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PRESS RELEASE

ViiV Healthcare announces US FDA approval for Rukobia (fostemsavir), a first-in-class treatment for HIV in adults with few treatment options available

In a phase III study, a majority (60%) of heavily treatment-experienced adults randomized to receive Rukobia with an optimized background therapy achieved and maintained viral suppression through 96 weeks, addressing a critical unmet need

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London, 2 July, 2020 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced that the US Food and Drug Administration (FDA) has approved Rukobia (fostemsavir), 600 mg extended-release tablets. Rukobia is a novel attachment inhibitor for the treatment of HIV-1 infection indicated for use in combination with other antiretroviral (ARV) therapies in heavily treatment-experienced (HTE) adults with multidrug-resistant HIV-1 infection, who are failing their current ARV regimen due to resistance, intolerance or safety considerations.

Significant advances over the past few decades have dramatically improved HIV treatment and for many, HIV is considered a manageable life-long condition. However, HTE adults – which account for approximately 6% of adults living with HIV who are on treatment – have little to no options left due to resistance, tolerability or safety considerations.[1] HTE adults are at risk of progressing to AIDS and death and in great need of additional therapies.

Deborah Waterhouse, CEO of ViiV Healthcare, said: "There is a small group of heavily treatment-experienced adults living with HIV who are not able to maintain viral suppression with currently available medication and, without effective new options, are at great risk of progressing to AIDS. The approval of Rukobia is a culmination of incredibly complex research, development, and manufacturing efforts to ensure we leave no person living with HIV behind."

The approval was supported by data from the phase III BRIGHTE study, which evaluated the safety and efficacy of Rukobia in combination with optimized background therapy (OBT) in HTE adults living

with multidrug-resistant HIV, many of whom had advanced HIV disease at study entry. In the randomized cohort, 60% (n=163/272) of individuals who received Rukobia in addition to an investigator-selected OBT achieved undetectable HIV viral load and clinically meaningful improvements to CD4+ T-cell count through Week 96.

The proportion of participants who discontinued treatment with Rukobia due to an adverse event was 7% at Week 96 (randomized: 5% and nonrandomized: 12%). The most common adverse reactions (all grades) observed in ≥5% of randomized and nonrandomized participants were nausea, fatigue and diarrhea. The most common adverse events leading to discontinuation were related to infections (3%). Serious drug reactions occurred in 3% of people taking Rukobia and included three cases of severe immune reconstitution inflammatory syndrome.[2]

Jacob P. Lalezari, M.D., Chief Executive Officer and Director of Quest Clinical Research, said: "As a novel HIV attachment inhibitor, fostemsavir targets the first step of the viral lifecycle offering a new mechanism of action to treat people living with HIV. In the BRIGHTE study, fostemsavir in combination with other ARVs effectively achieved and maintained long-term viral suppression and demonstrated clinically meaningful rise in CD4+ T-cell count even among heavily immunocompromised patients. These are exciting advances for the HTE population and an advancement the HIV community has long been waiting for. As an activist as well as researcher, I am very grateful to ViiV Healthcare for their commitment to heavily-treatment experienced people living with HIV."

Rukobia was reviewed and approved under the FDA's Fast Track and Breakthrough Therapy Designations which are intended to facilitate and expedite the development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition.

Gabriel Maldonado, Founder and CEO, TruEvolution, Inc., said: "Some members of the HIV community face very challenging treatment journeys and do not respond to available therapies for a variety of reasons. The approval of fostemsavir provides a sense of renewed hope for these adults who have few or no viable treatment options left and have been awaiting alternative medicines to control the virus."

Fostemsavir is currently under review by the European Medicines Agency and additional submissions to regulatory authorities around the world are planned throughout 2020 and 2021.

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About BRIGHTE

The BRIGHTE trial is an international, phase III, partially-randomized, double-blind, placebo-controlled study conducted in 371 HTE adults living with HIV-1 infection with multidrug resistance. All trial participants were required to have a viral load ≥400 copies/mL and ≤2 classes of antiretroviral medications remaining at baseline due to resistance, intolerability, contraindication, or other safety considerations. Trial participants were enrolled in either a randomized or nonrandomized cohort defined as follows:

- Within the randomized cohort (n = 272), participants had 1, but no more than 2, fully active and available antiretroviral agent(s) at screening which could be combined as part of an efficacious background regimen. Randomized participants received either blinded fostemsavir 600 mg twice daily (n = 203) or placebo (n = 69) in addition to their current failing regimen for 8 days of functional monotherapy. Beyond Day 8, randomized participants received open-label fostemsavir 600 mg twice daily plus an investigator-selected optimized background therapy (OBT).
- Within the nonrandomized cohort (n = 99), participants had no fully active and approved antiretroviral agent(s) available at screening. Nonrandomized participants were treated with open-label fostemsavir 600 mg twice daily plus OBT from Day 1 onward. The use of an investigational drug(s) as a component of the optimised background therapy was permitted in the nonrandomized cohort.

