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Beerse, Belgium, 29 September 2014 - Janssen-Cilag International NV (Janssen) today announced that the Committee for Medicinal Products for Human Use (CHMP) of 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. The CHMP also announced two label extensions for darunavir, a protease inhibitor marketed as PREZISTA® by Janssen.

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 Christiane Moecklinghoff, M.D Ph.D, Medical Director, Virology, Janssen EMEA. "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."

The darunavir and cobicistat fixed-dose combination was approved in Canada in June 2014 under the name PREZCOBIX [™], and is currently undergoing regulatory review by the FDA in the USA.

Janssen will continue to make darunavir available, as a single agent in tablets, so patients and their physicians can decide which HIV treatment regimen is best for them.

The CHMP has also issued two additional label extensions relating to darunavir. The first label extension is for the prescribing of once-daily dosing of darunavir/ritonavir in children aged 3-