Sofosbuvir in HCV-HIV Coinfection & HCV GT 1,2,3

PHOTON-1 Trial
PHOTON-1 Trial: Features

- **Design**: Open-label, nonrandomized, uncontrolled, phase 3 trial using sofosbuvir + ribavirin in HCV-HIV coinfection and HCV GT 1, 2, or 3

- **Setting**: 34 treatment centers in United States and Puerto Rico

- **Entry Criteria**
  - HIV coinfection; HCV Genotype 1, 2, or 3
  - Treatment naïve (GT 1,2,3) or treatment experienced (GT 2,3)
  - On antiretroviral therapy with HIV RNA $\leq$ 50 copies/ml and CD4 $\geq$ 200 or not on antiretroviral therapy and CD4 $\geq$ 500
  - Compensated cirrhosis permitted (<20% total patients)

- **Patient Characteristics**
  - N = 223 HCV-HIV coinfected patients
  - On ARV Rx: GT1 (98%); GT 2/3 naive (90%); GT 2/3 experienced (95%)

- **Primary End-Points**
  - Efficacy (SVR12), safety, and impact on HIV
### Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Treatment Naive</th>
<th>Treatment Experienced</th>
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<tbody>
<tr>
<td></td>
<td>GT 1 (n=114)</td>
<td>GT 2 or 3 (n=68)</td>
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<td>Age, mean (range)</td>
<td>48 (25-70)</td>
<td>49 (24-71)</td>
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<tr>
<td>Male, %</td>
<td>82%</td>
<td>81%</td>
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<tr>
<td>Black, %</td>
<td>32%</td>
<td>12%</td>
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<td>IL28B CC genotype, %</td>
<td>27%</td>
<td>37%</td>
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<td>Cirrhosis, %</td>
<td>4%</td>
<td>10%</td>
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<tr>
<td>On ART§, %</td>
<td>98%</td>
<td>90%</td>
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<td>CD4 count, cells/mm³, median</td>
<td>581</td>
<td>562</td>
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</tbody>
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§Tenofovir-emtricitabine plus [efavirenz, r-atazanavir, r-darunavir, raltegravir, rilpivirine, or other]

Sofosbuvir and Ribavirin for HCV-HIV Coinfection
PHOTON-1 Trial: Treatment Arms

GT 1
Naïve

Sofosbuvir + RBV
(n = 114)

GT 2,3
Naïve

Sofosbuvir + RBV
(n = 68)

GT 2,3
Experienced

Sofosbuvir + RBV
(n = 41)

Drug Dosing
Sofosbuvir: 400 mg once daily
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Sofosbuvir and Ribavirin for HCV-HIV Coinfection
PHOTON-1 Trial: Results

PHOTON-1: SVR12 with Sofosbuvir + RBV x 12-24 weeks

Conclusions and Relevance: “In this open-label, nonrandomized, uncontrolled study, patients with HIV who were coinfected with HCV genotype 1, 2, or 3 who received the oral, interferon-free combination of sofosbuvir and ribavirin for 12 or 24 weeks had high rates of SVR12. Further studies of this oral regimen in diverse populations of coinfected patients are warranted.”
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