The primary endpoint analysis, based on the adjusted mean decline in HIV-1 RNA from Day 1 at Day 8 in the randomized cohort, demonstrated superiority of fostemsavir to placebo (0.79 vs. 0.17 log10 copies/mL decline, respectively; P<0.0001, Intent-to-Treat-Exposed [ITT-E] population). In the randomized cohort, HIV-1 RNA <40 copies/mL was achieved in 53% and 60% of subjects at Weeks 24 and 96, respectively (ITT-E, Snapshot algorithm). Mean changes in CD4+ cell count from baseline continued to increase over time (i.e., 90 cells/mm3 at Week 24 and 205 cells/mm3 at Week 96). The most common adverse reaction (all grades) observed in ≥5% of participants were nausea. The proportion of participants who discontinued treatment with fostemsavir due to an adverse event was 7% at Week 96 (randomized: 5% and nonrandomized: 12%). In the nonrandomized cohort, HIV-1 RNA <40 copies/mL was achieved in 37% of subjects at Weeks 24 and 96. At these timepoints, the proportion of subjects with HIV-1 RNA <200 copies/mL was 42% and 39%, respectively (ITT-E, Snapshot algorithm). Mean changes in CD4+ cell count from baseline increased over time: 41

cells/mm3 at Week 24 and 119 cells/mm3 at Week 96. The most common adverse reactions reported in nonrandomized subjects were fatigue (7%), nausea (6%), and diarrhea (6%).

About Rukobia

The active ingredient in Rukobia is fostemsavir. Fostemsavir is a first-in-class HIV-1 attachment inhibitor. After oral administration, fostemsavir is converted to temsavir, which is then absorbed and exerts antiviral activity by attaching directly to the glycoprotein 120 (gp120) subunit on the surface of the virus, thereby blocking HIV from attaching to host immune system CD4+ T-cells and preventing the virus from infecting those cells and multiplying. As Rukobia is the first antiretroviral therapy to target this step of the viral cycle, there is no demonstrated resistance to other classes of antiretrovirals, which may help patients who have become resistant to most other medicines.

Important Safety Information (ISI)

The following ISI is based on the Highlights section of the Prescribing Information for RUKOBIA. Please consult the full Prescribing Information for all the labeled safety information for RUKOBIA.

INDICATIONS AND USAGE

- RUKOBIA, a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

DOSAGE AND ADMINISTRATION

- One tablet taken twice daily with or without food.

DOSAGE FORMS AND STRENGTHS

- Extended-release tablets: 600 mg

CONTRAINDICATIONS

- Hypersensitivity to fostemsavir or any of the components of the formulation.
- Coadministration with strong cytochrome P450 (CYP)3A inducers as significant decreases in temsavir plasma concentrations may occur, which may result in loss of virologic response.

WARNINGS AND PRECAUTIONS

- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapies.
- QTc prolongation: Use RUKOBIA with caution in patients with a history of QTc prolongation or with relevant pre-existing cardiac disease or who are taking drugs with a known risk of Torsade de Pointes.
- Elevations in hepatic transaminases in patients with hepatitis B or C virus co-infection: Elevations in hepatic transaminases were observed in a greater proportion of subjects with HBV and/or HCV co-infection compared with those with HIV mono-infection.
- Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions: The concomitant use of RUKOBIA and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to 1) Loss of therapeutic effect of RUKOBIA and possible development of resistance due to reduced exposure of temsavir 2) Possible prolongation of QTc interval from increased exposure to temsavir.

ADVERSE REACTIONS

- The most common adverse reactions (all grades) observed in ≥5% of randomized and non-randomized participants were nausea, fatigue and diarrhea.

DRUG INTERACTIONS

- See full prescribing information for complete list of significant drug interactions.
- Doses of oral contraceptives should not contain more than 30 mcg of ethinyl estradiol per day.

USE IN SPECIFIC POPULATIONS

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

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 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

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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 Support Program

ViiV Healthcare is committed to providing assistance to eligible people living with HIV who need our medicines. ViiV Healthcare's centralised service, ViiV Connect, provides comprehensive information on access and coverage to help patients 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

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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 any impacts of the COVID19 pandemic.

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[1] Hsu R, et al. Identifying Heavily Treatment-Experienced Patients in the OPERA Cohort. 22nd International AIDS Conference; July 23–27, 2018; Amsterdam, the Netherlands. Poster THPEB044.
[2] Rukobia (fostemsavir) Prescribing Information. US Approval 2020.