clearly patients and 66 patients who remained viraemic, apart from proportion of genotype 3 infections (43 vs 62%). At 30 months, hazard ratios for death and new HCCs were 0.44 (95% CI 0.23–0.84) and 0.43 (0.21–0.88) respectively, between HCV clear and viraemic patients. Among 42 patients with baseline HCC only 1 recurred after DAA.

**Conclusion:** This large real life cohort shows sustained benefit in survival and HCC development in patients with decompensated cirrhosis following viral clearance.

**LBP-010**

**High efficacy and safety of grazoprevir and elbasvir for 8 weeks in treatment-naive, non-severe fibrosis HCV GT1b-infected patients: Interim Results of the STREAGER Study**

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**Background and Aims:** Genotype 1b is the most common HCV genotype globally, accounting for the largest proportion of infections in Europe, Latin America, Russia, Turkey, and East Asia. Reducing treatment duration can improve adherence and reduce drug exposure. Accordingly, we evaluate the efficacy of 8 weeks of the treatment duration can improve adherence and reduce drug exposure. Accordingly, we evaluate the efficacy of 8 weeks of the protease inhibitor grazoprevir 100 mg/d (GZR) and NS5A inhibitor elbasvir 50 mg/d (EBR) among treatment-naive patients, with non-severe fibrosis. Recommend adding combined as a fixed dose combination single tablet.

**Method:** Pooled analysis included the 82 first treatment-naive (TN), with non-severe fibrosis (Fibroscan®<9.5 kPa and Fibrotest®<0.59), HCV GT1b mono-infected patients without advanced kidney disease enrolled in STREAGER trial, a study which aims to include 120 patients. The primary end point was the proportion of patients with HCV RNA below the lower limit of quantification (LLOQ) 12 weeks after treatment (SVR12).

**Table: Relapsers characteristics**

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Age</th>
<th>Sex</th>
<th>Viral load at screen (IU/ml)</th>
<th>Fibrosis (Fibroscan®)</th>
<th>RAS at relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td>1b</td>
<td>52</td>
<td>M</td>
<td>14,000,000</td>
<td>6.4 kPa</td>
<td>Y93H</td>
</tr>
<tr>
<td>1e</td>
<td>57.5</td>
<td>M</td>
<td>453.899</td>
<td>9.1 kPa</td>
<td>L28M</td>
</tr>
<tr>
<td>1b</td>
<td>60</td>
<td>F</td>
<td>16,437,573</td>
<td>5.1 kPa</td>
<td>L31M</td>
</tr>
</tbody>
</table>

**Results:** Mean age was 54 ± 13 years, 37% were male, viral load higher than 800,000 IU/ml: 51/82 (62%); ALT higher than the upper limit of normal: 35/82 (43%). Using Fibrotest® (FT), 48 had a F0-F1 fibrosis score (FT < 0.32); by Fibroscan® (FS) 73 had F0–1 fibrosis score (FS < 7.1 kPa). By end of treatment (EOT), 95% (78/82) of patients had HCV RNA < LLOQ. No adverse event grade III or IV was observed. Relapse occurred in 3 patients, including one patient with genotype 1b by Innolipa and one patient with genotype 1e by sequencing (wrongly included) (Table). After excluding the patient with genotype 1e, SVR12 was 79/81 (98%). In addition, it’s important to note that another patient relapsed 24 weeks after EOT (SVR24) despite reaching SVR 12. Additional efficacy data will be available at the EASL meeting.

**Conclusion:** High SVR12 (79/81, 98%) was achieved in a TN non-severe fibrosis GT1b-infected population in patients treated for 8 weeks by the combination grazoprevir and elbasvir.

**LBP-011**

**A pilot study of empagliflozin for the treatment of non-alcoholic steatohepatitis in patients with type 2 diabetes mellitus**


**Background and Aims:** Sodium-glucose cotransporter-2 inhibitors (SGLT2i) are a novel class of drugs that lower glucose by inducing renal glycosuria. SGLT2i confers multiple metabolic benefits and improves cardiovascular outcomes in patients with type 2 diabetes mellitus (T2DM). There is limited human data on SGLT2i for the treatment of non-alcoholic steatohepatitis (NASH).

