A Phase-II, Randomized, Double Blind, Placebo-controlled Trial of Aramchol for the Treatment of Non Alcoholic Fatty Liver Disease (NAFLD & NASH)

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**BACKGROUND**

- Aramchol is a novel synthetic lipid molecule, a conjugate of cholic acid and saturated fatty acid linked by an amide bond, designed to reduce liver fat
- Aramchol exerts its activity by partial inhibition of Starostin-CoA desaturase 1 (SCD1), a key regulator of lipid metabolism, and by up-regulation of the ABCA1 transporter, the universal cholesterol export pump, as shown in several animal studies
- Aramchol is indicated for long term treatment of NAFLD and NASH by reducing fat infiltration of the liver

**AIM**

To evaluate the safety, tolerability and short term effect of 3 months treatment of Aramchol in adult NAFLD and NASH patients.

**METHODS**

- A phase-II, randomized, double blind, placebo-controlled trial including 60 biopsy-confirmed NAFLD & NASH patients receiving a daily orally administered dose of 300 mg, 100 mg of Aramchol or placebo for 3 months (n=20 in each group)
- Primary endpoint: Change in liver fat concentration evaluated by Nuclear Magnetic Resonance Spectroscopy (NMRS)
- Secondary endpoints: Changes in fasting serum liver enzymes, adiponectin and endothelial function

**RESULTS**

**Primary and SecondaryEndpoints**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo</th>
<th>Aramchol 100 mg/d</th>
<th>Aramchol 300 mg/d</th>
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<tr>
<td>ALT (U/L)</td>
<td>-5.2%</td>
<td>-12.6%</td>
<td>-19.8%</td>
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**CONCLUSIONS**

- Aramchol appears as a safe and well-tolerated treatment in NAFLD and NASH patients
- Short term treatment reduced liver fat content in a dose-dependent manner
- Aramchol 300mg dose treatment induced positive trends on several metabolic parameters
- Aramchol long term effect should be evaluated in future clinical trials