Ledipasvir-Sofosbuvir in HCV Genotype 4
NIAID SYNERGY (Genotype 4

Ledipasvir-Sofosbuvir in Genotype 4 NIAID SYNERGY (GT4) Trial: Features

<table>
<thead>
<tr>
<th><strong>NIAID SYNERGY Trial</strong></th>
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<tbody>
<tr>
<td><strong>Design:</strong> Open-label, phase 2a trial using fixed dose ledipasvir-sofosbuvir for treatment-naïve and interferon treatment-experienced patients with chronic HCV genotype 4</td>
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<td><strong>Setting:</strong> single center (Clinical Center at NIH, United States)</td>
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<td><strong>Entry Criteria</strong></td>
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<td>- Age 18 years or older</td>
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<td>- Chronic HCV genotype 4</td>
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<td>- Treatment naïve or prior interferon treatment failure</td>
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<td>- HCV RNA ≥2,000 IU/mL</td>
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<td>- Exclusions: HBV, HIV, or decompensated liver disease</td>
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<td><strong>Primary End-Point:</strong> SVR12</td>
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Ledipasvir-Sofosbuvir in Genotype 4 NIAID SYNERGY (GT4) Trial: Features

**Genotype 4**
- Treatment Naïve (n = 13)
- Treatment Experienced (n = 8)

**n = 21**

**Drug Dosing**
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination; one pill once daily

Ledipasvir-Sofosbuvir in Genotype 4 NIAID SYNERGY (GT4) Trial: Key Baseline Characteristics

- Sex: Male 67%
- Race: 43% Black; 52% White; 5% Native American
- Country of Origin: 29% Egypt; 24% United States
- Treatment Experience: 62% naïve; 38% experienced
- HCV RNA >800,000 IU/mL: 62%

Ledipasvir-Sofosbuvir in Genotype 4 NIAID SYNERGY (GT4) Trial: Results

NIH SYNERGY: SVR 12, Intent to Treat Analysis

Ledipasvir-Sofosbuvir Treated Patients

*1 patient did not complete 12 weeks of treatment due to drug non-adherence

Interpretation: “Ledipasvir and sofosbuvir treatment for 12 weeks was well tolerated by patients with HCV genotype 4 and resulted in 100% SVR for all patients who received all 12 weeks of study drugs, irrespective of previous treatment status and underlying liver fibrosis. This is the first report of a single-pill, all-oral, interferon-free, ribavirin-free treatment for patients with HCV genotype 4.”