This analysis was performed to answer the following questions:

- **Primary outcome**: Liver Biopsy Resolution of NASH without worsening of fibrosis (% in Elafibranor treated groups vs % in placebo).
- Is Elafibranor-induced resolution of NASH similar to spontaneous resolution in placebo group with respect to fibrosis regression?
- Is resolution of NASH by Elafibranor associated with extra-hepatic changes associated with the resolution of NASH in the Elafibranor-120mg group (G120).

**Hepatic and extra-hepatic profile of resolution of steatohepatitis induced by GFT-505 (Elafibranor)**

**Background**
- Fibrinogen: V4
- FFA: Fibrinogen
- INTRODUCTION: V9
- V6
- V5
- V4
- Responder: V3

**Methods**

- Subjects of GOLDEN505 with NASH and NAFLD activity score (NAS) ≥ 4 at baseline (85% of the total population)
- A total of 202 subjects (EES) including 72 patients in the G80 arm met the criteria for comparison of Responders to Placebo.
- G120 - Responders showed reduction from baseline for all liver markers reaching statistical significance for NAS, 5.00 (1.30) vs 5.40 (0.97) in Non-Responders.
- In both groups, there was a highly significant increase in FGF21 from baseline.
- The difference between groups reaching significance for Fibrinogen.
- Both Responders and Non-Responders were dyslipidemic and insulin-resistant at baseline.
- There was no significant difference in body mass index (BMI) between responders and non-responders.
- Compared to PBO-Responders, G120-Responders showed no change in plasma lipids and in triglycerides.

**Results**

- In the Elafibranor treated group, resolution of histological NASH is associated with decreases in liver related activity (NAS≥4).
- Elafibranor-120mg significantly increases the proportion of patients experiencing reversal of the disease in the naïve population of NASH.

**Conclusions**

- Using a newly defined classification of resolution of histological NASH, the GOLDEN505 trial showed that Elafibranor 120mg significantly increased the proportion of patients experiencing reversal of the disease in the naïve population of NASH.
- This post hoc analysis clearly supported in the Elafibranor 120 mg group. Resolution of NASH is maintained in the Elafibranor treatment group. This significant post hoc analysis demonstrates that Elafibranor is effective in the long term survival of patients.
- The improvement of fibrosis stage is higher in Elafibranor than Non-Responders, although the difference reached significance only for fibrinogen.
- Compared to PBO Non-Responders, G120-Responders showed no significant change in plasma lipids and triglycerides.
- The difference between groups reaching significance for fibrinogen.

**References**

- Neuschwander-Tetri BA (2010).