ViiV Healthcare presents positive interim data showing Vocabria (cabotegravir) and Rekambys (rilpivirine) can be implemented successfully in a variety of European healthcare settings

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ViiV Healthcare, the global specialist HIV company majority owned by GlaxoSmithKline plc (“GSK”), with Pfizer Inc. and Shionogi Limited as shareholders, today presented positive interim data from the CARISEL (Cabotegravir and Rilpivirine Implementation Study in European Locations) study, which was initiated and conducted during the COVID-19 pandemic. The study evaluated perspectives of healthcare teams and people living with HIV, through surveys and interviews, around the implementation of Vocabria (cabotegravir injection) and Janssen Pharmaceutical Companies of Johnson & Johnson’s Rekambys (rilpivirine long-acting injectable suspension) administered every 2-months, with data showing that implementation of the long-acting regimen is realistic and achievable in a variety of European healthcare settings.,, Interim findings were presented at the 18th European AIDS Conference (EACS 2021) being held 27-30 October.

The majority of healthcare teams across Europe agreed or completely agreed that long-acting cabotegravir and rilpivirine was acceptable, appropriate and feasible to implement (mean scores 4.6, 4.1, 4.2, respectively, on a 5-point Likert scale). 1 People living with HIV on the trial were also receptive to the regimen, with 97% feeling it was acceptable to come to clinic for an injection visit every 2-months. 2

Dr Laurence Slama, CARISEL investigator, l’Hôtel Dieu Hospital, Paris, said:

> Despite some initial concerns around implementing long-acting

> cabotegravir and rilpivirine, the CARISEL study interim findings showed that healthcare teams and people living with HIV continued to feel positive about the regimen as the study progressed. These findings were seen across all five European countries in which the study was conducted, suggesting that implementation of this regimen can work well across diverse healthcare systems and settings. It is encouraging to see enthusiasm for this novel regimen for treating HIV among the medical community as well as people who have actually been receiving treatment, and we look forward to seeing the full study results.

Implementation concerns that were identified among healthcare teams at the start of the study reduced markedly when compared to the baseline across all European countries involved once the study began. 1,3 The barriers cited as being the most “moderately” to “extremely concerning” at Month 1 included risk of resistance (36%, compared to 16% at Month 5), enough staffing (34%, compared to 18% at Month 5), and injection pain/soreness (34%, compared to 25% at Month 5). 1 COVID-19 and national lockdowns presented a potential challenge in starting patients on this novel regimen, however, there were few documented COVID-related disruptions for the initiation of the long-acting regimen.

The interim data from CARISEL reinforce 12-month findings from the corresponding CUSTOMIZE study in the US*, presented in July 2021, which showed that the long-acting regimen, dosed monthly, can be successfully implemented into clinical practice in the US, across a variety of clinic types.

Harmony P. Garges, M.D., MPH, Chief Medical Officer at ViiV Healthcare said:

> At ViiV Healthcare, we are proud to offer innovative treatment choices that help address the evolving needs of people living with HIV. We are encouraged by the interim data from CARISEL, as it shows that implementation of the first complete long-acting HIV regimen is feasible, with positive sentiment seen across multiple European countries in varied clinical settings. The findings reinforce and are consistent with what we saw in CUSTOMIZE with monthly dosing in the US; that this innovative treatment option dosed every 2-months can also be

successfully implemented across Europe.

Additional findings from the interim CARISEL data included:

- Most people living with HIV who started treatment continued to feel positive about the long-acting regimen, with 91% feeling positive at Month 4 vs 84% at Month 1,2

- Healthcare teams also felt positive about the long-acting regimen, with 81% feeling positive at Month 5 1

- Most people living with HIV on the trial agreed or completely agreed that long-acting cabotegravir and rilpivirine was highly acceptable, appropriate and feasible to implement (mean scores of 4.6, 4.6, 4.6 respectively on a 5-point Likert scale) 2

- Most healthcare teams found long-acting cabotegravir and rilpivirine acceptable for people living with HIV citing factors including eliminating worry about carrying and taking HIV pills (44%) 3

ViiV Healthcare's cabotegravir in combination with Janssen Pharmaceutical Companies of Johnson & Johnson's rilpivirine was co-developed as part of a collaboration with Janssen and builds on ViiV Healthcare's industry-leading portfolio that is centred on delivering innovative medicines for the HIV community.

*The every 2-month dosing of the long-acting regimen of cabotegravir and rilpivirine is not currently approved in the US. Only the monthly dosing is currently approved by the FDA.

