1.00, 92% and 81%) which was better than LSPS (0.90, 0.81–0.99, 94% and 67%). ElastPQ SSM was superior to BavenoVI and Expanded BavenoVI criteria (Se 92%, for both; Sp 54% and 59%, respectively).

Conclusions ElastPQ SSM, particularly in combination with spleen diameter and platelet count, can be used as a reliable tool for the diagnosis of CSPH in patients with PSC.

OTU-13

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OTU-14 POSITIVE RESULTS FROM REGENERATE: A PHASE 3 INTERNATIONAL, RANDOMIZED, PLACEBO-CONTROLLED STUDY EVALUATING OBETICHOLIC ACID TREATMENT FOR NASH

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Introduction Obeticholic acid (OCA), an FXR agonist, improved both fibrosis and histologic features of nonalcoholic steatohepatitis (NASH) in the Ph2 FLINT study. This Month 18 pre-specified interim analysis of the ongoing Ph3 REGENERATE study evaluated the effect of OCA on liver histology in patients (pts) with biopsy-confirmed NASH.

Methods Pts with NASH and fibrosis stages F2–3 (ITT), and an exploratory group of F1 pts with metabolic syndrome, were randomized to placebo (PBO), OCA 10 mg, or OCA 25 mg QD. Primary endpoints were fibrosis improvement (≥1 stage) with no worsening of NASH, or NASH resolution with no worsening of liver fibrosis. The safety population included all randomized and dosed pts (F1–3, N=1968). Clinical outcomes will be evaluated at the end-of-study.

Results The ITT population included 931 pts (PBO [n=311], OCA 10 mg [n=312] or OCA 25 mg [n=308]), comprised of 44% F2 and 56% F3. Baseline characteristics were well-balanced across groups. Results in table 1. The primary fibrosis endpoint was met by 11.9% PBO, 17.6% OCA 10 mg (p=0.0446), and 23.1% OCA 25 mg (p=0.0002) pts (ITT). The primary NASH endpoint was not statistically significant (ITT); however, in a pre-specified analysis that included F1-F3 pts (N=1218), more OCA 25 mg pts achieved NASH. Pruritus was the most common AE (19% PBO, 28% OCA 10 mg, 51% OCA 25 mg) and was predominantly mild to moderate in severity (severe: <1% PBO, <1% OCA 10 mg, 5% OCA 25 mg). More OCA 25 mg pts discontinued due to pruritus (<1% PBO, <1% OCA 10 mg, 9% OCA 25 mg. SAEs occurred in 11% PBO, 11% OCA 10 mg and 14% OCA 25 mg pts. Increases in LDLc with OCA were observed by Wk 4, but approached baseline by M18 (OCA 25 mg: LS mean change Wk4 +22.6 mg/dL, M18 +4.0 mg/dL). Three deaths occurred; none were considered treatment-related (PBO n=2; OCA 25 mg n=1).

Abstract OTU-14 Table 1

	Placebo	OCA 10 mg	OCA 25 mg
Primary: ITT Population (F2 + F3)	**n=311**	**n=312**	**n=308**
Fibrosis improvement + no worsening of NASH	11.9%	17.6% p=0.0446	23.1% p=0.0002
NASH resolution + no worsening of fibrosis	8.0%	11.2% p=0.1814	11.7% p=0.1268
Additional: Full Efficacy Analysis (ITT + F1)	**n=407**	**n=407**	**n=404**
Fibrosis improvement + no worsening of NASH	10.6%	15.7% p=0.0286	21.0% p<0.0001
NASH resolution + no worsening of fibrosis	7.9%	11.3% p=0.0903	14.9% p=0.0013

Overall study discontinuations (ITT): 16% PBO, 17% OCA 10 mg, 15% OCA 25 mg.

Conclusion Treatment with OCA 25 mg improved liver fibrosis, key histologic features of steatohepatitis and liver biochemistry, demonstrating consistent efficacy with an overall AE profile similar to previous studies.

OTU-25 TREATING IN CHAOS: OUTCOMES OF HEPATITIS C TREATMENT IN NEWCASTLE'S HOMELESS DRUG USERS

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Introduction There is a high prevalence of Hepatitis C (HCV) among patients leading chaotic lives; this includes patients who are homeless, currently injecting drugs and dependently drinking alcohol. A HCV outreach treatment clinic was set up in the needle exchange in central Newcastle to bring treatment to those who have many barriers to attending treatment service in secondary care. This clinic was offered in conjunction with harm minimisation services.

Methods We retrospectively looked back at the referrals to the clinic and HCV treatment cure rates from September 2017 to November 2018. Data from the needle exchange's harm minimisation team was also collected to look at the number of HCV tests carried out during the first 3 months of the service running and the last 3 months of the study period to assess the impact treating chaotic patients is having on the prevalence of HCV in this community.

Results Between September 2017 and November 2018 54 patients were referred to the HCV outreach clinic following a HCV test. Of these patient 48 attended for treatment. 31 (65%) of the attenders were of no fixed abode (NFA). All the patients who attended for treatment stated intravenous drug use (IVDU) as their main risk factor for HCV and 73% of patients were still using IVDs at assessment for HCV treatment. A further 12 patients were also dependently drinking. 37 of the 48 patients assessed for treatment had commenced HCV treatment at the point of publication. 11 patients did not commence treatment due to 2 dying (both drug related deaths), 3 spontaneous clearance of HCV, 2 moved out of area, 2 being in custody and 2 did not reattend. Of the patients who commenced treatment 18 (49%) have achieved a