**Method:** In this investigator-initiated, single-arm, open-label, pilot study, empagliflozin 25mg daily was added to usual therapy of T2DM for 24 weeks in nine consecutive biopsy-proven non-cirrhotic NASH patients who had no prior exposure to SGLT2i therapy. A repeat liver biopsy was performed at the end of treatment. Histopathological examination was reported according to Non-alcoholic Steatohepatitis Clinical Research Network scoring system. The histological outcomes were compared with the placebo group of a 48-week clinical trial previously conducted at the same centre. Hepatic steatosis at baseline and follow-up were also evaluated by measurement of volumetric liver fat fraction (VLFF) using HepaFat-Scan.

**Results:** Median age was 55 (47–60) years old and 44% were male. All patients were obese with median body mass index of 30 (28–35) kg/m². The distribution of fibrosis stage at baseline was F0, 11%; F1, 67%; F2, 22%. There was significant reduction in BMI (median change, Δ = −0.7 kg per m², p = 0.011), waist circumference (Δ = −3 cm, p = 0.033), systolic blood pressure (Δ = −9 mmHg, p = 0.024), diastolic blood pressure (Δ = −6 mmHg, p = 0.033), fasting blood glucose (Δ = −1.7 mmol/l, p = 0.008), total cholesterol (Δ = −0.5 mmol/l, p = 0.011), gamma glutamyl transpeptidase (Δ = −19U/l, p = 0.013), VLLF (Δ = −7.8%, p = 0.017) and histological steatosis grade (Δ = −1, p = 0.014). All histological components either remained unchanged or improved, except in one patient who had worsening hepatocyte ballooning. The histological outcomes of patients who received empagliflozin, and when compared with historical placebo, are shown in Figure 1. Empagliflozin resulted in significantly greater steatosis improvement (78% vs. 26%, p = 0.025) and fibrosis improvement (33% vs. 6%, p = 0.040) compared with historical placebo.

**Conclusion:** Brief therapy with empagliflozin may be useful for the treatment of NASH. These promising preliminary findings justify the need for a further study.
Larger randomized, double-blind, placebo-controlled trial of empagliflozin in NASH for a longer duration.

**LBP-012**

Interim safety, tolerability pharmacokinetics, and antiviral activity of ABI-H0731, a novel core protein allosteric modulator, in healthy volunteers and non-cirrhotic viremic subjects with chronic hepatitis B

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**Background and Aims:** Core Protein Allosteric Modifiers (CpAMs) target the HBV core protein, a pleotropic protein involved in multiple steps of the HBV life cycle. ABI-H0731 is a potent and selective CpAM being developed to improve functional cure rates for chronic HBV (CHB) infection. Here we report the interim results on safety, tolerability, pharmacokinetic (PK) and antiviral efficacy in two ongoing studies: ABI-H0731-102 in healthy volunteers and ABI-H0731-101(B) in non-cirrhotic, viremic CHB patients.

**Method:** Up to 12 healthy volunteers or viremic CHB patients per cohort were randomized (10:2) and treated with 100–400 mg ABI-H0731 or placebo once daily for up to 14 days (Study 102) or up to 28 days (Study 101(B)) in double-blinded, placebo-controlled fashion. Patients were stratified by HBeAg status (7 pos:5 neg). Safety, PK and pharmacodynamic responses were monitored.

**Results:** Forty-nine subjects have been dosed to date in studies 102 (n = 24) and 101(B) (n = 25). Median (range) age was 38 (24–61) and 40 (26–55) years, respectively. In both studies, the majority were male (≥90%), with 13% and 76% Asian in studies 102 and 101(B), respectively. Mean baseline HBV DNA levels were 8.0 ± 1.0 log10 in HBeAg pos and 3.8 ± 1.5 log10 IU/ml in HBeAg neg patients. No serious adverse events (AEs) and no dose limiting laboratory toxicities have occurred in either study. A single G3 treatment-emergent AE leading to drug discontinuation was seen at 400 mg, otherwise all TEAEs were mild (G1) and/or unrelated to study drug. Treatment emergent laboratory abnormalities were infrequent, mild and/or deemed unrelated to study drug. Exposures increased in a dose proportional manner and were similar between CHB patients and healthy subjects. Steady state was readily achieved (<5 days) with approximately 2-fold accumulation seen in both patients and volunteers. HBV declines of 1.3 ± 0.3 and 2.2 ± 1.0 log10 IU/ml were seen in HBeAg pos/neg subjects (respectively) at 100 mg/day, the lowest dose tested, with greater declines observed at higher doses. HBV RNA reductions were generally proportional to reductions of plasma HBV DNA.

