NOTE TO EDITORS: ViiV Healthcare will hold a press conference at IAS 2019 on Tuesday 23 July, 9:00 – 9:45 am CDT to preview abstracts to be presented during the conference. To register, please visit: http://bit.ly/IAS-ViiV

PRESS RELEASE

IAS 2019: ViiV Healthcare showcasing innovation in HIV science

Data to be presented span the company’s diverse portfolio, challenging the current treatment paradigm and investigating new options to meet the evolving needs of people living with HIV

London, 15 July 2019 – ViiV Healthcare, the global specialist HIV company majority-owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, announced today that 20 abstracts from its portfolio of late-stage pipeline and authorised HIV treatments will be presented at the 10th International AIDS Society Conference on HIV Science (IAS 2019) in Mexico City, 21-24 July, in Mexico City, Mexico.

Since its inception 10 years ago, as the only pharmaceutical company solely focused on HIV, ViiV Healthcare continues its industry-leading commitment by delivering scientific advances that address the needs of the HIV community. The data presented at IAS 2019 further build upon the company’s innovative approach to research and development by investigating treatments that have the potential to reduce the number of medicines people living with HIV take during their lifetime and provide a range of options that meet their diverse and evolving needs.

Highlights at IAS 2019 include the presentation of safety and efficacy data for the 2-drug regimen (2DR) of dolutegravir plus lamivudine in treatment-naïve and treatment-experienced patients; longer-term clinical trial data of investigational fostemsavir in heavily treatment-experienced patients; and pooled clinical trial data and patient-reported outcomes from the investigational long-acting, injectable 2DR of cabotegravir plus rilpivirine.

John C. Pottage, Jr., M.D., Chief Scientific Officer and Medical Officer, ViiV Healthcare, said: “The depth and focus of our data at IAS 2019 is reflective of ViiV Healthcare’s patient-centred approach to
innovation. We have made significant advances in the development of 2-drug treatment regimens and we are looking forward to presenting additional data regarding this new treatment paradigm. We are also looking forward to presenting long-term data for a new first in class therapy for people with few or no treatment options. With our pipeline of innovative medicines, we are aiming to make a difference in the lives of people living with HIV.”

Key ViiV Healthcare abstracts to be presented at IAS 2019

- **Week 96 data for the 2DR of dolutegravir plus lamivudine in treatment-naïve patients (GEMINI 1 & 2):** The GEMINI 1 & 2 phase III studies compared a 2DR of dolutegravir plus lamivudine to a 3-drug regimen of dolutegravir plus the fixed-dose tablet tenofovir/emtricitabine (TDF/FTC). Week 48 results, which included the primary endpoint, were presented at the 2018 International AIDS Conference. The data presented at IAS 2019 will evaluate the efficacy of dolutegravir plus lamivudine compared to the 3-drug regimen at the Week 96 secondary endpoint. Dovato has been authorised in the EU and US as a once-daily, single-tablet regimen, with further regulatory marketing applications submitted worldwide.

- **Week 48 data for the 2DR of dolutegravir plus lamivudine in treatment-experienced patients (TANGO):** TANGO is a phase III, randomised, open-label, active-controlled, multicentre, parallel-group study comparing dolutegravir plus lamivudine once daily against continuation of a ≥3-drug tenofovir alafenamide (TAF)-based regimen over 48-weeks in HIV-1 infected, antiretroviral treatment-experienced, virally suppressed subjects. Headline results for the primary endpoint, efficacy at Week 48, were recently announced. The detailed results from the TANGO Week 48 data will be presented at IAS 2019.

- **Week 96 data for fostemsavir in heavily treatment-experienced patients (BRIGHTE):** The BRIGHTE study is a two-cohort (randomised and non-randomised), phase III clinical trial evaluating the safety and efficacy of the HIV-1 attachment inhibitor fostemsavir in heavily treatment-experienced adults with HIV-1 infection. Results from the primary endpoint, mean change in log10 HIV-1 RNA between day 1 and day 8 for the randomised cohort, and at Week 48 have been previously announced. The Week 96 data presented at IAS will offer further insight into the efficacy of fostemsavir over a longer period.

