Screening Visit date	Study number	Patient initials	
☐☐/☐☐☐/☐☐☐☐ (dd/mon/yyyy)	1701-☐☐☐☐☐-☐☐	☐☐☐☐ E.g. Smith John SMJO	SMART-C

SMART-C
ELIGIBILITY CRITERIA CHECKLIST

Inclusion Criteria:	**Yes/No (please tick)**
1. Participants have voluntarily signed the informed consent form.	Yes ☐ No ☐
2. 18 years of age or older.	Yes ☐ No ☐
3. Chronic HCV infection as defined by anti-HCV antibody or HCV RNA detection for greater than 6 months.	Yes ☐ No ☐
4. Detectable HCV RNA at screening (>10,000 IU/ml)	Yes ☐ No ☐
5. HCV genotypes 1-6.	Yes ☐ No ☐
6. HCV treatment naïve (no prior treatment with an approved or investigation anti-HCV medication).	Yes ☐ No ☐
7. Stage F0-3, based on: hepatic elastography < 12.5 kPa on Fibroscan® or APRI <1.0.	Yes ☐ No ☐
8. If co-infection with HIV is documented, the subject must meet the following criteria: - ART naïve with CD4 T cell count >500 cells/mm^3; OR - On a stable ART regimen for >8 weeks prior to screening visit, with CD4 T cell count >200 cells/mm^3 and a plasma HIV RNA level below the limit of detection. Permissible ARTs include: • Raltegravir • Dolutegravir • Rilpivirine • Elvitegravir/cobicistat • Tenofovir disoproxil fumarate • Tenofovir alafenamide • Emtricitabine • Lamivudine • Abacavir	Yes ☐ No ☐
9. Negative pregnancy test at screening and baseline (females of childbearing potential only).	Yes ☐ No ☐
10. All fertile females must be using effective contraception during treatment and during the 30 days after treatment end.	Yes ☐ No ☐

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Exclusion Criteria:	**Yes/No (please tick)**
1. History of any of the following: a. Clinically significant illness (other than HCV) or any other major medical disorder that may interfere with the participant treatment, assessment or compliance with the protocol; participants currently under evaluation for a potentially clinically significant illness (other than HCV) are also excluded. b. Clinical hepatic decompensation (i.e. ascites, encephalopathy or variceal haemorrhage). c. Solid organ transplant. d. History of severe, life-threatening or other significant sensitivity to any excipients of the study drugs.	Yes ☐ No ☐
2. Any of the following lab parameters at screening: a. ALT > 10 x ULN b. AST > 10 x ULN c. Direct bilirubin > ULN d. Platelets < 90,000/μL (cells/mm3) if Fibroscan® <12.5 kPa OR < 150,000/μL (cells/mm3) if Fibroscan® is unavailable and patient is included with APRI <1 e. Creatinine clearance (CL_{cr}) < 50 mL/min f. Haemoglobin < 12g/dL for males; <11g/dL for females g. Albumin < LLN h. INR > 1.5 ULN unless subject has known haemophilia or is stable on an anticoagulant regimen affecting INR	Yes ☐ No ☐
3. Pregnant or breastfeeding female.	Yes ☐ No ☐
4. HBV infection (HBsAg positive)	Yes ☐ No ☐
5. Use of prohibited concomitant medications as described in section 5.3 of the study protocol.	Yes ☐ No ☐
6. Chronic use of systematically administered immunosuppressive agents (e.g. prednisone equivalent >10mg/day for >2 weeks).	Yes ☐ No ☐
7. Therapy with any anti-neoplastic or immunomodulatory treatment (including supraphysiologic doses of steroids and radiation) ≤6 months prior to the first dose of study drug.	Yes ☐ No ☐
8. Any investigational drug ≤6 weeks prior to the first dose of study drug.	Yes ☐ No ☐
9. Ongoing severe psychiatric disease as judged by the treating physician.	Yes ☐ No ☐
10. Positive result of a urine drug screen at the Screening Visit for opiates, barbiturates, amphetamines, cocaine, benzodiazepines, phencyclidine, propoxyphene, or alcohol, with the exception of a positive result (including methadone) associated with documented short-term use or chronic stable use of a prescribed medication in that class.	Yes ☐ No ☐
11. Injecting drug use within the previous six months.	Yes ☐ No ☐
12. Inability or unwillingness to provide informed consent or abide by the requirements of	Yes ☐ No ☐

the study.	

Investigator Name: _____

Investigator Signature: _____

Date: _____