A 24-month Randomized Multicenter Study Evaluating Efficacy, Safety, Tolerability and Pharmacokinetics of Sotrastaurin and Tacrolimus vs. a Tacrolimus/Mycophenolate Mofetil-based Control Regimen in de Novo Liver Transplant Recipients

IRB#: TBA

Trial Status: Preparing for enrollment

Phase: II

Sponsor: Novartis

Why is this study being done?
This study will assess the safety and efficacy of different doses of sotrastaurin when combined with tacrolimus for the prevention of acute rejection after de novo liver transplantation.

Who is eligible to participate in the study?

Inclusion criteria:
- Recipients of any race, 18 years or older
- Recipients of primary de novo orthotopic liver transplant from a deceased donor
- Recipients of a kidney with a cold ischemia time < 30 hours
- HCV-negative recipients

Exclusion criteria:
- Prior organ/cellular transplant or multiple organ transplant
- MELD-score > 35
- HCC > Milan criteria
- Donor age < 12 years
- Cold ischemia > 15 hours
- Patients who are treated with drugs that are strong inducers or inhibitors of cytochrome P450 3A4 (CYP3A4) or drugs with QT-prolonging properties

Other protocol-defined inclusion/exclusion criteria may apply

Minimum age: 18
### What is involved in the study?

<table>
<thead>
<tr>
<th>Arm 1: Experimental</th>
<th>Drug: MMF(1000mg bid) + tacrolimus + standard of care medications</th>
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</thead>
<tbody>
<tr>
<td>MMF(1000mg bid) + tacrolimus + standard of care medications</td>
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<tr>
<td>Arm 2: Experimental</td>
<td>Drug: sotrastaurin (200mg bid) + tacrolimus + standard of care medications</td>
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<td>Arm 3: Experimental</td>
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<tr>
<td>Arm 4: Experimental</td>
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### How long will the study run?

March 2013

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

Name: Melissa Cohen  
Phone #: (612) 624-6649

### What are the locations of this trial?

**United States, California**

Novartis Investigative Site  
San Francisco, California, United States  
Contact 862-778-8300  
Not yet recruiting

**United States, Colorado**

Novartis Investigative Site  
Aurora, Colorado, United States  
Contact 862-778-8300  
Not yet recruiting

**United States, Illinois**

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Chicago, Illinois, United States  
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United States, Maryland
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Baltimore, Maryland, United States
Contact 862-778-8300

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Ann Arbor, Michigan, United States
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Novartis Investigative Site Not yet recruiting
Rochester, Minnesota, United States
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San Martin, Argentina
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Austria

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Belgium

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Canada

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Montreal, Canada

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Finland

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France

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Germany

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Italy

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Spain

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Switzerland

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