- **Clinical trial data and patient-reported outcomes on the long-acting injectable regimen of ViiV Healthcare’s cabotegravir plus Janssen’s rilpivirine (ATLAS and FLAIR):** Week 48 pooled analysis of the phase III ATLAS and FLAIR studies, as well as patient-reported views and outcomes from both studies, will be presented at IAS 2019. In ATLAS and FLAIR, patients were asked to report their treatment satisfaction (HIV-Treatment Satisfaction Questionnaire), acceptability of
treatment (general acceptance domain of ACCEPT) and health status (SF-12), as well as tolerability and acceptability of the cabotegravir and rilpivirine injections (Perception of Injections (PIN)). The findings presented at IAS expand on patient preference data presented at the 2019 Conference on Retroviruses and Opportunistic Infections. Development of this regimen is a collaboration with the Janssen Pharmaceutical Companies of Johnson & Johnson.

The full list of data that will be presented by ViiV Healthcare at IAS 2019 is listed below:

**Dolutegravir**

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<thead>
<tr>
<th>Format</th>
<th>Title of abstract</th>
<th>Author/presenter</th>
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<tbody>
<tr>
<td>Poster</td>
<td>Cost-effectiveness of dolutegravir in HIV-1 treatment-naïve patients in Mexico</td>
<td>Yogesh Punekar</td>
<td>MOPEB229</td>
<td>Embargo lifts: 22 July, 10:00</td>
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<tr>
<td>Poster</td>
<td>Gastrointestinal disorders following initiation of dolutegravir, elvitegravir, raltegravir or darunavir</td>
<td>Laurence Brunet</td>
<td>TUPEB221</td>
<td>Embargo lifts: 22 July, 10:00</td>
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<tr>
<td>Oral</td>
<td>Virologic failure in ART-naïve HIV patients with high pre-therapy viral load burden initiating on common core agents</td>
<td>Anthony M Mills</td>
<td>MOAB0104</td>
<td>Presentation time: 22 July, 11:45 Sala A</td>
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**Dolutegravir plus lamivudine**

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<tr>
<td>Poster</td>
<td>Is dolutegravir + lamivudine and dolutegravir + rilpivirine effective and safe in clinical practice? Evidence from real world data</td>
<td>Yogesh Suresh Punekar</td>
<td>MOPEB267</td>
<td>Embargo lifts: 22 July, 10:00</td>
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<td>Poster</td>
<td>Dolutegravir plus lamivudine versus dolutegravir plus tenofovir/emtricitabine fixed-dose combination in the GEMINI studies - viral load rebound including ‘blips’ through 48 weeks</td>
<td>Mark Underwood</td>
<td>MOPEB231</td>
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<td>Oral</td>
<td>TANGO: Switching to dolutegravir + lamivudine fixed dose combination (FDC) is non-inferior to continuing a TAF-based regimen in maintaining virologic suppression through 48 weeks (TANGO study)</td>
<td>Jean Van Wyk</td>
<td>WEAB0403LB</td>
<td>Presentation time: 24 July, 11:30 Sala A</td>
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<tr>
<td>Oral</td>
<td>GEMINI: Durable efficacy of dolutegravir plus lamivudine in antiretroviral treatment-naïve adults with HIV-1 infection - 96-Week results from the GEMINI Studies</td>
<td>Pedro Cahn</td>
<td>WEAB0404LB</td>
<td>Presentation time: 24 July, 11:45 Sala A</td>
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**Fostemsavir**

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<tr>
<td>Poster</td>
<td>A subgroup analysis of the Week 96 efficacy and safety results evaluating fostemsavir in heavily treatment-experienced HIV-1 infected participants in the phase 3 BRIGHTE study: results from the randomized cohort</td>
<td>Peter Ackerman</td>
<td>MOPEB234</td>
<td>Embargo lifts: 22 July, 10:00</td>
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<td>Oral</td>
<td>Week 96 safety and efficacy of the novel HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment experienced participants infected with multi-drug resistant HIV-1 (BRIGHTE Study)</td>
<td>Max Lataillade</td>
<td>MOAB0102</td>
<td>Presentation time: 22 July, 11:15 Sala A</td>
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**Cabotegravir plus rilpivirine**

