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Guidance on Rucaparib Camsylate

March 2021

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This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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In February 2018, FDA issued a draft product-specific guidance for industry on generic rucaparib camsylate. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

Active Ingredient: Rucaparib camsylate

Dosage Form; Route: Tablet; oral

Recommended Study: One study

1. Type of study: Steady state
   Design: Multiple-dose, two-period, two treatment, crossover
   Strength: EQ 300 mg Base
   Subjects: Non-pregnant, non-lactating female patients with deleterious BRCA mutation (germline and/or somatic) associated with advanced cancer who have been treated with two or more chemotherapies and are receiving a regimen of rucaparib camsylate
   Additional comments: Blood sampling for bioequivalence study should consist of appropriate sampling times over a 12-hour period after the administration of the morning dose and following the attainment of steady state. Advise females of reproductive

potential to use effective contraception during treatment and for 6 months following the last dose of rucaparib. The study should be designed around each patient's existing rucaparib regimen and no changes in dose or regimen should be made for the purpose of the bioequivalence study. Submit a Bio-IND as per 21 CFR 320.31 as rucaparib is considered a cytotoxic drug.

Analyte to measure: Rucaparib in plasma

Bioequivalence based on (90% CI): Rucaparib

Waiver request of in vivo testing: EQ 200 mg Base and EQ 250 mg Base based on (i) acceptable bioequivalence study on the EQ 300 mg Base strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

Revision History: Recommended February 2018; Revised March 2021

Unique Agency Identifier: PSG_209115