**Conclusion:** Preliminary data indicate that ABI-H0731 is generally safe and well tolerated, has a dose-proportional PK profile in patients similar to that in healthy volunteers, and once daily dosing results in potent antiviral activity. ABI-H0731 is progressing to Phase 2a proof of concept studies in 2018.

**LBP-013**

Comparisons the durability of 6 months and 12 months prolonged treatment duration after cessation chemotherapy in chronic hepatitis B patients with prophylaxis antiviral therapy: A open level randomized clinical trial

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**Background and Aims:** Prophylaxis antiviral therapy is the current recommendation for chronic hepatitis B patient receiving chemotherapy. According the American Association for the Study of Liver Diseases guideline in 2009, the treatment duration is guided by baseline HBV-DNA. However, there is no report to compare the ideal consolidation antiviral therapy duration after cessation chemotherapy. The aim of our study was to compare the relapse rate of finite 6-month and 12-month consolidation antiviral therapy in patients with HBV-DNA < 2000 IU/ml or HBV-DNA ≥ 2000 IU/ml after cessation chemotherapy.

**Method:** The enrolled patients were randomized into 4 groups. Patients received Tenofovir 300 mg or Entecavir 0.5 mg once daily orally one week before chemotherapy. In patients with baseline HBV DNA < 2000 IU/ml, consolidation therapy for 6 months after cessation of chemotherapy was assigned as group A and consolidation therapy for 12 months was assigned as group B. In patients with baseline HBV DNA ≥ 2000 IU/ml, consolidation therapy for 6 months was assigned as group C and consolidation therapy for 12 months was assigned as group D. Virological relapse was defined as the elevation of serum HBV DNA level > 1 log10 (IU/ml) with 3-month interval after cessation TDF or ETV treatment. Clinical relapse was defined as serum HBV DNA ≥ 2000 IU/ml and ALT > 80 IU/l after cessation antiviral therapy.

**Results:** A total of 61 patients were enrolled from 2013 to 2016. Fifty-six (91.8%) patients were HBeAg negative and 28 patients (45.9%) were breast cancer. Overall 1-year virological and clinical relapse was 52.1% and 23.2% respectively. There was no difference of virological and clinical relapse rate between the group A, B, C and D. Virological relapsers had higher end-treatment HBsAg levels than non-relapers. Clinical relapsers had higher pretreatment ALT and HBV DNA than non-relapsers. In univariate analysis, end-treatment HBsAg level ≥ 500 IU/ml and pre-treatment HBV DNA ≥ 2000 IU/ml were predictors of virological relapse. Pre-treatment HBV DNA ≥ 2000 IU/ml and ALT ≥ 40 IU/ml were predictors of clinical relapse. In multi-variate analysis, end-treatment HBsAg level ≥ 500 IU/ml was the significant predictor in predicting virological relapse (adjust hazard ratio (HR): 2.77 p = 0.02). Pre-treatment ALT ≥ 40 IU/ml was the significant predictor in predicting clinical relapse (HR: 11.20; p = 0.003).

**Conclusion:** There is no difference in relapse rate between 6 months or 12 months prolonged antiviral therapy in patients with HBV DNA < or ≥ 2000 IU/ml after cessation chemotherapy. Patient with ALT ≥ 40 IU/ml and/or end-treatment HBsAg level ≥ 500 IU/ml should be closely monitored after cessation NA therapy in area with limited resource or should keep antiviral therapy to the end point of HBV treatment.

**LBP-014**

Long-term Obeticholic Acid (OCA) treatment associated with reversal or stabilization of fibrosis/cirrhosis in patients with Primary Biliary Cholangitis (PBC)

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