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<tr>
<td>Poster</td>
<td>Monthly long-acting cabotegravir and rilpivirine is non-inferior to oral ART as maintenance therapy for HIV-1 infection: week 48 pooled analysis from the</td>
<td>Edgar T Overton</td>
<td>MOPEB257</td>
<td>Embargo lifts: 22 July, 10:00</td>
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phase 3 ATLAS and FLAIR studies

Poster  Patient reported outcomes on long-acting cabotegravir + rilpivirine as maintenance therapy: FLAIR 48 week results  Miranda Murray  MOPEB258  Embargo lifts: 22 July, 10:00

Poster  TDF/FTC pre-exposure prophylaxis (PrEP) from 2012 to 2018 in the OPERA Cohort  Jennifer Fusco  TUPEC418  Embargo lifts: 22 July, 10:00

Oral  Patient views on long acting HIV treatment: cabotegravir + rilpivirine as maintenance therapy (ATLAS 48 week results)  Miranda Murray  MOAB0103  Presentation time: 22 July, 11:30 Selina A

Additional abstracts

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<tr>
<td>Poster</td>
<td>Identifying heavily treatment-experienced patients in a large administrative claims database</td>
<td>Cassidy Henegar</td>
<td>MOPEB236</td>
<td>Embargo lifts: 22 July, 10:00</td>
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<td>Poster</td>
<td>Prevalence and outcomes for heavily treatment-experienced (HTE) individuals living with HIV in a European Cohort</td>
<td>Alvaro H Borges</td>
<td>TUPEB222</td>
<td>Embargo lifts: 22 July, 10:00</td>
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<tr>
<td>Poster</td>
<td>Loneliness among older people living with HIV: Why the “older old” are less lonely than the “younger old”</td>
<td>Peter Mazonson</td>
<td>TUPED739</td>
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<td>Poster</td>
<td>The SMAC mimetic AZD5582 reverses HIV latency as a single agent in resting primary CD4+ T cells</td>
<td>Richard Dunham</td>
<td>WEPEA060</td>
<td>Embargo lifts: 22 July, 10:00</td>
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<tr>
<td>Oral</td>
<td>Periconceptional antiretroviral exposure and central nervous system (CNS) and neural tube birth defects - data from Antiretroviral Pregnancy Registry (APR)</td>
<td>Lynne M Mofenson</td>
<td>TUAB0101</td>
<td>Presentation time: 23 July, 16:30 Palacio de Valparaíso 1</td>
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About dolutegravir plus lamivudine

Dolutegravir is an integrase inhibitor (INI) for use in combination with other antiretroviral agents for the treatment of HIV. INIs block 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. Dolutegravir is authorised in over 100 countries across North America, Europe, Asia, Australia, Africa and Latin America.

Lamivudine, commonly known as 3TC, is a nucleoside analogue used in combination with other antiretroviral agents for the treatment of HIV infection. Lamivudine is available in branded (Epivir®, 300mg) and generic forms.

Dolutegravir plus lamivudine (Dovato) is a once-daily, single-pill, 2-drug regimen that combines the INI dolutegravir (Tivicay, 50 mg) with the nucleoside analogue reverse transcriptase inhibitor (NRTI) lamivudine (Epivir, 300 mg). It is authorised in the EU for the treatment of HIV-1 infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine, and in the US for the treatment of HIV-1 infection in adults with no antiretroviral treatment history and with no known resistance to either dolutegravir or lamivudine.

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Important Safety Information

Important Safety Information for Dovato (50mg dolutegravir/300mg lamivudine) tablets in the EU

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

Dovato (50mg dolutegravir/300mg lamivudine)

Dovato is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.
The recommended dose of Dovato in adults and adolescents is one 50 mg/300 mg tablet once daily.

Method of administration
Oral use. Dovato can be taken with or without food.

