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FDA issues complete response letter for PREZISTA

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Singapore:Ã?Â The US Food and Drug Administration (FDA) has issued a complete response letter to Janssen Therapeutics for Supplemental New Drug Application (sNDA) for an 800mg tablet of PREZISTA (darunavir).

PREZISTA is approved for once-daily oral administration of 800mg, two 400mg tablets, for the treatment of human immunodeficiency virus (HIV-1) in treatment-naÃ?Æ?Ã?Â¯ve and treatment-experienced adult patients with no darunavir resistance-associated mutations. PREZISTA is always taken with and at the same time as ritonavir with food and in combination with other HIV medicines.

Janssen is developing the 800mg tablet dosage strength to allow patients taking PREZISTA once daily to reduce the number of PREZISTA tablets by half, taking one 800mg tablet instead of two 400mg tablets once a day with ritonavir 100mg and other antiretroviral medications.

The sNDA for the 800mg tablet strength was submitted in January 2012. Janssen is evaluating the FDA's letter and will respond to the agency as quickly as possible. The company does not expect additional clinical trials will be required to address the FDA's feedback in the Complete Response letter. Janssen continues to believe the 800mg PREZISTA tablet is an important option and is committed to making it available to patients.

PREZISTA is a protease inhibitor and was first approved in the United States in 2006.Ã?Â It is marketed in the US by Janssen Therapeutics.