaining viral suppression as continuing a daily oral three-drug regimen when injected intramuscularly in the buttocks once a month throughout the 48-week study period. In both studies, the most common adverse reactions (Grades 1 to 4) observed in ≥ 2% of clinical trial participants receiving Cabenuva were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness and rash. Serious adverse events occurred in 4% (24/591) of patients taking Cabenuva, and 3% (17/591) of adverse events led to withdrawal.[1]

Cabenuva was preferred by nine out of 10 patients over their previous daily oral therapy in these pivotal studies. Patient preference data was collected from clinical trial participants who received Cabenuva. In a pooled exploratory analysis of this Intent-to-Treat Exposed (ITT-E) population, 532 patients completed a single-item question at Week 48 (59 patients did not) and 88% (523/591) preferred Cabenuva compared with two percent (9/591) who preferred their previous ARV treatment. The results were descriptive in nature and are not intended to imply clinical significance.[2,3]

Dr. David Wohl, professor of medicine at the University of North Carolina Institute of Global Health and Infectious Diseases in Chapel Hill, said: "Among the scientific community, we recognize the innovation behind Cabenuva is truly meaningful. Not only is it the first, complete long-acting regimen, which allows for a dramatic reduction in the frequency of dosing, but it also was preferred by most clinical trial participants when compared to their prior daily oral regimens. The FDA approval of Cabenuva underscores the value of community-centric research and I am pleased this new option will be available for those living with HIV."

To support the successful delivery of the once-monthly regimen to people living with HIV (PLHIV), ViiV Healthcare sponsored the CUSTOMIZE trial, the first-ever, pre-approval implementation science study to identify and evaluate approaches to integrate Cabenuva into clinical practices in the US. Interim findings presented at AIDS2020 demonstrated that at four months, the majority of clinical staff participants continued to perceive the implementation of Cabenuva as highly acceptable, feasible and appropriate for PLHIV, and clinical staff had a substantial decrease in what they thought would be barriers to implementation of the injectable regimen.[4]

Brett Andrews, CEO of PRC, said: "PRC provides legal, workforce and behavioral health services for those affected by HIV/AIDS in San Francisco. For years, many of our clients have struggled to manage their health while working to stabilize key aspects of their lives. Cabenuva will provide some people living with HIV greater freedom to pursue vocational, educational and other opportunities, like travel, without the need for daily oral medication management. A long-acting regimen is an innovation we have been waiting for."

ViiV Healthcare will begin shipping Cabenuva to wholesalers and specialty distributors in the US in February 2021.

The New Drug Application for Vocabria (cabotegravir) 30 milligram (mg) oral tablets was also approved by the FDA. Vocabria is indicated, in combination with rilpivirine tablets, as a complete regimen for short-term treatment of HIV-1 infection in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as an oral lead-in to assess tolerability of cabotegravir prior to initiating Cabenuva and as an oral therapy for patients who will miss planned injection dosing of Cabenuva.

About Cabenuva (cabotegravir, rilpivirine)

Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies per milliliter [mL]) on a stable regimen, with no history of treatment failure, and with no known or suspected resistance to either cabotegravir or rilpivirine. Cabenuva is administered as two intramuscular injections (cabotegravir and rilpivirine) in the buttocks during the same visit at a specialist clinic by a healthcare professional.

The complete regimen combines the integrase strand transfer inhibitor (INSTI) cabotegravir, developed by ViiV Healthcare, with rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Rilpivirine is approved in the US as a 25mg tablet taken once-a-day for the treatment of HIV-1 in

combination with other antiretroviral agents in antiretroviral treatment-naïve patients 12 years of age and older and weighing at least 35-kg with a viral load ≤ 100,000 HIV RNA copies/mL.

INSTIs, like cabotegravir, inhibit HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection. Rilpivirine is an NNRTI that works by interfering with an enzyme called reverse transcriptase, which in turn stops the virus from multiplying.