Contraindications
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Dose adjustments
A separate preparation of dolutegravir is available where a dose adjustment is indicated due to drug-drug interactions (e.g. rifampicin, carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St. John’s wort, etravirine (without boosted protease inhibitors), efavirenz, nevirapine, or tipranavir/ritonavir. In these cases the physician should refer to the individual product information for dolutegravir.

Missed doses
If the patient misses a dose of Dovato, the patient should take Dovato as soon as possible, providing the next dose is not due within 4 hours. If the next dose is due within 4 hours, the patient should not take the missed dose and simply resume the usual dosing schedule.

Special warnings and precautions for use

Transmission of HIV
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.

Hypersensitivity reactions
Hypersensitivity reactions have been reported with dolutegravir, and were characterized by rash, constitutional findings, and sometimes, organ dysfunction, including severe liver reactions. Dovato and other suspect medicinal products should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by raised liver enzymes, fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, facial oedema, eosinophilia, angioedema). Clinical status including liver aminotransferases and bilirubin should be monitored. Delay in stopping treatment with Dovato or other suspect active substances after the onset of hypersensitivity may result in a life-threatening allergic reaction.

Weight and metabolic parameters
An increase in weight and in levels of blood lipids and glucose may occur during antiretroviral therapy. Such changes may in part be linked to disease control and lifestyle. For lipids, there is in
some cases evidence for a treatment effect, while for weight gain there is no strong evidence relating this to any particular treatment. For monitoring of blood lipids and glucose reference is made to established HIV treatment guidelines. Lipid disorders should be managed as clinically appropriate.

*Liver disease*

Patients with chronic hepatitis B or C and treated with combination antiretroviral therapy are at an increased risk of severe and potentially fatal hepatic adverse reactions. In case of concomitant antiviral therapy for hepatitis B or C, please refer also to the relevant product information for these medicinal products.

Dovato includes lamivudine, which is active against hepatitis B. Dolutegravir lacks such activity. Lamivudine monotherapy is generally not considered an adequate treatment for hepatitis B, since the risk for hepatitis B resistance development is high. If Dovato is used in patients co-infected with hepatitis B an additional antiviral is therefore generally needed. Reference should be made to treatment guidelines.

If Dovato is discontinued in patients co-infected with hepatitis B virus, periodic monitoring of both liver function tests and markers of HBV replication is recommended, as withdrawal of lamivudine may result in an acute exacerbation of hepatitis.

Patients with pre-existing liver dysfunction, including chronic active hepatitis have an increased frequency of liver function abnormalities during combination antiretroviral therapy, and should be monitored according to standard practice. If there is evidence of worsening liver disease in such patients, interruption or discontinuation of treatment must 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 (often referred to as PCP). 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 reactivation; however, the reported time to onset is more variable and these events can occur many months after initiation of treatment.
Liver chemistry elevations consistent with immune reconstitution syndrome were observed in some hepatitis B and/or C co-infected patients at the start of dolutegravir therapy. Monitoring of liver chemistries is recommended in patients with hepatitis B and/or C co-infection.

Osteonecrosis
Although the aetiology is considered to be multifactorial (including corticosteroid use, biphosphonates, alcohol consumption, severe immunosuppression, higher body mass index), cases of osteonecrosis have been reported in patients with advanced HIV-disease and/or long-term exposure to CART. Patients should be advised to seek medical advice if they experience joint aches and pain, joint stiffness or difficulty in movement.

Opportunistic infections
Patients should be advised that dolutegravir, lamivudine 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.

Undesirable effects
The most frequently reported adverse reactions are headache (3%), diarrhoea (2%), nausea (2%) and insomnia (2%).

The most severe adverse reaction reported with dolutegravir was a hypersensitivity reaction that included rash and severe liver effects.

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

Changes in laboratory biochemistries
Dolutegravir has been associated with an increase in serum creatinine occurring in the first week of treatment when administered with other antiretroviral medicinal products. Increases in serum creatinine occurred within the first four weeks of treatment with dolutegravir plus lamivudine and remained stable through 48 weeks. These changes are linked to the inhibiting effect of dolutegravir on renal tubular transporters of creatinine. The changes are not considered to be clinically relevant and do not reflect a change in glomerular filtration rate.

