STRIVE4: SOFOSBUVIR PLUS GLECAPREVIR-PIBRENTASVIR FOR FOUR WEEKS AMONG PEOPLE WITH HCV INFECTION AND EARLY LIVER DISEASE

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Background:
Short duration treatment may aid hepatitis C virus (HCV) elimination among key populations. This study evaluated the efficacy, safety and feasibility of sofosbuvir plus glecaprevir-pibrentasvir for four weeks among people with HCV infection.

Methods:
Strategic Treatment Reduction In Very Early liver disease (STRIVE4) is an ongoing single-arm multicentre trial in Australia. Adults with HCV infection (quantifiable HCV RNA at screening) and no significant liver fibrosis (liver stiffness measurement <7.5kPa by transient elastography, AST to platelet Ratio Index [APRI] <1.0, or Fibrosis-4 [FIB-4] score <1.45) received open-label sofosbuvir 400mg and glecaprevir-pibrentasvir 300mg-120mg daily for four weeks (NCT03855917). The primary and secondary efficacy endpoints were sustained virological response at four (SVR4) and 12 weeks (SVR12) post-treatment in the intention-to-treat (ITT) and per-protocol (PP) populations, respectively, defined as HCV RNA < lower limit of quantification (HCV RNA not detected, or detected, <20).

Results:
Between March 2025 and May 2026, 21 participants were screened, 20 enrolled, and 18 initiated treatment (median age 44 years [IQR 39, 52], women 28%, ever injected drugs 83%, median baseline HCV RNA 6.2$\log_{10}$IU/mL [range 1.6, 7.4], median liver stiffness measurement 5.8kPa [range 3.5, 7.3]). Of 18 who initiated treatment, 100% completed (adherence >90%, 17/18 [94%]). Among participants who have reached relevant timepoints, SVR4 ITT and PP were 100% (15/15; 95% CI 78%, 100%) and 100% (14/14; 95% CI 77%, 100%), respectively, and SVR12 ITT and PP were 80% (12/15; 95% CI 52%, 96%) and 92% (12/13; 95% CI 64%, 100%). Reasons for not achieving SVR12 included loss to follow up (n=1), reinfection (n=1), and virological failure (n=1; relapse confirmed on sequencing); immediate retreatment with sofosbuvir-velpatasvir-voxilaprevir for 12 weeks following relapse was successful (SVR12). No serious adverse events were reported.

Conclusion:
Sofosbuvir + glecaprevir-pibrentasvir for four weeks was highly effective among people with HCV infection and early liver disease, supporting further evaluation.

Trial Registration:
clinicaltrials.gov Identifier: NCT03855917

Disclosure of Interest Statement:

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