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## Prevalence of Nonalcoholic Fatty Liver Disease in Patients with Severe Hypertriglyceridemia (SHTG) – Initial Baseline data from an Ongoing Phase 2 Study

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### Abstract

#### Background/Synopsis:

Fibroblast growth factor 21 (FGF21) is an endogenous metabolic hormone that regulates energy expenditure, lipid, and carbohydrate metabolism. BIO89-100, a glycoPEGylated FGF21 analog, is currently being evaluated in ENTRIGUE, a “Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Explore the Efficacy and Safety in Subjects with Severe Hypertriglyceridemia.”

Objective/Purpose: To elucidate the baseline prevalence of hepatic steatosis in SHTG patients participating in ENTRIGUE.

Methods: Descriptive statistics summarize baseline characteristics of screened/enrolled SHTG participants opting to obtain MRI-PDFF.

Results: Demographic characteristics were as follows: age range 40-70 years, male 57.1%, white 100%, Hispanic/Latino 28.6%, BMI range 25.4 - 40.1, T2D 28.5%, and on background lipid therapy 35.7%. Metabolic baseline measurements included TG – median 665 mg/dL (range 499 – 1054), glucose – median 126 mg/dL (range 89 – 214), HbA1c – median 6.6% (range 5.2 – 9.4), HOMA-IR – median 10.3 mg/dL x mIU/L (range 3.1 – 26.4) and Adipo-IR – median 17.7 mmol/L x  $\mu$ IU/mL (range 6.9 – 33.7). Baseline MRI-PDFF demonstrated clinically meaningful liver fat content (MRI-PDFF  $\geq$  6%) in 100% of these first 14 participants (mean 20.1, range 6.2% -29.0%). The percentage of steatosis did not appear to correlate with TG values, BMI, or T2D status. Presented results will be updated for any new participants with baseline MRI-PDFF data.

Conclusion: Prevalence and severity of hepatic steatosis was greater than expected in this study population, especially given that not all patients had obesity, and the majority did not have T2D. These preliminary baseline findings from ENTRIGUE suggest that routine assessment of hepatic steatosis may be warranted in SHTG patients.

**Keywords:** Fibroblast growth factor 21; Severe hypertriglyceridemia; hepatic steatosis; non-alcoholic fatty liver disease

**Abbreviations:** FGF21; SHTG; NAFLD; MRI-PDFF

### Funding and Conflicts of Interest

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