Co-infection with Hepatitis B or C
In the Phase III studies for the dolutegravir single agent, patients with hepatitis B and/or C co-infection were permitted to enrol provided that baseline liver chemistry tests did not exceed 5 times the upper limit of normal (ULN). Overall, the safety profile in patients co-infected with hepatitis B and/or C was similar to that observed in patients without hepatitis B or C co-infection, although the rates of AST and ALT abnormalities were higher in the subgroup with hepatitis B and/or C co-
infection for all treatment groups. Liver chemistry elevations consistent with immune reconstitution syndrome were observed in some subjects with hepatitis B and/or C co-infection at the start of dolutegravir therapy, particularly in those whose anti-hepatitis B therapy was withdrawn.

**Drug interactions**

No drug interaction studies have been conducted using Dovato. Dovato contains dolutegravir and lamivudine, therefore any interactions identified for these individually are relevant to Dovato. No clinically significant drug interactions are expected between dolutegravir and lamivudine. The recommended dose of dolutegravir is 50 mg twice daily when co-administered with rifampicin, carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St. John’s wort, etravirine (without boosted protease inhibitors), efavirenz, nevirapine, or tipranavir/ritonavir.

Dovato should not be co-administered with polyvalent cation-containing antacids. Polyvalent cation-containing antacids are recommended to be taken 2 hours after or 6 hours before Dovato. When taken with food, Dovato and supplements or multivitamins containing calcium, iron or magnesium can be taken at the same time. If Dovato is administered under fasting conditions, supplements or multivitamins containing calcium, iron or magnesium are recommended to be taken 2 hours after or 6 hours before Dovato.

Dolutegravir increased metformin concentrations. A dose adjustment of metformin should be considered when starting and stopping coadministration of Dovato with metformin, to maintain glycaemic control. Metformin is eliminated renally and, therefore, it is of importance to monitor renal function when co-treated with Dovato. This combination may increase the risk for lactic acidosis in patients with moderate renal impairment (stage 3a creatinine clearance 45–59 mL/min) and a cautious approach is recommended. Reduction of the metformin dose should be highly considered.

The combination of Dovato with cladribine is not recommended.

Dovato should not be taken with any other medicinal product containing dolutegravir or lamivudine, except where a dose adjustment of dolutegravir is indicated due to drug-drug interactions.

Other established and theoretical interactions with selected antiretrovirals and non-antiretroviral medicinal products are listed in the full information leaflet.

**Fertility, pregnancy and lactation**

Women of childbearing potential (WOCBP) should undergo pregnancy testing before initiation of Dovato. WOCBP who are taking Dovato should use effective contraception throughout treatment.

**Pregnancy**
The safety and efficacy of a dual regimen has not been studied in pregnancy. Preliminary data from a surveillance study has suggested an increased incidence of neural tube defects (0.9%) in mothers exposed to dolutegravir (a component of Dovato) at the time of conception compared with mothers exposed to non-dolutegravir containing regimens (0.1%).

The incidence of neural tube defects in the general population ranges from 0.5-1 case per 1,000 live births (0.05-0.1%). As neural tube defects occur within the first 4 weeks of foetal development (at which time the neural tubes are sealed) this potential risk would concern women exposed to dolutegravir at the time of conception and in early pregnancy. Due to the potential risk of neural tube defects with dolutegravir, Dovato should not be used during the first trimester unless there is no alternative.

More than 1000 outcomes from second and third trimester exposure to dolutegravir in pregnant women indicate no evidence of increased risk of malformities and foeto/neonatal negative effects. However, as the mechanism by which dolutegravir may interfere in human pregnancy is unknown, the safety in use during the second and third trimester cannot be confirmed. Dovato should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

In animal reproductive toxicology studies with dolutegravir, no adverse development outcomes, including neural tube defects, were identified. Dolutegravir was shown to cross the placenta in animals.

A large amount of data on the use of lamivudine in pregnant women (more than 3000 outcomes from first trimester) indicates no malformative toxicity.

Animal studies showed lamivudine may inhibit cellular DNA replication (see section 5.3). The clinical relevance of these findings is unknown.