About CARISEL (NCT04399551)

CARISEL is a Phase IIIb, open-label, multicentre, one-year study examining different implementation strategies in a broad range of clinical settings across European countries to identify strategies which best meet the needs in each local context. The study, which involved 437 patient study participants and 70 healthcare team participants from 18 clinics across Spain, France, Netherlands, Belgium, and Germany, assessed the effect of various implementation strategies on the acceptability, appropriateness and feasibility of delivering the new long-acting regimen of cabotegravir and rilpivirine to appropriate people living with HIV.

About Vocabria (cabotegravir injection) and Rekambys (rilpivirine injection),

Cabotegravir injection used in combination with rilpivirine injection is a complete long-acting regimen dosed monthly or every 2-months, for the treatment of HIV-1 in adults who are virologically suppressed (HIV-1 RNA

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.

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.

Important Safety Information

The following Important Safety Information is based on the Summary of Product Characteristics for Vocabria. Please consult the full Summary of Product Characteristics for all the safety information.

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

Vocabria injection is indicated for the treatment of HIV-1 in combination with rilpivirine injection, therefore, the prescribing information for rilpivirine injection should be consulted for recommended dosing.

Vocabria tablets are indicated in combination with rilpivirine tablets for the short-term treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1

RNA

- 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.

Prior to starting Vocabria injection, healthcare professionals should have carefully selected patients who agree to the required injection schedule and counsel patients about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses.

Following discontinuation of Vocabria and rilpivirine injection, it is essential to adopt an alternative, fully suppressive antiretroviral regimen no later than one month after the final injection of Vocabria when dosed monthly and no later than two months after the final injection of Vocabria when dosed every 2 months.

Elderly (≥65 years of age): No dose adjustment is required in elderly patients. There are limited data available on the use of cabotegravir in patients aged 65 years and over.

Paediatrics (

Hypersensitivity to cabotegravir or rilpivirine or to any of the excipients.

Concomitant use with: rifampicin, rifapentine, carbamazepine, oxcarbazepine, phenytoin or phenobarbital.

Special Warnings and Precautions for Use

| Risk of resistance following treatment discontinuation

To minimise the risk of developing viral resistance it is essential to

adopt an alternative, fully suppressive antiretroviral regimen no later than one month after the final injection of Vocabria when dosed monthly and no later than two months after the final injection of Vocabria when dosed every 2 months. |

Residual concentrations of cabotegravir may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer), therefore, physicians should take the prolonged release characteristics of Vocabria injection into consideration when the medicinal product is discontinued.

If virologic failure is suspected, an alternative regimen should be adopted as soon as possible.

Baseline factors associated with virological failure

Before starting the regimen, it should be taken into account that multivariable analyses indicate that a combination of at least 2 of the following baseline factors may be associated with an increased risk of virological failure: archived rilpivirine resistance mutations, HIV-1 subtype A6/A1, or BMI ≥30 kg/m2. In patients with an incomplete or uncertain treatment history without pre-treatment resistance analyses, caution is warranted in the presence of either BMI ≥30 kg/m2 or HIV-1 A6/A1 subtype.

Hypersensitivity reactions

Hypersensitivity reactions have been reported in association with other integrase inhibitors. These reactions were characterised by rash, constitutional findings and sometimes organ dysfunction, including liver injury. While no such reactions have been observed to date in association with Vocabria, physicians should remain vigilant and should discontinue Vocabria and other suspected medicinal products immediately, should signs or symptoms of hypersensitivity develop (including, but not limited to, severe rash, or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, facial oedema, hepatitis, eosinophilia or angioedema). Clinical status, including liver aminotransferases should be monitored and appropriate therapy initiated. Administration of oral lead-in is recommended to help identify patients who may be at risk of a hypersensitivity reaction.

Hepatotoxicity has been reported in a limited number of patients

receiving Vocabria with or without known pre-existing hepatic disease.

Monitoring of liver chemistries is recommended and treatment with Vocabria should be discontinued if hepatotoxicity is suspected.

Patients with hepatitis B co-infection were excluded from studies with Vocabria. It is not recommended to initiate Vocabria in patients with hepatitis B co-infection. Physicians should refer to current treatment guidelines for the management of HIV infection in patients co-infected with hepatitis B virus.

Limited data is available in patients with hepatitis C co-infection. Monitoring of liver function is recommended in patients with hepatitis C co-infection.

Interactions with medicinal products

Caution should be given to prescribing Vocabria injection and tablets with medicinal products that may reduce its exposure.

Concomitant use of Vocabria injection with rifabutin is not recommended.

Polyvalent cation containing antacids are recommended to be taken at least 2 hours before and 4 hours after taking Vocabria tablets.

