Treatment Naïve and Treatment Experienced

Ledipasvir-Sofosbuvir +/- RBV in HCV Genotype 4

Egyptian Multicenter Study

Source: Shiha G, et al. Gut. 2019:68:721-8.

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

Egyptian Multicenter Study

- **Design**: 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
- **Setting**: multicenter in Egypt
- **Entry Criteria**
  - Age 18 years or older
  - Chronic HCV genotype 4
  - Treatment naïve or prior interferon treatment failure
  - HCV RNA ≥10,000 IU/mL for treatment naïve and interferon-experienced
  - HCV RNA ≥ 15 IU/mL for ledipasvir-sofosbuvir-experienced
  - Exclusions: HBV, HIV, or decompensated liver disease
- **Primary End-Point**: SVR12

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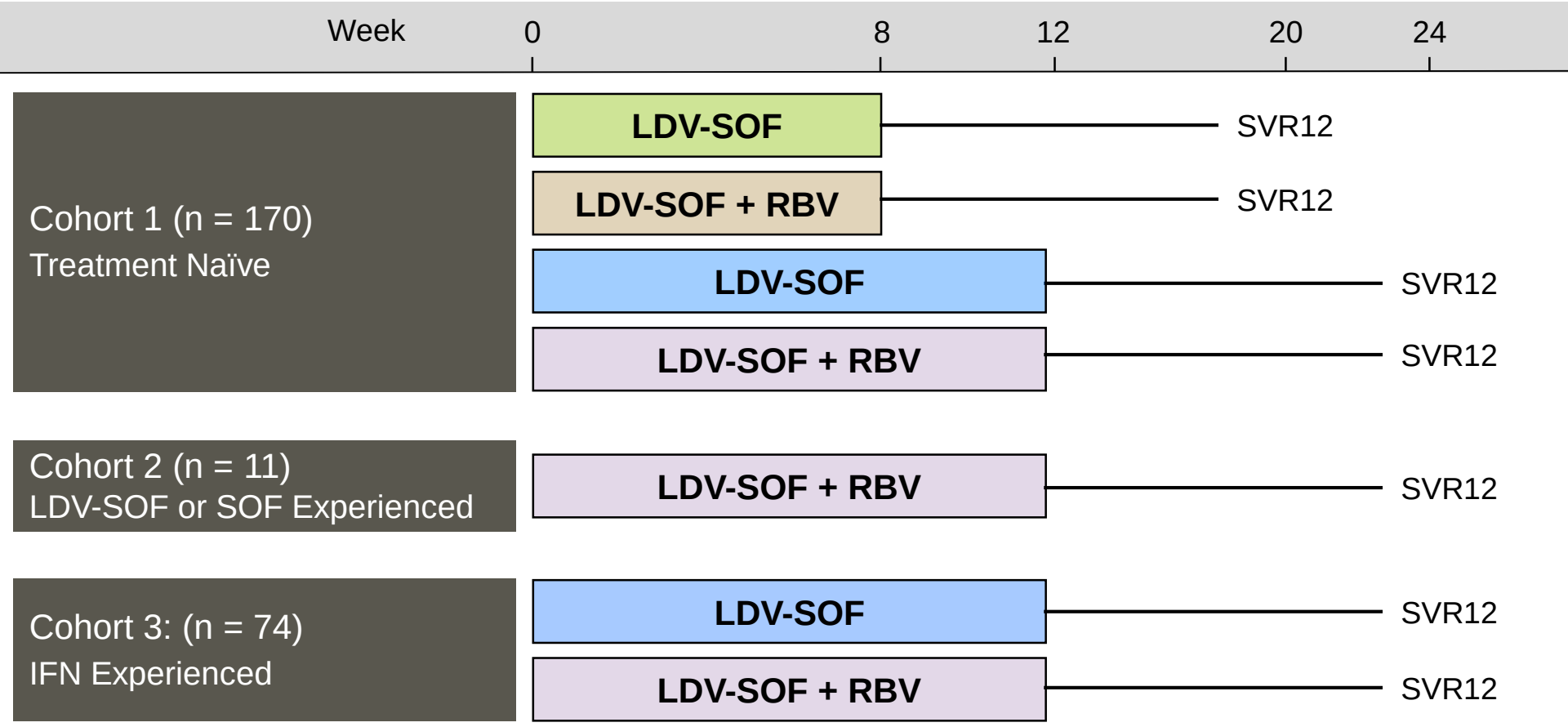
Ledipasvir-Sofosbuvir +/- RBF in HCV Genotype 4 Egyptian Multicenter Study: Design



