Abstract P023 Figure 1

diagnosis. The mean duration of UDCA monotherapy was 62 months with a median dose of 19 mg/kg/day (range 11–26). At the time of commencing bezafibrate, the median ALP was 296 U/L (mean 301 U/L), mean ALT was 52 U/L and mean albumin was 36 g/L. The median bilirubin was 8 μ mol/L (range 5–37) and no patients had evidence of clinically significant portal hypertension. 3 patients had radiological evidence of cirrhosis.

The bezafibrate was continued at 400 mg/day in 14 patients and 200 mg/day in 1 patient who developed myalgia. Figure 1 shows the median ALP at the start of bezafibrate therapy and an improvement in median ALP at 6 and 12 months of therapy. After 12 months, the median ALP was 141 U/L with a mean of 178 U/L. 80% of patients (12/15) achieved an ALP of < 217 U/L. Of the 3 who didn't; 1 died from metastatic breast cancer; 1 was referred for liver transplantation and 1 has commenced obeticholic acid. No patients developed renal impairment.

Conclusion Our case series demonstrates that bezafibrate is a highly effective second line therapy for PBC, in combination with UDCA, for patients who don't have an adequate biochemical response with monotherapy.

REFERENCE

1. Hirschfield GM, Dyson JK, Alexander GJM, *et al.* The british society of gastroenterology/UK-PBC primary biliary cholangitis treatment and management guidelines. *Gut* 2018;**67**:1568–1594.

P024

KEYNOTE-937 TRIAL IN PROGRESS: ADJUVANT PEMBROLIZUMAB FOR HEPATOCELLULAR CARCINOMA AND COMPLETE RADIOLOGIC RESPONSE AFTER SURGICAL RESECTION OR LOCAL ABLATION

¹Lipika Goyal*, ²Arndt Vogel, ¹Andrew X Zhu, ³Ann-Lii Cheng, ⁴Thomas Yau, ⁵Jian Zhou, ¹Raul N Uppot, ⁶Eunhee Kim, ⁶Usha Malhotra, ⁶Abby B Siegel, ⁷Masatoshi Kudo. ¹Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, USA; ²Hannover Medical School, Hannover, Germany; ³National Taiwan University Cancer Center and National Taiwan University Hospital, Taipei, Taiwan; ⁴University of Hong Kong, Queen Mary Hospital, Hong Kong, China; ⁵Zhongshan Hospital, Fudan University, Shanghai, China; ⁶Merck and Co., Inc., Kenilworth, USA; ⁷School of Medicine, Kindai University, Osaka, Japan

10.1136/gutjnl-2021-BASL33

Introduction Hepatocellular carcinoma (HCC) is a leading cause of cancer-related deaths worldwide. Surgical resection and local ablation are potentially curative options for patients with HCC; however, tumor recurrence is not uncommon. The

lack of a standard-of-care adjuvant therapy for HCC highlights an urgent therapeutic need to prevent disease recurrence and improve overall survival. Pembrolizumab, a PD-1 inhibitor, has shown evidence of a favorable benefit-to-risk profile in the adjuvant setting for many tumor types but has not been investigated in HCC. The KEYNOTE-937 study (NCT03867084) will evaluate the safety and efficacy of pembrolizumab versus placebo as adjuvant therapy in patients with HCC who had a complete radiologic response after surgical resection or local ablation.

Methods KEYNOTE-937 is a randomized, double-blind, phase 3 study. Adults with confirmed HCC, complete radiologic response after surgical resection or local ablation, Eastern Cooperative Oncology Group performance status of 0 or 1, and Child-Pugh liver class A are eligible. Patients with past or ongoing hepatitis C or controlled hepatitis B virus infection may be enrolled if they meet prespecified criteria. Patients will be randomly assigned 1:1 to receive pembrolizumab 200 mg intravenously or placebo intravenously every 3 weeks for up to 17 cycles or until disease recurrence, unacceptable toxicity, or withdrawal and will be stratified by geographic region, prior local therapy (resection vs ablation), recurrence risk, and alpha-fetoprotein level at diagnosis. Coprimary end points are recurrence-free survival and overall survival; secondary end points are safety and tolerability (graded per National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.0) and health-related quality of life; exploratory end points include distant metastasis-free survival, time to recurrence, and genomic, metabolic, and/or proteomic biomarkers. Tumor imaging will be assessed until recurrence, and adverse events will be recorded up to 30 days after the last dose (90 days for serious adverse events).

Results Recruitment began in May 2019. The planned sample size is 950 patients.

Discussion Results of the KEYNOTE-937 study will show the efficacy and safety of pembrolizumab as adjuvant therapy for patients with HCC who had a complete radiologic response after surgical resection or local ablation.

P025

OSHI (OPEN SOURCE HEALING INITIATIVE): AN EXAMPLE OF PATIENT-LED INNOVATION IN LIVER SERVICES

James Halls*, Dianne Backhouse, Neil Gordon, Lynsey Corless. Hull University Teaching Hospitals, UK

10.1136/gutjnl-2021-BASL34

Introduction Alcohol use disorders and alcohol related liver disease have a significant adverse impact on individuals, healthcare and society. Although abstinence is highly effective, engagement with traditional community alcohol support services (CASS) is poor, thereby reducing opportunities to improve outcomes. Reasons for this are complex, but inflexibility of access to existing services is important, and many patients do not feel comfortable discussing alcohol in clinical/group settings.

To address these potential barriers to engagement, we introduced a personalized intervention. OSHI, which stands for Open Source Healing Initiative as well as being the Japanese word for 'friend that supports', was developed and delivered by a patient who joined our team as a peer-support volunteer.