Ledipasvir-Sofosbuvir +/- RBV in HCV Genotype 4
Egyptian Multicenter Study

**Ledipasvir-Sofosbuvir +/- RBF in HCV Genotype 4 Egyptian Multicenter Study: Study Design**

<table>
<thead>
<tr>
<th><strong>Egyptian Multicenter Study</strong></th>
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<tr>
<td><strong>Design</strong>: Open-label, open-label, phase 3, multicenter study evaluated the efficacy of ledipasvir-sofosbuvir, with or without ribavirin, for 8 or 12 weeks in 255 Egyptian adults with HCV genotype 4 infection</td>
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<td><strong>Setting</strong>: multicenter in Egypt</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 ≥10,000 IU/mL for treatment naïve and interferon-experienced</td>
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<td>HCV RNA ≥ 15 IU/mL for ledipasvir-sofosbuvir-experienced</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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**Week 0**
- LDV-SOF
- LDV-SOF + RBV
- LDV-SOF
- LDV-SOF + RBV

**Week 8**
- LDV-SOF
- LDV-SOF + RBV
- LDV-SOF
- LDV-SOF + RBV

**Week 12**
- LDV-SOF
- LDV-SOF + RBV
- LDV-SOF
- LDV-SOF + RBV

**Week 20**
- LDV-SOF
- LDV-SOF + RBV
- LDV-SOF
- LDV-SOF + RBV

**Week 24**
- LDV-SOF
- LDV-SOF + RBV
- LDV-SOF
- LDV-SOF + RBV

**Cohort 1 (n = 170)**
- Treatment Naïve

**Cohort 2 (n = 11)**
- LDV-SOF or SOF Experienced

**Cohort 3: (n = 74)**
- IFN Experienced

**Drug Dosing**
Ledipasvir-sofosbuvir (LDV-SOF) (90/400 mg): fixed dose combination; one pill once daily
Ribavirin (RBV): weight based, 1000 mg/day if weight <75kg and 1200 mg/day if weight ≥75kg

Ledipasvir-Sofosbuvir +/- RBV in HCV Genotype 4 Egyptian Multicenter Study: Results

**Conclusion:** “Among non-cirrhotic treatment-naive patients with HCV genotype 4, 8 weeks of ledipasvir/sofosbuvir ± ribavirin was highly effective. Twelve weeks of ledipasvir/sofosbuvir ± ribavirin was highly effective regardless of presence of cirrhosis or prior treatment experience, including previous treatment with sofosbuvir or ledipasvir/sofosbuvir.”