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ViiV Healthcare's long-acting HIV treatment *Cabenuva* (cabotegravir + rilpivirine) meets primary endpoint of superior viral suppression vs. daily oral therapy in people with viremia

- CROWN is the first large, phase IIIb international trial to evaluate the investigational use of long-acting *Cabenuva* versus daily oral therapy in people with a history of antiretroviral treatment and unsuppressed HIV
- Results build on LATITUDE study and robust body of evidence supporting investigational use of long-acting cabotegravir + rilpivirine treatment in delivering viral suppression across treatment-experienced populations, including people with viremia at initiation
- Data to be shared with health authorities for regulatory review

GSK plc (LSE/NYSE: GSK) announced that ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Shionogi as a shareholder, today announced the phase IIIb CROWN study met its primary endpoint, demonstrating that at six months, long-acting *Cabenuva* (cabotegravir + rilpivirine [CAB + RPV LA]) achieved superior rates of viral suppression compared with standard-of-care oral antiretroviral therapy (ART) in adults and adolescents living with HIV-1 who had detectable virus when they entered the study.

Findings build on the LATITUDE study, which demonstrated that CAB + RPV LA was superior to daily oral therapy in maintaining viral suppression among people with HIV who had achieved viral suppression on oral ART but had a history of adherence challenges. CROWN addresses a remaining evidence gap by evaluating direct initiation of the regimen in people who still had detectable virus at study entry and had no evidence of resistance to INSTIs (integrase inhibitors) or NNRTIs (non-nucleoside reverse transcriptase inhibitors). Use of CAB + RPV LA in people with detectable viremia is investigational and has not been approved by regulatory authorities.

Jean van Wyk, MBChB, MFPM, Chief Medical Officer at ViiV Healthcare, said: "People living with HIV who experience challenges achieving or maintaining viral suppression with daily oral therapy continue to face significant barriers to optimising care. The CROWN study was designed to address this important evidence gap. These findings add to the growing body of data around long-acting treatment with cabotegravir plus rilpivirine, and provide important insights into the potential role of this approach for treatment-experienced people living with HIV."

CROWN is an international, randomised, open-label study designed to evaluate whether people living with HIV-1 who have detectable virus despite a history of daily oral ART can directly initiate CAB + RPV LA, administered six times a year, and achieve viral suppression. The study enrolled approximately 326 participants, including adults and adolescents, across eight countries at 85 study sites.

CAB + RPV LA is currently approved in the US and other markets under the brand name *Cabenuva* and *Vocabria + Rekambys* in the EU and Japan for the treatment of HIV-1 infection in adults and adolescents who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

Full results are planned for presentation at an upcoming scientific meeting.



About *Cabenuva* (cabotegravir + rilpivirine)

Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 c/ml) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

The complete regimen combines the integrase strand transfer inhibitor (INSTI) cabotegravir, developed by ViiV Healthcare, with rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Johnson & Johnson. Rilpivirine tablets are approved in the US and when used with cabotegravir is indicated for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

INSTIs 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 disease. Rilpivirine is an NNRTI that works by interfering with an enzyme called reverse transcriptase, which stops the virus from multiplying.

Please consult the full Prescribing Information [here](#).

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About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 with GSK (LSE: GSK) and Shionogi as current shareholders. The company is dedicated to delivering advances in treatment and care for people living with HIV and for people who could benefit from HIV prevention. ViiV Healthcare'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.

About GSK

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 www.gsk.com.

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Press release

For media and investors only



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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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2025, and GSK's Q2 Results for 2026.

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