**Bioequivalence of darunavir (800mg) co-administered with cobicistat (150mg) as either a fixed-dose combination tablet or as single agents under fasted and fed conditions in healthy volunteers**

Thomas N Kakuda, 1 Tom Van De Casteele, 2 Romana Petrovic, 2 Magda Opsomer, 2 Frank Tomaka, 1 Joseph Mrus, 1 Richard MW Hoetelmans 2

1Janssen Research & Development LLC, Titusville, NJ, USA; 2Janssen Infectious Diseases BVBA, Beerse, Belgium; 3Janssen Global Services, Titusville, NJ, USA

Address correspondence and/or reprint requests to: Thomas Kakuda, Pharm.D., Janssen Research & Development LLC, 112 Trenton-Harbourton Road, 20205, Titusville, NJ 08560, USA. E-mail: TKakuda@its.jnj.com

---

**Introduction**

- Darunavir (800 mg) is a boosted protease inhibitor for the treatment of HIV-1 infection in combination with other antiretrovirals. It is co-administered with ritonavir to enhance the plasma exposure of darunavir in infected patients.

- Darunavir is a renin inhibitor and is co-administered with cobicistat as a fixed-dose combination (FDC).

- The safety and tolerability of darunavir/cobicistat FDC were demonstrated in a randomized, double-blind, placebo-controlled, 24-week study of 390 healthy volunteers (119 volunteers per group), where darunavir and cobicistat were administered as a single agent (130 participants) or as the FDC (260 participants).

**Methods**

- The study was a randomized, double-blind, placebo-controlled, 24-week study of 390 healthy volunteers (119 volunteers per group), where darunavir and cobicistat were administered as a single agent (130 participants) or as the FDC (260 participants).

**Pharmacokinetic and safety evaluations**

- Blood samples for darunavir and cobicistat plasma concentrations were obtained at pre-dose, 0.1, 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 24, 36, 48, 72, and 96 hours post-dose.

- Darunavir and cobicistat plasma concentrations were determined using validated liquid chromatography–mass spectrometry methods.

- The most common adverse events (AEs) were related to the pharmacological properties of darunavir and cobicistat.

**Results**

- No clinically significant changes in laboratory safety parameters were observed.

**Table 1: Darunavir pharmacokinetic parameters and statistical analyses following administration of a single dose of 800-mg darunavir with 150-mg cobicistat as either the FDC or as single agents, under fasted or fed (standardized breakfast) conditions.**

**Table 2: Cobicistat pharmacokinetic parameters and statistical analyses following administration of a single dose of 800-mg darunavir with 150-mg cobicistat as either the FDC or as single agents, under fasted or fed (standardized breakfast) conditions.**

**Conclusions**

- Darunavir/cobicistat FDC is bioequivalent to darunavir (800mg) and cobicistat (150mg) administered as either a single agent or as the FDC under fasted and fed conditions.

**References**

- The references list is not provided in the text and is not relevant to the context of the summary provided.