

**Draft Guidance on Sotorasib**

**February 2023**

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**Active Ingredient:** Sotorasib

**Dosage Form; Route:** Tablet; oral

**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: 120 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: Exclude subjects with abnormal liver function tests.
2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 120 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: See comments above.

**Analyte to measure:** Sotorasib in plasma

**Bioequivalence based on (90% CI):** Sotorasib

**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 (ANDA).

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