Effect of other medicinal products on the pharmacokinetics of cabotegravir

Cabotegravir is primarily metabolised by uridine diphosphate glucuronosyl transferase (UGT) 1A1 and to a lesser extent by UGT1A9. Medicinal products which are strong inducers of UGT1A1 or UGT1A9 are expected to decrease cabotegravir plasma concentrations leading to lack of efficacy.

Summary of the safety profile

The most frequently reported adverse reactions (ARs) from monthly dosing studies were injection site reactions (up to 84%), headache (up to 12%) and pyrexia* (10%).

The most frequently reported ARs from ATLAS-2M every 2-month dosing were injection site reactions (76%), headache (7%) and pyrexia* (7%).

*Pyrexia includes the following: feeling hot, body temperature increased.

Description of selected adverse reactions

Local injection site reactions (ISRs)

Up to 1% of subjects discontinued treatment with Vocabria plus rilpivirine because of ISRs. When dosing monthly, up to 84% of subjects reported injection site reactions; out of 30393 injections, 6815 ISRs were reported. When dosing every 2 months, 76% of patients reported injection site reactions; out of 8470 injections, 2507 ISRs were reported.

The severity of reactions was generally mild (Grade 1, 70%-75% of subjects) or moderate (Grade 2, 27%-36% of subjects). 3-4% of subjects experienced severe (Grade 3) ISRs. The median duration of overall ISR events was 3 days. The percentage of subjects reporting ISRs decreased over time.

At the Week 48 time point, subjects in studies FLAIR and ATLAS, who received Vocabria plus rilpivirine gained a median of 1.5 kg in weight subjects continuing on their current antiretroviral therapy (CAR) gained a median of 1.0 kg (pooled analysis). In the individual studies FLAIR and ATLAS, the median weight gains in the Vocabria plus rilpivirine arms were 1.3 kg and 1.8 kg respectively, compared to 1.5 kg and 0.3 kg in the CAR arms.

At the 48 week timepoint, in ATLAS-2M the median weight gain in both the monthly and 2-monthly CAB+RPV dosing arms was 1.0 kg.

There are a limited amount of data from the use of cabotegravir in pregnant women. The effect of Vocabria on human pregnancy is unknown.

Cabotegravir was not teratogenic when studied in pregnant rats and rabbits but, exposures higher than the therapeutic dose showed reproductive toxicity in animals. The relevance to human pregnancy is unknown.

Vocabria injection is not recommended during pregnancy unless the expected benefit justifies the potential risk to the foetus.

Cabotegravir has been detected in systemic circulation for up to 12 months or longer after an injection

It is expected that cabotegravir will be secreted into human milk based on animal data, although this has not been confirmed in humans. Cabotegravir may be present in human milk for up to 12 months or longer after the last cabotegravir injection.

It is recommended that HIV infected women do not breast-feed their infants under any circumstances in order to avoid transmission of HIV.

Rekambys (rilpivirine injection) ISI

The following Important Safety Information is based on the Summary of Product Characteristics for REKAMBYS (rilpivirine injection). Please consult the full Summary of Product Characteristics for all the safety information.

REKAMBYS is indicated, in combination with cabotegravir injection, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA

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).

The healthcare professional and patient may decide to use rilpivirine tablets as an oral lead-in prior to the initiation of REKAMBYS injections to assess tolerability or proceed directly to REKAMBYS therapy.

When used for oral lead-in prior to the initiation of REKAMBYS, rilpivirine oral tablets, together with cabotegravir oral tablets, should be taken for approximately 1 month (at least 28 days) to assess tolerability to rilpivirine and cabotegravir. One rilpivirine 25mg tablet should be taken with a meal with one cabotegravir 30mg tablet once daily.

Prior to starting REKAMBYS, the healthcare professional should carefully select patients who agree to the required injection schedule

and counsel patients about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance associated with missed doses.

Following discontinuation of REKAMBYS in combination with cabotegravir injection, it is essential to adopt an alternative, fully suppressive antiretroviral regimen no later than one month after the last every 1 month injection of REKAMBYS or two months after the last every 2 months injection of REKAMBYS.

Elderly: There is limited information regarding the use of REKAMBYS in patients > 65 years of age. No dose adjustment of REKAMBYS is required in older patients.

Paediatric Patients: The safety and efficacy of REKAMBYS in children and adolescents aged

Hypersensitivity to the active substance or to any of the excipients.

REKAMBYS must not be co-administered with the following medicinal products, which may result in loss of therapeutic effect of REKAMBYS:

- the anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, phenytoin

- the antimycobacterials rifabutin, rifampicin, rifapentine

- the systemic glucocorticoid dexamethasone, except as a single dose treatment

- St John’s wort (Hypericum perforatum).