About ATLAS and FLAIR

ATLAS (NCT02951052) is a phase III, open-label, active-controlled, multicenter, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of long-acting, injectable cabotegravir and rilpivirine dosed every four weeks compared to continuation of current oral ARV of two nucleoside reverse transcriptase inhibitors (NRTIs) plus an integrase inhibitor (INI), NNRTI, or protease inhibitor (PI) among virally suppressed individuals. The primary endpoint for ATLAS is the proportion of participants with plasma HIV-1 RNA ≥50 c/mL per the FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, ITT-E population). Subjects were required to be virally suppressed for six months or greater, on first or second regimen, with no prior failure.

ATLAS includes 616 men and women living with HIV and is being conducted at research centers in Argentina, Australia, Canada, France, Germany, Italy, Mexico, Russia, South Africa, South Korea, Spain, Sweden, and the United States.

FLAIR (NCT02938520) is a phase III, randomized, open-label, multicenter, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of intramuscular, long-acting, injectable cabotegravir and rilpivirine in virologically suppressed adults living with HIV, following 20 weeks of induction therapy with Triumeq (abacavir/dolutegravir/lamivudine). The primary endpoint for FLAIR is the proportion of participants with plasma HIV-1 RNA ≥50 c/mL per the FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, ITT-E population).

FLAIR includes 566 men and women living with HIV and is being conducted at research centers in Canada, France, Germany, Italy, Japan, the Netherlands, Russia, South Africa, Spain, the United Kingdom, and the United States.

Important Safety Information for Cabenuva

Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

CONTRAINDICATIONS

- Do not use Cabenuva in patients with previous hypersensitivity reaction to cabotegravir or rilpivirine.
- Do not use Cabenuva in patients receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, systemic dexamethasone (>1 dose), and St John's wort.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Hypersensitivity reactions, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported during postmarketing experience with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries.
- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with Cabenuva.
- Discontinue Cabenuva immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. Prescribe the oral lead-in prior to administration of Cabenuva to help identify patients who may be at risk of a hypersensitivity reaction.

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Post-Injection Reactions:

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in blood pressure. These events may have been associated with inadvertent (partial) intravenous administration and began to resolve within a few minutes after the injection.
- Carefully follow the Instructions for Use when preparing and administering Cabenuva to avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a post-injection reaction occurs, monitor and treat as clinically indicated.

Hepatotoxicity:

- Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors.
- Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations.
- Monitoring of liver chemistries is recommended and treatment with Cabenuva should be discontinued if hepatotoxicity is suspected.

Depressive Disorders:

- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation or attempt) have been reported with Cabenuva or the individual products.
- Promptly evaluate patients with depressive symptoms.

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

- The concomitant use of Cabenuva and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions).

- Rilpivirine doses 3 and 12 times higher than the recommended oral dosage can prolong the QTc interval. Cabenuva should be used with caution in combination with drugs with a known risk of Torsade de Pointes.

Long-Acting Properties and Potential Associated Risks with Cabenuva:

- Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). Select appropriate patients who agree to the required monthly injection dosing schedule because non-adherence to monthly injections or missed doses could lead to loss of virologic response and development of resistance.
- To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of Cabenuva. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2%, all grades) with Cabenuva were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash.

DRUG INTERACTIONS

- Refer to the applicable full Prescribing Information for important drug interactions with Cabenuva, Vocabria, or rilpivirine.
- Because Cabenuva is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.
- Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease the plasma concentrations of cabotegravir. Drugs that induce or inhibit CYP3A may affect the plasma concentrations of rilpivirine.
- Cabenuva should be used with caution in combination with drugs with a known risk of Torsade de Pointes.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are insufficient human data on the use of Cabenuva during pregnancy to adequately assess a drug-associated risk for birth defects and miscarriage. Discuss the benefit-risk of using Cabenuva during pregnancy and conception and consider that cabotegravir and rilpivirine are detected in systemic circulation for up to 12 months or longer after discontinuing injections of Cabenuva. An Antiretroviral Pregnancy Registry has been established.
- **Lactation:** The CDC recommends that HIV-1–infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. Breastfeeding is also not recommended due to the potential for developing viral resistance in HIV-positive infants, adverse reactions in a breastfed infant, and detectable cabotegravir and rilpivirine concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of Cabenuva.