Mitochondrial dysfunction

Nucleoside and nucleotide analogues have been demonstrated in vitro and in vivo to cause a variable degree of mitochondrial damage. There have been reports of mitochondrial dysfunction in HIV-negative infants exposed in utero and/or post-natally to nucleoside analogues, these have predominantly concerned treatment with regimens containing zidovudine. The main adverse reactions reported are haematological disorders (anaemia, neutropenia), and metabolic disorders (hyperlactatemia, hyperlipasemia). These reactions have often been transitory. These findings do not affect current national recommendations to use antiretroviral therapy in pregnant women to prevent vertical transmission of HIV.

Breast-feeding

It is unknown whether dolutegravir is excreted in human milk. Available toxicological data in animals has shown excretion of dolutegravir in milk. In lactating rats that received a single oral dose of 50
mg/kg at 10 days postpartum, dolutegravir was detected in milk at concentrations typically higher than blood.

Based on more than 200 mother/child pairs treated for HIV, serum concentrations of lamivudine in breastfed infants of mothers treated for HIV are very low (< 4% of maternal serum concentrations) and progressively decrease to undetectable levels when breastfed infants reach 24 weeks of age. There are no data available on the safety of lamivudine when administered to babies less than three months old.

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

Fertility

There are no data on the effects of dolutegravir or lamivudine on human male or female fertility. Animal studies indicate no effects of dolutegravir or lamivudine on male or female fertility.

Effects on ability to drive and use machines

Dovato has no or negligible influence on the ability to drive and use machines. Patients should be informed that dizziness and somnolence has been reported during treatment with dolutegravir. The clinical status of the patient and the adverse reaction profile of Dovato should be borne in mind when considering the patient’s ability to drive or operate machinery.

Please refer to the full European Summary of Product Characteristics for dolutegravir/lamivudine for full prescribing information, including contraindications, special warnings and precautions for use. For the US, please refer to the US Prescribing Information.

About fostemsavir

Fostemsavir is an investigational prodrug of temsavir, an HIV-1 attachment inhibitor class, and is not authorised by regulatory authorities anywhere in the world. Fostemsavir is being developed by ViiV Healthcare for the treatment of HIV-1-infected heavily treatment-experienced patients in combination with other antiretroviral agents.

About cabotegravir

Cabotegravir is an investigational integrase inhibitor (INI) and is not authorised by regulatory authorities anywhere in the world. Cabotegravir is being developed by ViiV Healthcare for the treatment and prevention of HIV. It is being evaluated as a long-acting formulation for intramuscular injection and also as a once-daily oral tablet for use as a lead-in, to establish the tolerability of cabotegravir prior to long-acting injection.
About rilpivirine

EDURANT® (rilpivirine) is a once daily non-nucleoside reverse transcriptase inhibitor (NNRTI) used for the treatment of human immunodeficiency virus (HIV-1) infection in combination with other antiretroviral agents in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV RNA copies/mL. Long-acting injectable rilpivirine is not authorised by regulatory authorities anywhere in the world.

Rilpivirine was developed by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Rilpivirine is authorised in the U.S. and E.U. as EDURANT® as a 25mg tablet taken once-a-day and is always taken with a meal. The most common side effects of EDURANT include: depression, headache, trouble sleeping (insomnia) and rash.

Important Safety Information (ISI) for EDURANT® (Rilpivirine)

Note: this is taken from the US label and local variations apply. Please refer to applicable local labelling.

About EDURANT® (Rilpivirine)

- EDURANT® (rilpivirine) is a prescription medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in people 12 years of age and older and who weigh at least 77 lbs (35 kg):
  - Have never taken HIV medicines before, and
  - Have an amount of HIV in their blood (called “viral load”) that is no more than 100,000 copies/mL

- EDURANT® is not recommended for patients less than 12 years of age or who weigh less than 77 lbs (35 kg)

IMPORTANT SAFETY INFORMATION

Who should not take EDURANT®?