Special Warnings and Precautions for Use

Risk of resistance following treatment discontinuation

| To minimise the risk of developing viral resistance it is essential to adopt an alternative, fully suppressive antiretroviral regimen no later than one month after the last every 1 month injection of REKAMBYS or two months after the last every 2 months injection of REKAMBYS.

If virologic failure is suspected, an alternative regimen should be adopted as soon as possible. |

Long-acting properties of rilpivirine injection

Residual concentrations of rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 4 years in some patients) and should be considered upon discontinuation of REKAMBYS.

Baseline factors associated with virological failure

Before starting the regimen, it should be taken into account that multivariable analyses indicate that a combination of at least 2 of the following baseline factors may be associated with an increased risk of virological failure: archived rilpivirine resistance mutations, HIV-1 subtype A6/A1, or BMI ≥30 kg/m2. In patients with an incomplete or uncertain treatment history without pre-treatment resistance analyses, caution is warranted in the presence of BMI ≥30 kg/m2 and/or HIV-1 subtype A6/A1.

Partial intravenous administration may result in AEs due to temporarily high plasma concentrations. In clinical studies, serious post-injection reactions were reported within minutes after the injection of rilpivirine, including dyspnoea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in blood pressure. These events were very rare and began to resolve within a few minutes after the injection.

Carefully follow the Instructions for Use when preparing and administering REKAMBYS to avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a patient experiences a post-injection reaction, monitor and treat as clinically indicated.

REKAMBYS should be used with caution when co-administered with a medicinal product with a known risk of Torsade de Pointes. At supra-therapeutic doses (75 and 300 mg once daily), oral rilpivirine has been associated with prolongation of the QTc interval of the electrocardiogram (ECG). Oral rilpivirine at the recommended dose of 25 mg once daily is not associated with a clinically relevant effect on QTc. Plasma rilpivirine concentrations after REKAMBYS injections are comparable to those during such oral rilpivirine therapy.

Patients with hepatitis B co-infection were excluded from studies with REKAMBYS. It is not recommended to initiate REKAMBYS in patients

with hepatitis B co-infection. In patients co-infected with hepatitis B receiving oral rilpivirine, the incidence of hepatic enzyme elevation was higher than in patients receiving oral rilpivirine who were not hepatitis B co-infected. Physicians should refer to current treatment guidelines for the management of HIV infection in patients co-infected with hepatitis B virus.

Limited data is available in patients with hepatitis C co-infection. In patients co-infected with hepatitis C receiving oral rilpivirine, the incidence of hepatic enzyme elevation was higher than in patients receiving oral rilpivirine who were not hepatitis C co-infected. The pharmacokinetic exposure of oral and injectable rilpivirine in co-infected patients was comparable to that in patients without hepatitis C co-infection. Monitoring of liver function is recommended in patients with hepatitis C co-infection.

Interactions with other medicinal products

REKAMBYS should not be administered with other antiretroviral medicinal products, except for cabotegravir injection for the treatment of HIV-1 infection.

There are limited data of REKAMBYS in pregnant women. REKAMBYS is not recommended during pregnancy unless the expected benefit justifies the potential risk. Lower exposures of oral rilpivirine were observed when rilpivirine 25 mg once daily was taken during pregnancy. In the Phase 3 studies with oral rilpivirine, lower rilpivirine exposure, similar to that seen during pregnancy, has been associated with an increased risk of virological failure, therefore viral load should be monitored closely. Alternatively, switching to another ART regimen could be considered.

Immune reactivation syndrome

In HIV-infected patients with severe immune deficiency at the time of institution of combination antiretroviral therapy (CART), an inflammatory reaction to asymptomatic or residual opportunistic pathogens may arise and cause serious clinical conditions, or aggravation of symptoms. Typically, such reactions have been observed within the first few weeks or months of initiation of CART. Relevant examples are cytomegalovirus retinitis, generalised and/or focal mycobacterial infections, and Pneumocystis jirovecii pneumonia. Any inflammatory symptoms should be evaluated and treatment

instituted when necessary. Autoimmune disorders (such as Graves' disease and autoimmune hepatitis) have also been reported to occur in the setting of immune reconstitution, however, the reported time to onset is more variable and these events can occur many months after initiation of treatment.

While effective viral suppression with antiretroviral therapy has been proven to substantially reduce the risk of sexual transmission, a residual risk cannot be excluded. Precautions to prevent transmission should be taken in accordance with national guidelines.

