ViiV Healthcare announces public tender agreement with Botswana Ministry of Health for dolutegravir

Agreement supports the first ‘Treat All’ programme for HIV in sub-Saharan Africa, where 70% of people with HIV live

London, UK, Friday 3 June, 2016 – ViiV Healthcare, a global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today confirmed a public tender agreement with the Ministry of Health in Botswana to support the implementation of a new national ‘Treat All’ programme which aims to ensure people living with HIV in the country get tested and receive treatment. This is the first time dolutegravir will be made available as part of a national health programme in sub-Saharan Africa since the WHO recommended dolutegravir as alternative first line treatment in HIV patients in late 2015.

This is the largest tender ever secured by ViiV Healthcare in the African sub-continent, a region particularly impacted by the HIV epidemic with nearly three quarters of the global HIV population living there. As part of the agreement, ViiV Healthcare has committed to providing dolutegravir 50mg. The medicine would be used as a first line core-agent to treat newly diagnosed patients tested under the programme in Botswana.

Dr Dominique Limet, Chief Executive Officer, ViiV Healthcare said: “This tender agreement is a great moment as part of our commitment to accelerating access to our treatments in Africa. It will allow people living with HIV in Botswana to have access to dolutegravir as part of a national test and treat initiative, locally referred to as the ‘Treat All’ programme. It is even more of an achievement for us as it happens less than three years after the product was first approved and less than one year after it was included in the WHO guidelines.”

The public tender agreement has resulted from positive negotiations with the Botswana Government and is the latest project in a series of initiatives undertaken by ViiV Healthcare to support the response to the HIV epidemic across Africa. It follows two other recent announcements, including the company’s involvement in a new national programme launched in Lesotho to double the number of children at risk of HIV in care and on treatment in the country within three years. Most recently, ViiV Healthcare also announced the extension of its licence agreement with the Medicines Patent Pool for the adult formulation of dolutegravir to include all lower middle-income countries, a number of which are on the African continent.
About dolutegravir

Dolutegravir (Tivicay) is an integrase strand transfer inhibitor (INSTI) for use in combination with other antiretroviral agents for the treatment of HIV. Integrase inhibitors 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. Tivicay is approved in over 90 countries across North America, Europe, Asia, Australia, Africa and Latin America. Tivicay is a registered trademark of the ViiV Healthcare group of companies.

Important Information about Tivicay® (dolutegravir)

FDA Indication and Usage: Tivicay is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Use of Tivicay in INSTI-experienced patients should be guided by the number and type of baseline INSTI substitutions. The efficacy of Tivicay 50 mg twice daily is reduced in patients with an INSTI-resistance Q148 substitution plus 2 or more additional INSTI-resistance substitutions including T66A, L74I/M, E138A/K/T, G140S/A/C, Y143R/C/H, E157Q, G163S/E/K/Q, or G193E/R.

Important Safety Information for Tivicay® (dolutegravir)

Contraindication: Tivicay is contraindicated (1) in patients with previous hypersensitivity reaction to dolutegravir, and (2) in patients receiving dofetilide (antiarrhythmic) due to the potential for increased dofetilide plasma concentrations and the risk for serious and/or life-threatening events.

Hypersensitivity Reactions: Hypersensitivity reactions have been reported and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury. The events were reported in 1% or fewer subjects receiving Tivicay in Phase 3 clinical trials. Discontinue Tivicay and other suspect agents immediately if signs or symptoms of hypersensitivity reaction develop, (including but not limited to, severe rash or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters or peeling of the skin, oral blisters or lesions, conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, difficulty breathing.) Monitor clinical status, including liver aminotransferases, and initiate appropriate therapy. Delay in stopping treatment with Tivicay or other suspect agents after the onset of hypersensitivity may result in a life-threatening reaction. Tivicay is contraindicated in patients who have experienced a hypersensitivity reaction to dolutegravir.

Effects on Serum Liver Biochemistries in Patients with Hepatitis B or C Coinfection: Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of Tivicay. In some cases the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation particularly in the setting where anti-hepatitis therapy was withdrawn. Appropriate laboratory testing prior to initiating therapy and monitoring for hepatotoxicity during therapy with Tivicay are recommended in patients with underlying hepatic disease such as hepatitis B or C.

Fat Redistribution: Redistribution/accumulation of body fat has been observed in patients receiving antiretroviral therapy.
Immune Reconstitution Syndrome: During the initial phase of treatment, immune reconstitution syndrome can occur, which may necessitate further evaluation and treatment. Autoimmune disorders have been reported to occur in the setting of immune reconstitution; the time to onset is more variable and can occur many months after initiation of treatment.

Adverse Reactions: The most commonly reported (≥2%) adverse reactions of moderate to severe intensity in treatment naive adult subjects in any one trial receiving Tivicay in a combination regimen were insomnia (3%), fatigue (2%), and headache (2%).

Drug Interactions: Co-administration of Tivicay with drugs that are strong inducers of UGT1A1 and/or CYP3A4 may result in reduced plasma concentrations of dolutegravir and require dose adjustments of Tivicay.

- Tivicay should be taken 2 hours before or 6 hours after taking cation-containing antacids or laxatives, sucralfate, oral iron supplements, oral calcium supplements, or buffered medications.

- Consult the full Prescribing Information for Tivicay for more information on potentially significant drug interactions, including clinical comments.

Pregnancy: Pregnancy category B. Tivicay should be used during pregnancy only if the potential benefit justifies the potential risk. An Antiretroviral Pregnancy Registry has been established.

Breastfeeding: Breastfeeding is NOT recommended due to the potential for HIV transmission and the potential for adverse reactions in nursing infants.

Paediatric Patients: Safety and efficacy of Tivicay has not been established in children younger than 12 years old, or weighing <40 kg, or in INSTI-experienced paediatric patients with documented or clinically suspected INSTI resistance.

Please visit the following link for the full US prescribing and patient information: https://www.viivhealthcare.com/media/58599/us_tivicay.pdf.

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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. 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 new HIV medicines, 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 – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

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