PARITAPREVIR/RITONAVIR/OMBITASVIR, DASABUVIR + RIBAVIRIN IN PEOPLE WITH HCV GENOTYPE 1 AND RECENT INJECTING DRUG USE OR RECEIVING OST: D3FEAT STUDY

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Background: Direct-acting antiviral therapy is safe and effective in people with HCV receiving opioid substitution therapy (OST), but there are little data among people with recent injecting drug use (IDU). The aim of this study was to evaluate the efficacy, and safety of paritaprevir/ritonavir, ombitasvir, dasabuvir with or without ribavirin for chronic HCV genotype (G) 1 among people with recent IDU and/or receiving OST.

Methods: D3FEAT is an international open-label study that recruited untreated participants with recent IDU (past 6 months) and chronic HCV G1 infection between June 2016 and February 2017 in seven countries. Participants received paritaprevir/ritonavir, ombitasvir, dasabuvir with (G1a) or without ribavirin (G1b) administered twice daily in a one-week electronic blister pack (records timing of each dose) for 12 weeks. The primary endpoint was undetectable HCV RNA 12 weeks post-treatment (SVR12).

Results: Among 87 participants (mean age 48; 78% male; 8% with cirrhosis, 90% G1a), 21% were not receiving OST and had recent IDU, 43% were receiving OST

with no recent IDU and 37% were receiving OST and had recent IDU. Overall, 94% (82/87) completed 12 weeks of therapy and 97% (84/87) had undetectable HCV RNA at the end of treatment (ETR), including 96% (75/78) and 100% (9/9) in those with HCV G1a and G1b, respectively. ETR was similar in those with and without recent IDU prior to screening (96% vs. 97%, *P*=0.743). Among those with an expected SVR result by May 16, 2017, SVR was 93% (68/73). In modified intent-to-treat analyses excluding those lost to follow-up between ETR and SVR (n=2), SVR was 96% (68/71). There were no virological failures and one virologic recurrence (phylogenetic analysis pending to confirm reinfection vs. relapse).

Conclusion: Paritaprevir/ritonavir/ombitasvir, dasabuvir with or without ribavirin for 12 weeks is effective among people with HCV genotype 1 with recent IDU and/or receiving OST.