Patients should be advised that REKAMBYS or any other antiretroviral therapy does not cure HIV infection and that they may still develop opportunistic infections and other complications of HIV infection. Therefore, patients should remain under close clinical observation by physicians experienced in the treatment of these associated HIV diseases.

This medicine contains less than 1 mmol sodium (23 mg) per injection, that is to say essentially 'sodium-free'.

The most frequently reported ARs from every 1 month dosing studies were injection site reactions (up to 84%), headache (up to 12%) and pyrexia (10%).

The most frequently reported ARs from every 2 months dosing were injection site reactions (76%), headache (7%) and pyrexia (7%).

Tabulated list of adverse reactions is available in the full information leaflet.

Description of selected adverse reactions

Local Injection Site Reactions (ISRs)

Up to 1% of subjects discontinued treatment with rilpivirine and cabotegravir injections because of ISRs. When dosed every 1 month in ATLAS, FLAIR, and ATLAS-2M (Q4W arm), up to 84% of subjects reported injections site reactions; out of 30393 injections, 6815 ISRs were reported. When dosed every 2 months in ATLAS-2M (Q8W arm), 76% of subjects reported injection site reactions; out of 8470 injections, 2507 ISRs were reported.

Injection site reactions were generally mild (Grade 1, 70%-75% of subjects) or moderate (Grade 2, 27%-36% of subjects). 3-4% of subjects experienced severe (Grade 3) ISRs. The median duration of ISR events was 3 days. The percentage of subjects reporting ISRs decreased over time.

At the Week 48 time point, subjects in Phase 3 Studies FLAIR and ATLAS, who received rilpivirine plus cabotegravir gained a median of 1.5 kg in weight; subjects continuing on their current antiretroviral regimen (CAR) group gained a median of 1.0 kg (pooled analysis). In the individual studies FLAIR and ATLAS, the median weight gains in the rilpivirine plus cabotegravir arms were 1.3 kg and 1.8 kg respectively, compared to 1.5 kg and 0.3 kg in the CAR arms.

At the 48 week timepoint, in ATLAS-2M the median weight gain in both the monthly and every 2 months rilpivirine + cabotegravir dosing arms was 1.0 kg.

Changes in laboratory chemistry

Changes in laboratory chemistry Elevated transaminases (ALT/AST) were observed in subjects receiving rilpivirine plus cabotegravir during the clinical studies. These elevations were primarily attributed to acute viral hepatitis. A few subjects on oral rilpivirine plus oral cabotegravir treatment had transaminase elevations attributed to suspected drug-related hepatotoxicity; these changes were reversible upon discontinuation of treatment. Small, non-progressive increases in total bilirubin (without clinical jaundice) were observed with treatment with rilpivirine plus cabotegravir. These changes are not considered clinically relevant as they likely reflect competition between cabotegravir and unconjugated bilirubin for a common clearance pathway (UGT1A1). Elevated lipases were observed during clinical trials with rilpivirine plus cabotegravir. Grade 3 and 4 lipase increases occurred at a higher incidence with rilpivirine plus cabotegravir compared with CAR. These elevations were generally asymptomatic and did not lead to rilpivirine plus cabotegravir discontinuation. One case of fatal pancreatitis with Grade 4 lipase and confounding factors (including history of pancreatitis) has been reported in study ATLAS-2M for which the causality to the injection regimen could not be ruled out.

The effect of REKAMBYS on human pregnancy is unknown. A

moderate amount of data with oral rilpivirine in pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or foetal/neonatal toxicity of rilpivirine. A study of 19 pregnant women treated with oral rilpivirine in combination with a background regimen during the second and third trimesters, and postpartum, showed lower exposures of oral rilpivirine during pregnancy, therefore viral load should be monitored closely if REKAMBYS is used during pregnancy.

Animal studies do not indicate reproductive toxicity. REKAMBYS is not recommended during pregnancy unless the expected benefit justifies the potential risk.

An alternative oral regimen should be considered in line with current treatment guidelines. After discontinuation of REKAMBYS, rilpivirine may remain in systemic circulation for up to 4 years in some patients.

It is expected that rilpivirine will be secreted into human milk based on animal data, although this has not been confirmed in humans. Rilpivirine may be present in human milk for up to 4 years in some patients after discontinuation of REKAMBYS.

It is recommended that HIV infected women do not breast-feed their infants under any circumstances in order to avoid transmission of HIV.

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 living with HIV and for people who are at risk of becoming infected with HIV. Shionogi joined as shareholders 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 science-led global healthcare company. For further information please visit https://www.gsk.com/en-gb/about-us/.

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 in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

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