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

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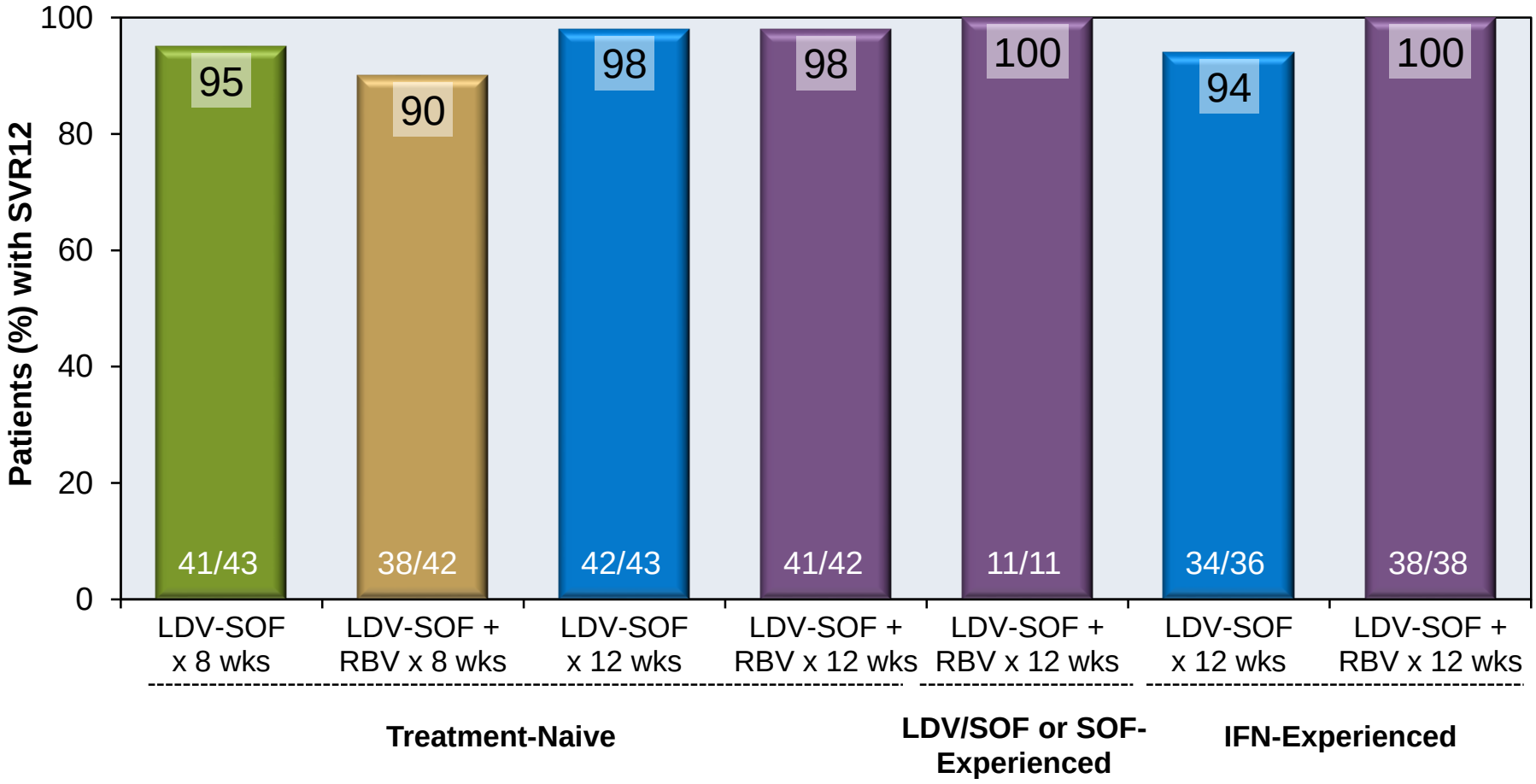
Ledipasvir-Sofosbuvir +/- RBF in HCV Genotype 4 Egyptian Multicenter Study: Results



Source: Shiha G, et al. Gut. 2019:68:721-8.

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

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.”

Source: Shiha G, et al. Gut. 2019:68:721-8.