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Draft Guidance on Mobocertinib Succinate

August 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: Mobocertinib succinate

Dosage Form: Capsule

Route: Oral

Strength: EQ 40 mg Base

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: EQ 40 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females of reproductive potential should use non-hormonal contraceptives during the study and continue to use effective contraceptives for two weeks after the last dose of mobocertinib. Males with female partners of reproductive potential should use effective contraceptives during the study and for one week after the last dose of mobocertinib. Exclude subjects with risk factors for prolonged QTc interval and Torsades de Pointes. Monitor subjects for electrocardiogram changes during the study.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 40 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Mobocertinib in plasma

Bioequivalence based on (90% CI): Mobocertinib

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

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