



## **News Release**

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## **Complete Response Letter Issued from U.S. FDA for Investigational Long-Acting HIV Regimen**

**TITUSVILLE, N.J., December 21, 2019** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) in response to ViiV Healthcare’s (ViiV) New Drug Application for the two-drug long-acting (LA) injectable regimen of ViiV’s cabotegravir and Janssen’s rilpivirine for the treatment of HIV-1 infection in adults. The regimen was co-developed as part of a collaboration between Janssen and ViiV.

The reasons given in the CRL relate to Chemistry, Manufacturing and Controls (CMC). There have been no reported safety issues related to CMC, and the CRL does not relate to the clinical safety data submitted as part of the package.

Janssen will work closely with ViiV and the FDA to determine the appropriate next steps for this New Drug Application.

“We believe the once-monthly, long-acting regimen represents an important therapeutic advance for those living with HIV,” said Brian Woodfall, M.D., Global Head, Development, Infectious Diseases, Janssen Biopharma, Inc. “We will continue to collaborate with our partners and the FDA to fully understand the requirements needed to support U.S. approval as we continue in our efforts to change the course of the HIV epidemic.”

The HIV LA regimen is an investigational product and not currently approved anywhere in the world. It is a combination of rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Janssen Sciences Ireland Unlimited Company, with the integrase strand transfer inhibitor (INSTI) cabotegravir, developed by ViiV Healthcare.

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we’re creating a future where disease is a thing of the past. We’re the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we

can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com) and follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal) and [www.twitter.com/JanssenUS](https://www.twitter.com/JanssenUS). Janssen Biopharma, Inc., and Janssen Sciences Ireland Unlimited Company are members of the Janssen Pharmaceutical Companies of Johnson & Johnson. To learn more about Janssen's commitment to the prevention and treatment of HIV, please visit [jnj.com/HIV](http://jnj.com/HIV).

### ***Notice to Investors Concerning Forward-Looking Statements***

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding rilpivirine and development of potential preventive and treatment regimens for HIV. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Sciences Ireland Unlimited Company, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*