ViiV Healthcare receives approval from China’s National Medical Products Administration (NMPA) for Vocabria (cabotegravir) used in combination with Rekambys (rilpivirine), the first and only complete long-acting HIV-1 injectable treatment

PUBLISHED OCT 26, 2023
BY GSK

For media and investors only

- The marketing authorisation for rilpivirine long-acting injection was received on the 18 October 2023

- The complete long-acting regimen enables people living with HIV in China, who are virologically suppressed to reduce the treatment dosing days from 365 to 12 or 6 per year after initiation.

- With an estimated 1.045 million people living with HIV in China,expanding treatment options is critical to reduce the scale of the epidemic in the country.

GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders announced that the National Medical Products Administration (NMPA) of China has approved ViiV Healthcare’s Vocabria (cabotegravir injection) used in combination with the Janssen Pharmaceutical Companies of Johnson & Johnson's Rekambys (rilpivirine long-acting injection) for the treatment of HIV-1 infection. Prior to the recent marketing authorisation for rilpivirine long-acting injection, cabotegravir injection and tablets were approved

in China in July 2023.

Cabotegravir injection is indicated in combination with rilpivirine long-acting injection for the treatment of human immunodeficiency virus type-1 (HIV-1) infection in adults who are virologically suppressed, on a stable antiretroviral (ARV) regimen without present or past evidence of viral resistance to, and no prior virological failure with, agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) classes. Vocabria (cabotegravir) tablets are approved for use in combination with rilpivirine tablets (trade name Edurant) as an optional oral lead-in before initiating injections or as oral therapy for those who will miss planned injection doses.

By the end of October 2020, there were an estimated 1.045 million people living with HIV in China. Advancements in treatment mean many people living with HIV can now live long and healthy lives, however, some may still struggle with daily oral HIV medication. It may act as a constant reminder of HIV, be a cause of fear that their HIV status will be accidently disclosed or create challenges with adherence.

Deborah Waterhouse, CEO of ViiV Healthcare, said:

> At ViiV Healthcare, we are proud to be able to offer innovative solutions that meet the evolving needs of people living with HIV. The approval of cabotegravir injection and rilpivirine long-acting injection marks a step forward in helping to change the treatment experience for some people living with HIV in China who may have challenges with daily HIV therapies. We look forward to working closely with our partners in China to make this treatment available to those who could benefit from a long-acting regimen, part of our commitment to ensuring no person living with HIV is left behind.

This approval is based on data from three pivotal trials: the ATLAS (Antiretroviral Therapy as Long-Acting Suppression) and FLAIR (First Long-Acting Injectable Regimen) studies, and the phase IIIb ATLAS-2M study, which collectively included more than 1,200 participants from 16 countries. ATLAS and FLAIR demonstrated the efficacy and safety of cabotegravir and rilpivirine compared to standard-of-care oral regimens, while ATLAS-2M showed that once every two month dosing had comparable efficacy to once monthly., , In ATLAS, 92.5% of participants receiving long-acting therapy and 95.5% of those

receiving oral therapy remained virally suppressed at week 48 (adjusted difference: -0.3%; 95% confidence interval [CI]: -6.7% to 0.7%), meeting the criterion for non-inferiority. In FLAIR, 93.6% of participants receiving long-acting therapy and 93.3% of participants receiving oral therapy remained virally suppressed at week 48 (adjusted difference: 0.4%; 95% CI: –3.7% to 4.5%), meeting the criterion for non-inferiority. In the pooled analysis of ATLAS and FLAIR most long-acting recipients (83%) experienced injection site reactions, which decreased in incidence over time. Injection site reactions led to the withdrawal of 6 (1%) participants. The serious adverse event rate was 4% in each arm. In ATLAS-2M, cabotegravir plus rilpivirine long-acting every eight weeks was non-inferior to dosing every four weeks (adjusted difference: 0.8%; 95% CI: -0.6% to 2.2%) after 48 weeks of treatment. The safety profile was similar between dosing groups, with 844 (81%) of 1,045 participants having adverse events (excluding injection site reactions); no treatment-related deaths occurred.

ViiV Healthcare's mission is to leave no person living with HIV behind. As the only pharmaceutical company solely focused on HIV and AIDS, ViiV Healthcare is working to deliver a broad range of treatments that meet the needs of a wide variety of people living with HIV. The long-acting regimen approved on the 18 October 2023 was developed in collaboration between ViiV Healthcare and Janssen. This builds on ViiV Healthcare's industry-leading portfolio which is centred on delivering innovative medicines for the HIV community.

Cabotegravir is an integrase strand transfer inhibitor (INSTI) developed by ViiV Healthcare for the treatment of HIV-1 in virologically suppressed adults. It is approved as a long-acting formulation for use in combination with a rilpivirine long-acting formulation in the US, the EU and in other countries.

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.

About rilpivirine and rilpivirine long-acting

Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that works by interfering with an enzyme called reverse transcriptase, which in turn stops the virus from multiplying. It is approved as

Edurant, an oral formulation, for the treatment of HIV-1 infection in combination with other antiretroviral agents in antiretroviral treatment-naïve patients 12 years of age and older and weighing at least 35kg with a viral load ≤100,000 HIV RNA copies/mL. It is also approved as Rekambys, a long-acting formulation that 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

Administration and dosing of cabotegravir and rilpivirine

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

For once-monthly dosing, each person will receive a loading dose that includes one 600 mg injection of cabotegravir and one 900 mg injection of rilpivirine administered intramuscularly in the gluteal site. Then, each month after that, each person will receive one 400 mg injection of cabotegravir and one 600 mg injection of rilpivirine.

For once every two months dosing, each person will receive a loading dose that includes one 600 mg injection of cabotegravir and one 900 mg injection of rilpivirine, which is repeated one month later. Then, every two months after that, each person will receive one 600 mg injection of cabotegravir and one 900 mg injection of rilpivirine as a continuation dose.

Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (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 acquiring HIV. Shionogi became a ViiV shareholder 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 viivhealthcare.com.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company.

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 2022, and Q2 Results for 2023.

Jun-Jie X, Meng-Jie H, Yong-Jun J, et al. Prevention and control of HIV/AIDS in China: lessons from the past three decades. Chinese Medical Journal 2021; 134(23):2799-2809.

Swindells S, Andrade-Villanueva J-F, Richmond G, et al. Long-acting cabotegravir and rilpivirine for maintenance of HIV-1 suppression. New England Journal of Medicine 2020; 382:1112-1123.

Orkin C, Arasteh K, Hernandez-Mora MG, et al. Long-acting cabotegravir and rilpivirine after oral induction for HIV-1 infection. New England Journal of Medicine 2020; 382:1124-1135.

Overton ET, Richmond G, Rizzardini G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 48-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. The Lancet 2020; 396(10267):1994-2005.

Rizzardini G, Overton ET, Orkin C, et al. Long-Acting Injectable Cabotegravir + Rilpivirine for HIV Maintenance Therapy: Week 48 Pooled Analysis of Phase 3 ATLAS and FLAIR Trials. J Acquir Immune Defic Syndr 2020; 1;85(4):498-506.

Press release distributed by Wire Association on behalf of GSK, on Oct 26, 2023. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/viiv-healthcare-receives-approval-from-chinas-national-medical-products-administration-nmpa-for-vocabria-cabotegravir-used-in-combination-with-rekambys-rilpivirine-the-first-and-only-complete-long-acting-hiv-1-injectable-treatment-1730

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/
