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

PHOTON-1 Trial

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

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 ≤ 50 copies/ml and CD4 ≥ 200 or not on antiretroviral therapy and CD4 ≥ 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

Source: Sulkowski MS, et al. JAMA. 2014;312:353-61.

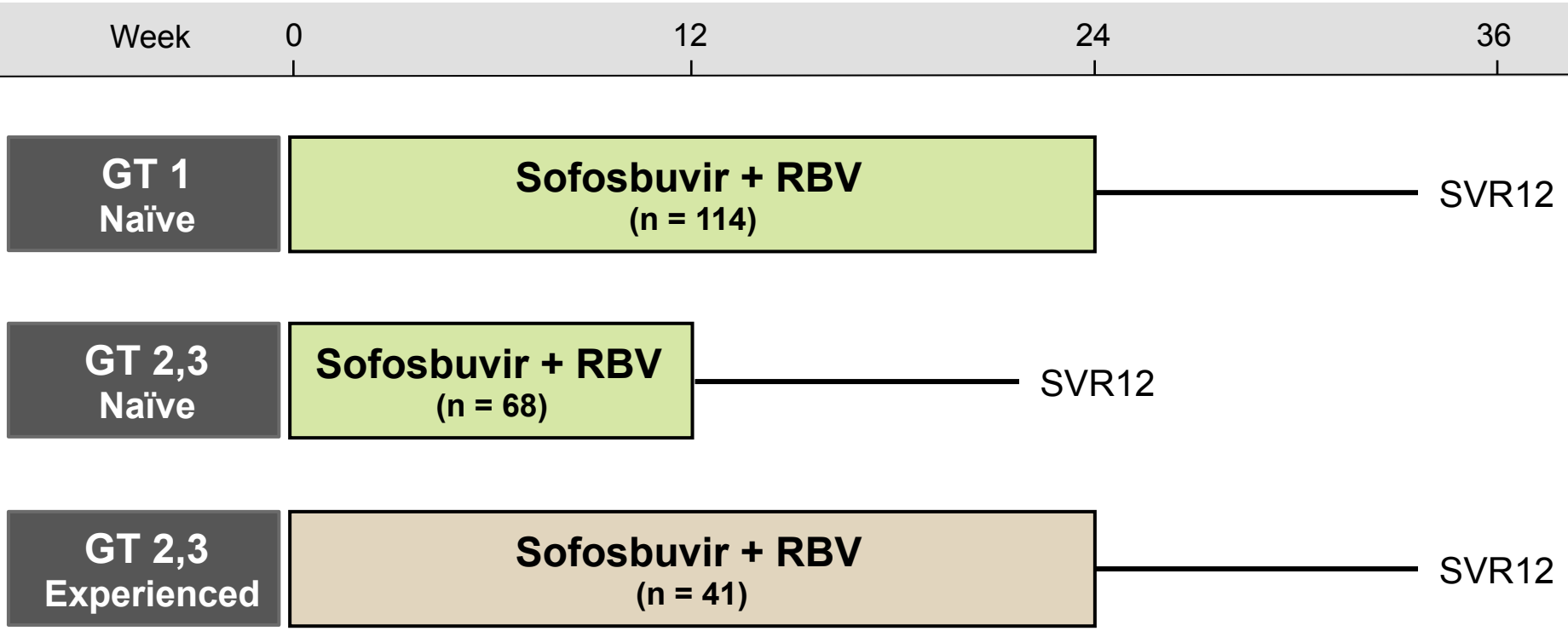
Sofosbuvir and Ribavirin for HCV-HIV Coinfection
PHOTON-1 Trial: Participants

Baseline Characteristics	Treatment Naive		Treatment Experienced
	GT 1 (n=114)	GT 2 or 3 (n=68)	GT 2 or 3 (n=41)
Age, mean (range)	48 (25-70)	49 (24-71)	54 (34-68)
Male, %	82%	81%	90%
Black, %	32%	12%	17%
IL28B CC genotype, %	27%	37%	49%
Cirrhosis, %	4%	10%	24%
On ART§, %	98%	90%	95%
CD4 count, cells/mm^3, median	581	562	579

§Tenofovir-emtricitabine plus [efavirenz, r-atazanavir, r-darunavir, raltegravir, rilpivirine, or other]

Source: Sulkowski MS, et al. JAMA. 2014;312:353-61.

