Active Ingredient: Lusutrombopag

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period, crossover in vivo
   Strength: 3 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Ensure adequate washout periods between treatments in the crossover study due to its long terminal elimination half-life. Consider using a parallel study design. For long half-life drug products with low intra-subject variability in distribution and clearance, an AUC truncated to 72 hours may be used in place of AUC0-t or AUC0-∞. For either a crossover or parallel study, sample collection time should be adequate to ensure completion of gastrointestinal transit of the drug product and absorption of the drug substance. Sufficient blood samples should be collected to adequately characterize the peak concentration and time to reach peak concentration.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period, crossover in vivo
   Strength: 3 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above

Analyte to measure (in appropriate biological fluid): Lusutrombopag in plasma

Bioequivalence based on (90% CI): Lusutrombopag

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each strength of the test and

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