Treatment Naïve, Phase 3

# Elbasvir-Grazoprevir in HCV GT 1,4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR



#### Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR: Study Features

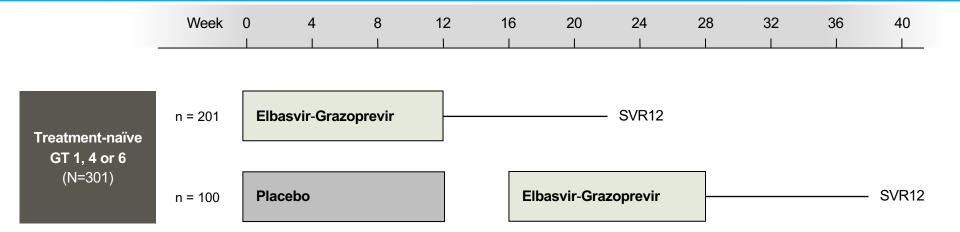
Design: Randomized, phase 3, placebo-controlled, double-blind, multi-site trial using a fixed-dose combination of elbasvir-grazoprevir in treatment-naïve chronic HCV genotype 1, 4, or 6 in persons who inject drugs who are receiving opiate agonist therapy

#### Entry Criteria

- Chronic HCV Genotype 1, 4, or 6
- No prior treatment
- 18 years or older
- Opiate Agonist Therapy for ≥3 months and kept ≥ 80% of appointments
- HCV RNA ≥10,000 IU/mL
- Cirrhosis allowed with goal 20% of subjects with cirrhosis
- HIV infection allowed
- Primary End-Point: SVR12



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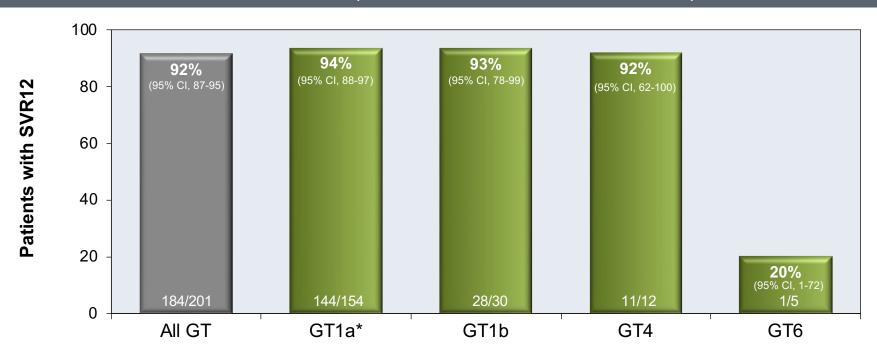
**Drug Dosing** 

Grazoprevir-elbasvir (100/50 mg): fixed dose combination; one pill once daily



### Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR: Results in Immediate-Treatment Group

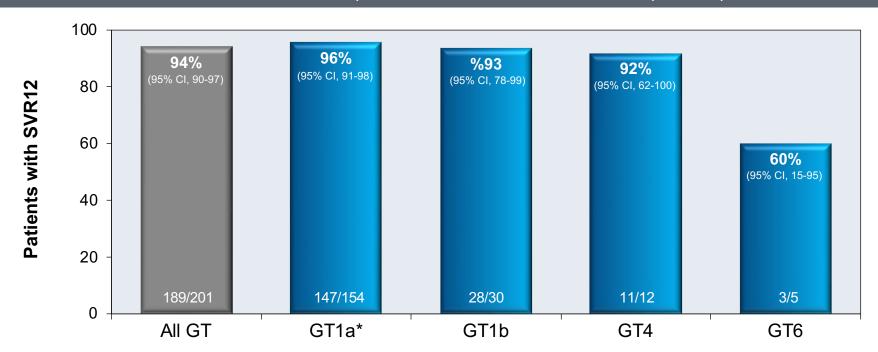
C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Failures)





## Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR: Results in Immediate-Treatment Group

#### C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Responses)





### Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy C-EDGE CO-STAR: Results in Deferred-Treatment Group

C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Failures)