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



Drug Dosing

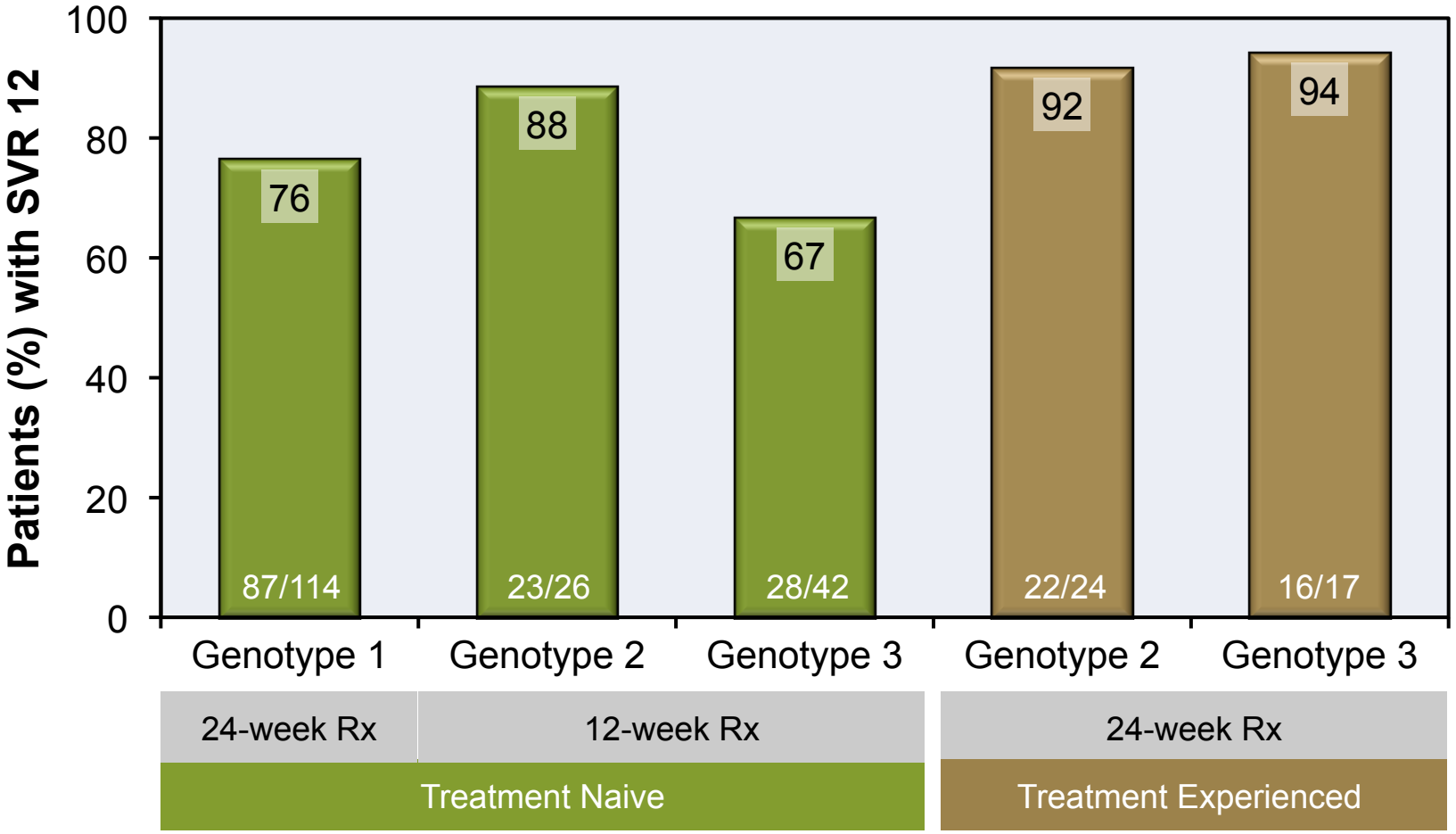
Sofosbuvir: 400 mg once daily

Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Source: Sulkowski MS, et al. JAMA. 2014;312:353-61.

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

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



Source: Sulkowski MS, et al. JAMA. 2014;312:353-61.

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

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."

Source: Sulkowski MS, et al. JAMA. 2014;312:353-61.

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

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