**Background:** Cenicriviroc (CVC) is an oral CCR2/5 antagonist under treatment evaluation for liver fibrosis in adults with non-alcoholic steatohepatitis (NASH). CVC had significant antifibrotic benefit over placebo (PBO) at the 1 year (Y1) primary endpoint; herein, we report year 2 (Y2) data of the Phase 2b CENTAUR study (NCT02217475).
**Method:** Adults with histologically-confirmed NASH, non–alcoholic fatty liver disease activity score (NAS) ≥ 4, and liver fibrosis (NASH Clinical Research Network stage 1–3) were randomized 2:1:1 to CVC 150 mg once daily or PBO. Arms A and C received CVC or PBO, respectively, for 2 years; Arm B received PBO in Y1 and crossed over to CVC in Y2. Fibrosis, NASH, and NAS status were assessed in liver biopsies at baseline (BL), Y1, and Y2 by a central pathologist. All analyses were prespecified.
**Results:** 289 adults were randomized: 52% diabetes, mean BMI 34 kg/m$^2$, and 67% fibrosis stage 2–3 (F2-3). 242 subjects continued after Y1 (121, 61, and 60 per Arm A, B, and C); 213 had paired BL and Y2 biopsies, with missing data for 42, 12, and 16 subjects per arm. For Y1 PBO nonresponders (i.e., those who did not achieve ≥1-stage fibrosis improvement and no worsening of NASH at Y1), fibrosis improvement without worsening of NASH was seen in subjects crossing over to CVC vs. remaining on PBO (24% [10/41] in Arm B vs. 17% [6/35] in Arm C; p = 0.36), while 16/41 (39%) on CVC and 10/35 (29%) on PBO achieved ≥1-stage fibrosis reduction. Over 2 years, a similar proportion on CVC or PBO achieved ≥1-stage fibrosis improvement and no worsening of NASH (15% [15/99] in Arm A vs. 17% [9/54] in Arm C); however, a greater proportion on CVC achieved ≥2-stage fibrosis improvement and no worsening of NASH (11% [7/65] in Arm A vs. 3% [1/34] in Arm C). For those with biopsies at BL, Y1, and Y2, a greater proportion on CVC achieving ≥1-stage fibrosis improvement at Y1 maintained benefit at Y2 (60% [18/30] in Arm A vs. 30% [3/10] in Arm C); in CVC subjects with BL F3 that improved, upto 86% (12/14) maintained benefit at Y2. Greater reductions in hs-CRP and fibrinogen, but no effect on NASH or liver enzymes were observed with CVC. Adverse events were comparable for CVC and PBO and no deaths occurred.
**Conclusion:** CVC was well tolerated and provided antifibrotic activity in adults with NASH and liver fibrosis, confirming the Year 1 primary endpoint. A majority of subjects achieving ≥1-stage fibrosis improvement at Year 1 maintained benefit at Year 2 with CVC, with greater effect in those with advanced fibrosis.

### GS-003
### Sorafenib with versus without concurrent conventional transarterial chemoembolization (*c*TACE) in patients with advanced hepatocellular carcinoma (HCC): Results from a multicenter, open-label, randomized, controlled phase III STAH trial

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**Background and Aims:** Sorafenib is the standard first-line therapy for patients (pts) with advanced HCC (aHCC). *c*TACE is an effective treatment for unresectable HCC. A previous phase II study revealed that sorafenib combined with concurrent *c*TACE (SOR+T) tended to improve outcomes. Herein, we present the results from an investigator-initiated phase III trial that evaluated the effects of SOR+T in pts with aHCC.
**Method:** Pts were randomly assigned (1:1) into one of two arms, to receive sorafenib with *c*TACE (Arm C) or without *c*TACE (Arm S) according to modified International Union Against Cancer tumor stage, extent of vascular invasion, Child-Pugh score and serum alpha fetoprotein level. All eligible pts received 800 mg sorafenib within 3 days (Arm S and C) and *c*TACE within 7-21 days after randomization, and repeating *c*TACE on demand (Arm C). The study continued until progression or unacceptable toxicities were observed. The primary endpoint was overall survival (OS), and secondary endpoints included time to progression (TTP), progression-free survival (PFS), tumor response rate (TRR), and safety profile.
**Results:** Between January 2013 and December 2015, 339 pts were enrolled from 13 hospitals in South Korea, and the last pt completed the trial on June 2017. Pts baseline characteristics were well balanced. For Arm C and S, respectively, median OS was 12.8 vs. 10.8 months (m) (hazard ratio [HR], 0.91; 95% confidence interval [CI] 0.69–1.21; p = 0.290); median TTP was 5.3 vs. 3.5 m (HR, 0.67; 95% CI, 0.53–0.85; p = 0.003); median PFS was 5.2 vs. 3.6 m (HR, 0.73; 95% CI, 0.59–0.91; p = 0.01); TRR was 60.6% vs. 47.3% (p = 0.005).
For Arm C and S, respectively, serious adverse events (AE) were 33.3% vs. 19.8% (p = 0.006), and grade ≥ 3 AE were increased alanine aminotransferase (20.3% vs. 3.6%), hyperbilirubinemia (11.8% vs. 3.0%), ascites (11.8% vs. 4.2%), thrombocytopenia (7.2% vs. 1.2%), anorexia (7.2% vs. 1.2%), hyponatremia (5.2% vs. 0%) (p < 0.05); hand-foot skin reaction (10.5% vs. 11.4%), encephalopathy (5.2% vs. 1.2%) and diarrhea (5.2% vs. 4.2%).
Subgroup analysis showed a survival benefit in pts (46.4%) of Arm C who received ≥2 *c*TACE sessions when compared to pts in Arm S (18.6 vs. 10.8 m; HR, 0.58; 95% CI, 0.40-0.82; p = 0.006).
**Conclusion:** SOR+T therapy did not improve OS versus sorafenib alone in pts with aHCC. However, SOR+T therapy significantly improved TTP, PFS, and TRR, and a survival benefit was observed in the pts who received SOR+T ≥2 *c*TACE sessions.

### GS-004
### Integrative molecular classification of extrahepatic cholangiocarcinoma

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**Background and Aims:** Cholangiocarcinoma (CCA) is a malignancy of the biliary tree that can be divided into intrahepatic (iCCA) or extrahepatic (eCCA), with differences in pathogenesis and clinical management. There are no effective systemic molecular therapies for eCCA and no comprehensive molecular profiling of this cancer has been performed in western patients. Thus, understanding the main molecular classes and drivers of this tumor will lead to a more precise therapeutic approach.
**Method:** A total of 189 FFPE primary eCCA treated by resection were retrospectively collected at seven international centers from 1995 to 2015. Median survival of the cohort was of 48.5mo. Whole gene-expression profiling (Affymetrix) was performed and data was