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J&J reports positive results for injectable HIV treatment regimen

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ATLAS-2M study met its primary objective of demonstrating similar efficacy of long-acting rilpivirine and cabotegravir administered every two months compared to monthly administration



The Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) has announced positive top-line results from the Phase 3 ATLAS-2M study of the investigational, long-acting two-drug injectable regimen of its rilpivirine and ViiV Healthcare's cabotegravir for the treatment of HIV.

The study achieved its primary objective, showing that administering the long-acting (LA) injectable regimen of Janssen's rilpivirine and ViiV's cabotegravir every two months was as effective in maintaining viral suppression throughout the 48-week study period as monthly dosing in adults living with HIV-1 infection, whose viral load is suppressed and not resistant to rilpivirine or cabotegravir.

Non-inferiority was measured by the proportion of participants with plasma HIV-RNA? 50 copies per milliliter (c/mL) using the FDA Snapshot algorithm at Week 48 (Intent-to-Treat Exposed [ITTE] population). Overall safety, virologic response, and drug resistance results for the LA regimen were consistent with results from the Phase 3 ATLAS study[1]

The ATLAS-2M study is a Phase 3, randomized, open-label, active-controlled, multicenter, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of the LA regimen administered every two months compared to the LA regimen administered monthly over a 48-week treatment period in 1,045 adults living with HIV-1. The study is being conducted at research centers in Australia, Argentina, Canada, France, Germany, Italy, Mexico, Russia, South Africa, South Korea, Spain, Sweden and the United States.

The LA regimen is being co-developed as a collaboration with ViiV Healthcare and has been submitted to regulatory authorities in the United States, Canada and Europe. A Priority Review Designation for the once-monthly injectable regimen was granted by the US FDA.