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Draft Guidance on Futibatinib

November 2023

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In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Futibatinib

Dosage Form: Tablet

Route: Oral

Strength: 4 mg

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 4 mg (at a dose of 8 mg (2 tablets of 4 mg))
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Perform a comprehensive ophthalmological examination prior to enrollment and exclude subjects with ophthalmological abnormalities. Female subjects of reproductive potential should use non-hormonal contraception during the study and for one week after the last dose. Male subjects with female partners of reproductive potential should use effective contraception during the study and for one week after the last dose.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 4 mg (at a dose of 8 mg (2 tablets of 4 mg))
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Futibatinib in plasma

Bioequivalence based on (90% CI): Futibatinib

Waiver request of in vivo testing: Not applicable

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 each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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