Please see full Prescribing Information.

Important Safety Information for Vocabria

Vocabria is a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with rilpivirine for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as:

- oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva (cabotegravir; rilpivirine) extended-release injectable suspensions.
- oral therapy for patients who will miss planned injection dosing with Cabenuva.

CONTRAINDICATIONS

- Previous hypersensitivity reaction to cabotegravir.
- Coadministration with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine.

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WARNINGS AND PRECAUTIONS

- Hypersensitivity reactions have been reported in association with other integrase inhibitors. Discontinue Vocabria immediately if signs or symptoms of hypersensitivity reactions develop.
- Hepatotoxicity has been reported in patients receiving cabotegravir. Monitoring of liver chemistries is recommended. Discontinue Vocabria if hepatotoxicity is suspected.
- Depressive disorders have been reported with Vocabria. Prompt evaluation is recommended for depressive symptoms.
- Risks Associated with Combination Treatment: Review the prescribing information for rilpivirine prior to initiation of Vocabria in combination with rilpivirine.

ADVERSE REACTIONS

The most common adverse reactions (Grades 1 to 4) observed in at least 3 subjects receiving Vocabria were headache, nausea, abnormal dreams, anxiety, and insomnia.

DRUG INTERACTIONS

- Refer to the full prescribing information for important drug interactions with Vocabria.
- Because Vocabria in combination with rilpivirine is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.
- Drugs that induce uridine diphosphate glucuronosyltransferase (UGT)1A1 may decrease the plasma concentrations of cabotegravir.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission.

Please see full Prescribing Information.

About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people

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living with HIV and for people who are at risk of becoming infected with HIV. Shionogi joined in October 2012. The company's aim is to take a deeper and broader interest in HIV/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.

About ViiV Healthcare's Patient Assistance Program

ViiV Healthcare is committed to providing assistance to eligible people living with HIV in the US who need our medicines. ViiV Healthcare's centralized service, ViiV Connect, provides comprehensive information on access and coverage to help patients living in the US get their prescribed ViiV Healthcare medicines whether they are insured, underinsured or uninsured. ViiV Connect provides one-on-one support from dedicated access coordinators, as well as having an integrated website, one site with many resources, including a portal. For more information on ViiV Connect, visit www.viivconnect.com.

About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

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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 the company's Annual Report on Form 20-F for 2019 and as set out in GSK's "Principal risks and uncertainties" section of the Q3 Results and any impacts of the COVID-19 pandemic.

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[1] Cabenuva (cabotegravir, rilpivirine) Prescribing Information. US Approval January 2021.

[2] Swindells S, Andrade-Villnueva J-F, Richmond GJ, et al. Long-Acting Cabotegravir and Rilpivirine for Maintenance of HIV-1 Suppression. New England Journal of Medicine, 382(12), 1112–1123. https://doi.org/10.1056/nejmoa1904398

[3] Orkin C, Arastéh K, Hernández-Mora MG, et al. Long-Acting Cabotegravir and Rilpivirine after Oral Induction for HIV-1 Infection. New England Journal of Medicine, 382(12), 1124–1135. https://doi.org/10.1056/nejmoa1909512

[4] Czarnogorksi M, Garris C, Wannamaker P, et al. Perceived Implementation Barriers Decrease During Initial Stages of an Implementation Science Hybrid III Study (CUSTOMIZE) of Cabotegravir and Rilpivirine Long-Acting (CAB + RPV LA) in US Healthcare Settings: Healthcare Team Perspective. Presented at 23rd International AIDS Conference 2020.