A Phase 2, Randomized, Multicenter, Placebo-Controlled, Double-Blind, Parallel-Group Study to Evaluate the Efficacy, Safety, and Population Pharmacokinetics of Once-Daily Oral E5501 Tablets Used Up to 7 Days in Subjects With Chronic Liver Diseases and Thrombocytopenia Prior to Elective Surgical or Diagnostic Procedures

IRB#: 0908M71242

Trial Status: Open for enrollment

Phase: 2

Sponsor: Eisai

Why is this study being done?

The purpose of this study is to evaluate the efficacy of once-daily Oral E5501 in subjects with chronic liver diseases and thrombocytopenia prior to elective surgical or diagnostic procedures, to evaluate the safety of short-term administration of E5501 and to evaluate the pharmacokinetics (PK) of E5501.

Who is eligible to participate in the study?

Key Inclusion Criteria:

1. Males or females ≥ 18 years of age.
2. Thrombocytopenia diagnosis.
3. Chronic liver diseases due to one of the following three categories:
   - Chronic Viral Hepatitis
   - NASH (Nonalcoholic Steatohepatitis) or "Fatty Liver Disease"
   - Alcoholic liver disease
4. Subjects who are scheduled to undergo an elective invasive procedure soon after the last dose of study drug.
5. Adequate renal function as evidenced by a calculated creatinine clearance ≥50 mL/minute per the Cockcroft and Gault formula.
6. Life expectancy ≥3 months.

Key Exclusion Criteria:

1. Hepatic encephalopathy that cannot be effectively treated.
2. Platelet transfusion within 7 days prior to the first dose of study drug.
3. Received blood products, e.g., FFP and cryoprecipitate 7 days prior to the first dose of study drug.
4. Have surgical or diagnostic procedure scheduled during the Randomization Phase (Day 1 to Day 8) of this study.
5. Interferon use within 2 weeks of Day 1.
6. History of human immunodeficiency virus (HIV) infection.
7. Any prohibited concomitant medications or therapy that cannot be discontinued by Visit 1.
8. Current use of recreational drug
9. History of active alcoholic hepatitis (chronic alcoholic hepatitis is allowed) within 6 months of the study start.
11. History of arterial or venous thrombosis (2 events within a year or any event within 6 months of study start).
12. History of arterial or venous thrombosis within 7-12 months of study start AND have one of the following risk factors: hereditary thrombophilic disorders (e.g., Factor V Leiden, ATIII deficiency, Protein C, etc.), hormone replacement therapy, systemic contraception therapy (containing estrogen), smoking, diabetes, hypercholesterolemia, or taking medication for hypertension or cancer.
13. Active gastrointestinal (GI) or central nervous system (CNS) bleeding.
15. Pre-diagnosed Idiopathic Thrombocytopenic Purpura (ITP).
16. History of Myelodysplastic Syndrome (MDS).
17. Post transplant patients
18. Subjects who have participated in another investigational trial within thirty days prior to first visit.

**Minimum age:** 18

**What is involved in the study?**

<table>
<thead>
<tr>
<th>Number</th>
<th>Type</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1:</td>
<td>Experimental</td>
<td>Drug: <strong>E5501</strong>&lt;br&gt;Oral <strong>E5501</strong> on Day 1 as 100 mg loading dose and then once daily as oral <strong>E5501</strong> at 20 mg for up to 6 additional doses.</td>
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<tr>
<td>2:</td>
<td>Experimental</td>
<td>Drug: <strong>E5501</strong>&lt;br&gt;Oral <strong>E5501</strong> on Day 1 as 100 mg loading dose and then once daily as oral <strong>E5501</strong> at 40 mg for up to 6 additional doses.</td>
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<tr>
<td>3:</td>
<td>Experimental</td>
<td>Drug: <strong>E5501</strong>&lt;br&gt;Oral <strong>E5501</strong> on Day 1 as 100 mg loading dose and then once daily as oral <strong>E5501</strong> at 80 mg for up to 6 additional doses.</td>
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<td>4:</td>
<td>Placebo</td>
<td>Drug: Placebo&lt;br&gt;Matching placebo (Day 1 loading, then once-daily up to 6 additional oral doses).</td>
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</tbody>
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**How long will the study run?**

6 weeks

**Who can I contact to find out more about this trial?**

Name: Cathleen Boeck  
Phone #: (612) 624-4628
What are the locations of this trial?

Ochsner Clinic, Louisiana
University of Minnesota, Minnesota
Other locations (not disclosed on clinicaltrials.gov)