Essential Phospholipids

Clinical data reconfirming benefit in steatosis reduction and QoL improvement in patients with MASLD

Opella.

MASLD: GLOBAL DISEASE BURDEN

Global prevalence[1]

30%

MASLD is the most common liver disorder worldwide[2]
This is associated with disease progression, the presence of symptoms, as well as limitations in daily living[3]

Prevalence of MASLD in patients with comorbidities[4]

50% severe obese

60% patients with T2D

10% overall world's adult population[4]

Only

5%

of patients with suspected MASLD are aware of their risk[2]

MASLD: IMPACT ON QoL

MASLD negatively impacts HRQoL and **PROs** with symptoms such as **fatigue and abdominal pain** having high importance to patients[2,5]

Why Excel Study Is Unique?

First hepatoprotector study (RCT) to combine advanced liver testing using CAP with real-life QoL questionnaire to assess liver steatosis and QoL in patients with MASLD

New Clinical Evidence: EXCEL Study Results

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EXCEL Study Details

193
randomized patients with MASLD

Treatment arms were EPL + SoC or Placebo + SoC

165
patients in the mITT population analyzed

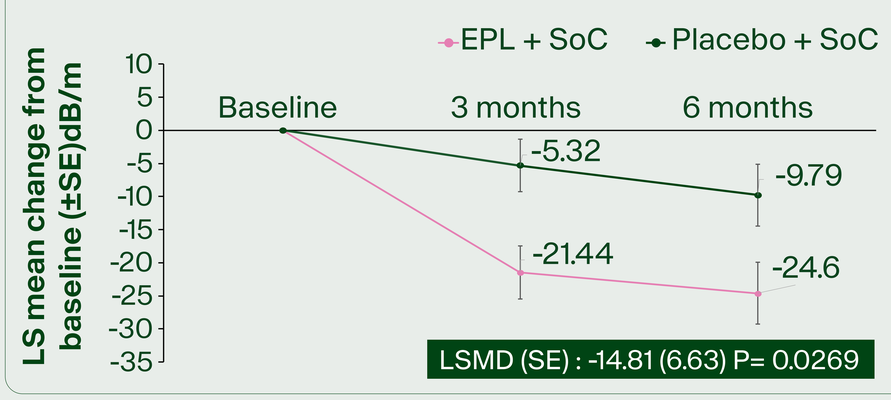
Main analysis at 6 months timepoint

Key Outcomes

Primary outcome Steatosis by Fibroscan CAP score reduction[6]

EPL **significantly reduced steatosis** vs placebo at month 6

Change in CAP score from baseline



Secondary outcome QoL by CLDQ score[6]

EPL led to numerical trend **improvement of overall QoL** and significantly **improved CLDQ fatigue** sub-score vs placebo in patients with MASLD

Exploratory outcome HbA1c improvement[7]

EPL **demonstrated glycemic control** by significantly reducing HbA1c levels

Generalizability of the findings

Study included MASLD patients with cardiometabolic comorbidities, thereby, making the results applicable to a diverse patient population

Fibroscan CAP score improvement followed by trends in PROs improvement

EPL as an adjuvant treatment to SoC improved Fibroscan CAP which was accompanied with observed improvement in fatigue CLDQ sub-score QoL in patients with MASLD, in association to their SoC

Early and prolonged efficacy

The reduction in CAP score was observed as early as at 3 months and sustained at 6 months till 9 months (3 months post treatment)

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*Several global cohorts have reported that almost all patients (98-99%) previously diagnosed with NAFLD or MAFLD fulfil the criteria for MASLD, which suggests that these terms can be used interchangeably.[8]

CAP, controlled attenuated parameter; CLD, chronic liver disease; CLDQ, chronic liver disease questionnaire; EPL, essential phospholipid; HCP, healthcare professional; HRQoL, Health Related Quality of Life; LSMD, least square mean difference; MAFLD, metabolic dysfunction-associated fatty liver disease; MASLD, metabolic dysfunction-associated steatotic liver disease; mITT, modified intention-to-treat; NAFLD, non-alcoholic fatty liver disease; PRO, patient reported outcomes; QoL, quality of life; SE, standard error; SoC, standard-of-care.

1. Golabi P, et al. Clin Liver Dis. 2023;27(2):173-186; 2. Gofton C, et al. Clin Mol Hepatol. 2023;29(Suppl):S17-S31; 3. Grønkjær LL, et al. JHEP Rep. 2021;3(6):100370; 4. Miao L, et al. Trends Endocrinol Metab. 2024;35(8):697-707; 5. Younossi ZM, et al. Liver Int. 2017;37(8):1209-1218; 6. Stefan N, et al. Poster presented at: AASLD; November 15 – 19, 2024; San Diego, CA, USA. (Poster ID: 5037); 7. Stefan N, et al. Poster presented at: EASL SLD Summit; January 23 – 25, 2025; Estoril, Portugal. (Poster ID: PO7-01); 8. Arora U, et al. J Hepatol. 2024;80(2):e89-e91.

Take control of liver health. Act early, take action, and make a difference.