Do not take EDURANT® if you also take:

- anti-seizure medicines:
  - carbamazepine
  - oxcarbazepine
• phenobarbital
• phenytoin

• anti-tuberculosis (anti-TB) medicines:
  o rifampin
  o rifapentine

• proton pump inhibitor (PPI) medicine for certain stomach or intestinal problems:
  o esomeprazole
  o lansoprazole
  o omeprazole
  o pantoprazole sodium
  o rabeprazole

• more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate

• St. John’s wort (Hypericum perforatum)

What should I tell my healthcare provider before taking EDURANT®?
Before taking EDURANT®, tell your healthcare provider about all your medical conditions, including if you:
• have or had liver problems, including hepatitis B or C virus infection
• have kidney problems
• have ever had a mental health problem
• are pregnant or plan to become pregnant. It is not known if EDURANT® will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with EDURANT®.
• are breastfeeding or plan to breastfeed. Do not breastfeed if you take EDURANT®.
  o You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  o It is not known if EDURANT® passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby during EDURANT® treatment.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take EDURANT® with other medicines.

How should I take EDURANT®?
• Take EDURANT® every day exactly as your healthcare provider tells you to.
• **Take EDURANT® 1 time each day with a meal.** A protein drink alone does not replace a meal.

• Do not change your dose or stop taking EDURANT® without first talking with your healthcare provider. Stay under the care of your healthcare provider during treatment with EDURANT®.

• Do not miss a dose of EDURANT®.

• If you take an H₂-receptor antagonist (famotidine, cimetidine, nizatidine, or ranitidine), you should take these medicines at least 12 hours before or at least 4 hours after you take EDURANT®.

• If you take antacids, or other products that contain aluminum, calcium carbonate, or magnesium hydroxide, you should take these medicines at least 2 hours before or at least 4 hours after you take EDURANT®.

• If you miss a dose of EDURANT® within 12 hours of the time you usually take it, take your dose of EDURANT® with a meal as soon as possible. Then, take your next dose of EDURANT® at the regularly scheduled time. If you miss a dose of EDURANT® by more than 12 hours of the time you usually take it, wait and then take the next dose of EDURANT® at the regularly scheduled time.

• Do not take more than your prescribed dose to make up for a missed dose.

• If you take too much EDURANT®, call your healthcare provider or go to the nearest hospital emergency room right away.

**What are the possible side effects of EDURANT®?**

EDURANT® can cause serious side effects including:

• **Severe skin rash and allergic reactions.** Skin rash is a common side effect of EDURANT®. Skin rash can be serious. Call your healthcare provider right away if you get a rash. In some cases, rash and allergic reaction may need to be treated in a hospital.

If you get a rash with any of the following symptoms, **stop taking EDURANT® and get medical help right away:**

- fever
- skin blisters
- mouth sores
- trouble breathing or swallowing
- pain on the right side of the stomach (abdominal) area
- redness or swelling of the eyes (conjunctivitis)
- dark-colored urine “tea colored”
- swelling of the face, lips, mouth, tongue, or throat

- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection or who have certain liver function test changes may have an increased risk of developing new or worsening liver problems during treatment with EDURANT®. Liver problems have also happened during treatment with EDURANT® in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with EDURANT®.

- **Depression or mood changes.** Tell your healthcare provider right away if you have any of the following symptoms:
  - feeling sad or hopeless
  - feeling anxious or restless
  - have thoughts of hurting yourself (suicide) or have tried to hurt yourself

- **Changes in body fat** can happen in people who take HIV medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

**The most common side effects of EDURANT® include** depression, headache, trouble sleeping (insomnia), and rash.

This is not a complete list of all side effects. If you experience these or other symptoms, contact your healthcare provider right away. Do not stop taking EDURANT® or any other medications without first talking to your healthcare provider.

You are encouraged to report side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. You may also report side effects to Janssen Products, LP, at 1-800-JANSSEN (1-800-526-7736).
Please see accompanying full Product Information for more details.

Full US prescribing information including is available at:

For the EU Summary of Product Characteristics, please visit:

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 living with HIV and for people who are at risk of becoming infected with HIV. Shionogi joined in October 2012. The company’s aims 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 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.

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 'Principal risks and uncertainties' in the company's Annual Report on Form 20-F for 2018.

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