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General session II and award ceremony I

GS-007

First real-world data on safety and effectiveness of glecaprevir/pibrentasvir for the treatment of patients with chronic hepatitis C virus infection: Data from the German Hepatitis C-Registry

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GS-008

Sustained efficacy of adjuvant immunotherapy with cytokine-induced killer cells for hepatocellular carcinoma: an extended 5-year follow-up

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Background and Aims: A previous randomized controlled trial demonstrated that adjuvant immunotherapy with cytokine-induced killer (CIK) cells prolonged both recurrence-free and overall survivals of patients with hepatocellular carcinoma (HCC) receiving curative treatment. We aimed to investigated whether the efficacy of CIK cell immunotherapy might be sustained after cessation of repeated transfer of CIK cells.
Method: We performed a follow-up study of our multicenter, randomized trial reported in 2015. We included 226 patients: 114 patients in the immunotherapy group (injection of 6.4×10^9 CIK cells, 16 times during 60 weeks) and 112 patients in the control group (no treatment) after potentially curative treatments for HCC. Among them, 162 patients (89 of the immunotherapy group and 73 of controls) underwent extended follow-up until 60 months after randomization of the last patient. The primary endpoint was recurrence-free survival (RFS); secondary endpoints included overall survival.
Results: The median follow-up duration was 68.5 (interquartile range, 45.0–82.2) months. During follow-up, the immunotherapy group maintained a significantly lower risk of recurrence or death (hazard ratio [HR] with immunotherapy was 0.67; 95% confidence interval [CI], 0.48–0.94; p = 0.009 by one-sided log-rank test). The 5-year RFS rate was 44.8% in the immunotherapy group and 33.1% in the control group. HRs were also lower in the immunotherapy

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than control group for all-cause death (0.33; 95% CI, 0.15–0.76; p = 0.006).
Conclusion: In patients who underwent curative treatment for HCC, significant gain in recurrence-free and overall survival by adjuvant CIK cell immunotherapy was maintained for over 5 years. ClinicalTrials.gov number: NCT01890291.

GS-009

MGL-3196, a selective thyroid hormone receptor-beta agonist significantly decreases hepatic fat in NASH patients at 12 weeks, the primary endpoint in a 36 week serial liver biopsy study

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Background and Aims: MGL-3196 is a liver-directed, orally active, highly selective THR-β agonist currently in Phase 2 for treatment of non-alcoholic steatohepatitis (NASH). In Phase 1 studies, 3196 demonstrated rapid reductions in lipids, LDL cholesterol (30%), triglycerides (40–60%), and lipoprotein(a) (Lp(a))(40%). This ongoing Phase 2 study evaluated the primary endpoint, relative reduction in (magnetic resonance imaging – proton density fat fraction) MRI-PDFF, biomarkers and safety in 116 NASH patients at 12 weeks.
Method: MGL-3196-05 (NCT02912260) is a 36 week multicenter, randomized, double-blind, placebo-controlled study in adults with biopsy-confirmed NASH (NAS ≥ 4, F1-F3) and hepatic fat fraction ≥10%, assessed by (MRI-PDFF). Randomized 2:1, MGL-3196 to placebo, patients receive MGL-3196 80mg, or placebo oral, once daily, for 36 weeks. Blinded increase or decrease in dose based on exposure was possible. The primary endpoint, relative reduction in MRI-PDFF, was assessed at 12 weeks, patients continued on treatment blinded, and, at 36 weeks, secondary endpoints were assessed by second liver biopsy and third MRI-PDFF, with ongoing safety and biomarker assessments at 12 and 36 weeks.
Results: Baseline characteristics (mean or %): age, 50.3 years; women, 50.4%; type 2 diabetes, 38.4%; BMI, 35 kg/m^2; Hispanic, 47.2%; mean hepatic fat fraction (FF), 20.2%; NAS 4.9 (44% F2-3). Baseline characteristics were similar among groups. The primary endpoint was met (p < 0.0001, LS mean), with 78 MGL-3196 treated patients demonstrating −36.3% relative and −7.6% absolute change from baseline (CFB) MRI-PDFF: −9.6%, −1.6%, respectively, in 38 placebo patients (median). Forty-seven/78 (60.3%) MGL-3196 treated (6/47 ≥ 5% weight loss) compared with 7/38 (18.4%) placebo treated (5/7 with ≥5% weight loss) demonstrated ≥30% reduction in MRI-PDFF (p < 0.0001). In MGL-3196 treated patients, lipids decreased, LDL-C −12.9, triglycerides −30.1 and Lp(a)−37.5 (% CFB relative to placebo) p < 0.0001; ALT, AST decreased 16.1%,16.2% relative to mean baseline (51.0, 35.7U/l) p < 0.01. Study drug was well-tolerated, AEs were generally mild (85%) or moderate (15%); 3 SAEs occurred and were considered unrelated (study remains blinded). Additional dose/exposure, biomarkers (safety, lipid, inflammatory, fibrosis, multiparametric MRI (subset)) still under analyses will be presented.
Conclusion: MGL-3196 QD for 12 weeks, compared with placebo, significantly decreased hepatic fat in patients with NASH relative to placebo. These combined results suggest that MGL-3196 has beneficial effects in NASH. Histopathologic assessment at 36 weeks will allow for comparison to baseline histology as well as multiple biomarkers (serologic and imaging).

GS-011

Results of a randomised controlled trial of budesonide add-on therapy in patients with primary biliary cholangitis and an incomplete response to ursodeoxycholic acid

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