SAFETY, TOLERABILITY, AND OUTCOMES OF SOFOSBUVIR/VELPATASVIR IN TREATMENT OF CHRONIS HEPATITIS C VIRUS DURING PREGNANCY: INTERIM RESULTS FROM THE STORC STUDY

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Background:

There are currently no interventions recommended for use during pregnancy to treat HCV infection or prevent perinatal HCV transmission. AASLD/IDSA guidelines state that "treatment can be considered during pregnancy on an individual basis after a patient-physician discussion about the potential risks and benefits," yet limited safety data exist for these discussions. STORC is an international, multi-center study evaluating the safety and efficacy of sofosbuvir/velpatasvir (SOF/VEL) in pregnant people.

Methods:

In this phase 4, open-label, single-arm study, pregnant persons with HCV infection are enrolled between 20+0- and 30+0-weeks' gestation and treated with 12 weeks of SOF/VEL. HCV RNA testing is performed at screening, enrollment, 4, 8 and 12 weeks after SOF/VEL initiation, at delivery and 12 weeks after SOF/VEL completion (SVR12). The primary outcomes are gestational age at delivery and SVR12.

Results:

From July 2022 to September 2023, 32 pregnant people with HCV were screened and 26 enrolled. Five were excluded because of incarceration (n=2), declined enrollment (n=1), clinically significant drug use (n=1), or hemolytic disease of the fetus (n=1). The enrolled participants had a median age of 30.5 (range 18, 40). 21 (81%) identified as White, 5 (19%) identified as other races, including 3 (11.5%) identified as Hispanic. After initiation of SOF/VEL, 19/25 (76%) at 4 weeks,19/21 (90%) at 8 weeks and 19/19 (100%) at 12 weeks of treatment had undetectable HCV RNA (Figure). All participants with HCV RNA obtained at delivery (n=15) and at the SVR12 (n=12) visit were undetectable. 19 participants delivered at a median gestational age of 38+0 weeks' (range 33+5, 41+1) and 2 (10.5%) had preterm delivery. All adverse events related to SOF/VEL were ≤grade 2 and none discontinued treatment.

Conclusion:

The interim data provide preliminary reassurance regarding the safety and efficacy of SOF/VEL after 20 weeks' gestation. STORC recruitment is ongoing.

Figure: HCV viral response to sofosbuvir/velpatasvir during pregnancy