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# J&J's HIV drug receives EU nod

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Johnson & Johnson's, Janssen-Cilag International NV (Janssen) has announced that the European Medicines Agency (EMA) has granted a positive opinion recommending REZOLSTA (darunavir/cobicistat) in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older.

REZOLSTA is a new once-daily, fixed-dose combination tablet containing darunavir and the pharmacokinetic enhancing or "boosting" agent cobicistat (marketed as Tybost by Gilead Sciences, Inc.). The Janssen filing was based on bioequivalence data evaluating the use of a darunavir and cobicistat fixed-dose combination tablet versus single agents, and a clinical study evaluating the safety and efficacy of cobicistat-boosted darunavir for the treatment of HIV-1 in adults with no darunavir resistance-associated mutations.

"People with HIV are living longer than ever before thanks to the development and introduction of effective HIV treatments," said Ms Christiane Moecklinghoff, medical director, virology, Janssen. She added, "For this reason, expanding existing treatment options, especially those which will improve patients' lives by simplifying regimens and supporting adherence are critical. If approved, this new treatment option eliminates the need to take a boosting agent in a separate tablet with once-daily darunavir, reducing the pill burden for patients. We look forward to a final decision from the European Commission in the coming months."