

ADVANCES IN CHRONIC HEPATITIS C: MANAGEMENT AND TREATMENT

INDEPENDENT REPORTING ON AASLD 2015

COMPREHENSIVE EXPERT REVIEW AND DISCUSSION OF KEY PRESENTATIONS

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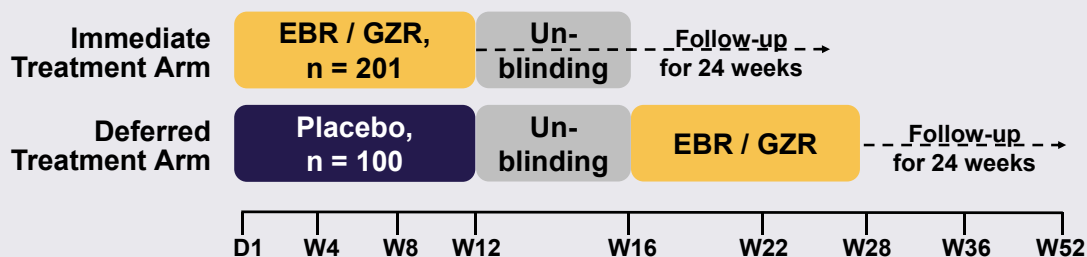
C-EDGE CO-STAR: Efficacy of Grazoprevir and Elbasvir in Persons who Inject Drugs (PWID) Receiving Opioid Agonist Therapy

Gregory Dore, Frederick Altice, Alain H. Litwin, Olav Dalgard, Edward J. Gane, Oren Shibolet, Anne Luetkemeyer, Ronald Nahass, Cheng-Yuan Peng, Brian Conway, Jason Grebely, Anita Y. Howe, Bach-Yen T. Nguyen, Janice Wahl, Eliav Barr, Michael Robertson, Heather L. Platt

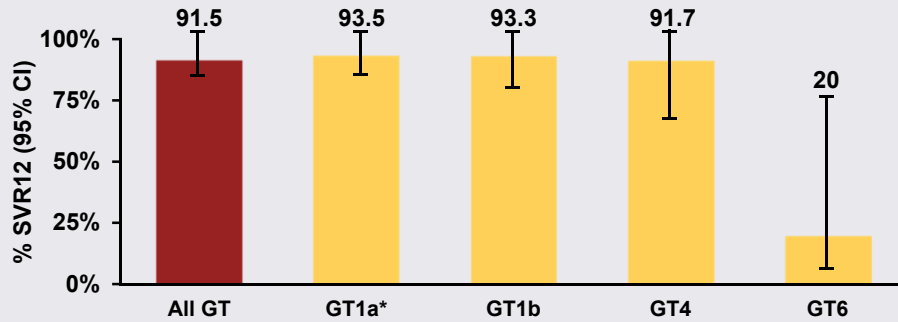
Abstract 40

C-EDGE Co-Star: Trial Design

- Phase 3, randomized, parallel-group, placebo-controlled, double-blind trial
- Treatment naïve, GT1, 4, 6; mixed genotypes of 1, 4, and 6 allowed
- On opiate agonist therapy (OAT) for at least 3 months, and consistently kept at least 80% of scheduled appointment while on OAT
- Goal of 20% with cirrhosis and may be co-infected with HIV



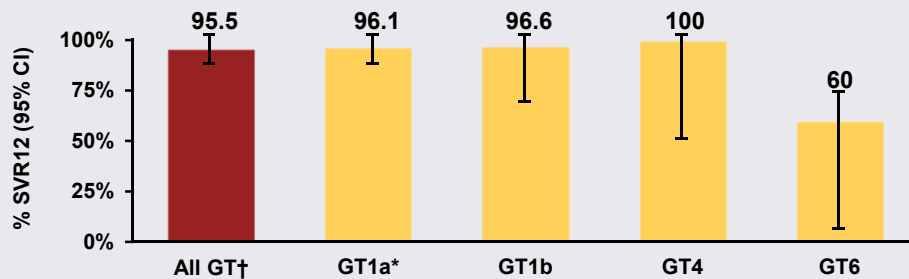
C-EDGE Co-Star: SVR12 in the Immediate Treatment Group - Full Analysis (FAS)



	184/201	144/154	28/30	11/12	1/5
Relapse	7	4	1	0	2
Reinfection	5	3	0	0	2
LTFU of discontinued unrelated to VF†	5	3	1	1	0

Dore G, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. 40.

C-EDGE Co-Star: SVR12 in the Immediate Treatment Group Modified Full Analysis (mFAS)



	189/198	147/153	28/29	11/11	3/5
Failures					
Relapse	7	4	1	0	2
Discontinuation	2	2	0	0	0
Reinfection-counted as success	5	3	0	0	2
LTFU or discontinued unrelated to Virologic Failure-excluded from mFAS analysis	3	1	1	1	0

Dore G, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. 40.

*Includes one subject with mixed infection (GT1a and GT1b) who achieved SVR12

C-EDGE Co-Star: Probable Reinfections in the Immediate Treatment Group

- 5 patients were successfully treated for their baseline virus, but at the time of virologic failure had a different genotype, subtype, or viral strain detected
- In all 5 cases, population sequencing and phylogenetic analysis of the nucleotide sequences support phylogenetically distinct viral strains at follow-up compared to baseline

Demographics	Fibrosis Stage	GT at Baseline	UDS at Baseline*	UDS at TW12*	Time Point of Detectable HCV RNA	GT at Follow-up
48 yo Asian male	NC	1a	BZP, OPA	BZP	FW8	6a
33 yo White female	NC	1a	--	AMP, OPA	FW8	1a
55 yo White female	C	1a	BZP, OPA	BZP, OPA	FW8	3a
45 yo Asian male	NC	6a	--	OPA	FW8	1b
37 yo Asian female	NC	6a	AMP, BZP, OPA	AMP, BZP, OPA	FW8	6a

*Excludes opiate agonist therapy; AMP=amphetamines; BZP=benzodiazepines; opa=opiates
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