PTC-Lycosome Treatment for Nonalcoholic Fatty Liver Disease, Nonalcoholic Liver and Pancreas Steatosis

Global prevalence of Nonalcoholic Fatty Liver Disease and of Nonalcoholic Steatosis of the Liver and Pancreas, NAFLD/NASH, are estimated to be 24% and affect both adults and children.

Steatosis of the liver and the pancreas often develop simultaneously and are the main pathologies behind Metabolic Syndrome, Diabetes and Obesity. NAFLD/NASH are leading causes of liver deterioration and the development of cirrhosis, the end-stage condition, which requires liver transplantation. Despite this there is only one drug on the market - Essentiale (Sanofi), the active molecule of which is phosphatidylcholine, PTC.

Essential indications are for NAFLD and NASH but not pancreatic steatosis. The main limitation of the drug is patient compliance, since its daily therapeutic dose is 1,800 mg of PTC in 6 capsules.

PTC-Lycosome, a new product developed by Lycotec, targets not only NAFLD/NASH, but also steatosis in the pancreas. Additionally, it can be used to mitigate the toxic impact on the liver of alcohol intoxication.

Lycosome

PTC Lycosome, PTCL, is a combinatory product, where molecules of phosphatidylcholine are embedded into clusters of *trans*-lycopene. This embedment, Lycosome, provides protection of the former from the stomach environment by the acid resistant molecules of the latter. As a result of this, low doses of PTC can be used to achieve a comparable, or even superior, therapeutic effect to its unprotected form.

In addition, *trans*-lycopene serves in this formulation not only as a facilitating delivery entity, but also as a bioactive anti-hypoxia molecule, which is important for improvement of microcirculation particular in tissues affected by steatosis. Therefore, a combination of high potency PTC and lycopene molecules could provide a synergetic therapeutic effect in patients with NAFLD /NASH and some metabolic / toxic impairments in the liver and potentially other organs.

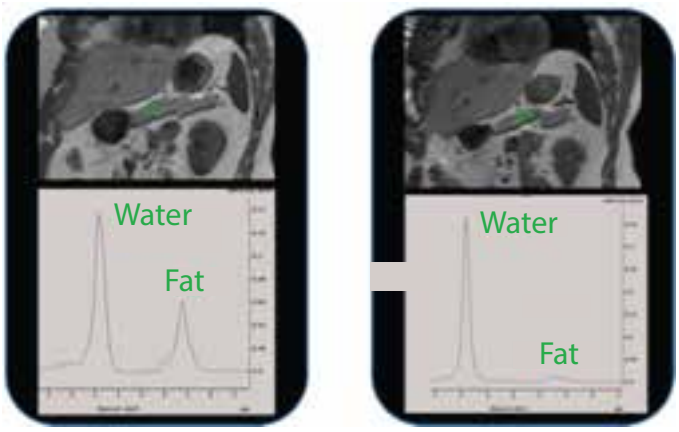
NAFLD - Clinical Trial Proof-of-concept Phase IIa

In a clinical randomised, double-blind, controlled study on 29 patients with NAFLD it was demonstrated that administration for 2 months of PTCL (daily dose 450 mg PTC and 7 mg *trans*-lycopene) resulted in a significantly stronger reduction of the liver span (ultrasonography), the Midclavicular line by 9 mm and the Midsternal line by 4 mm. In the group which took 450 mg of the control PTC product for 2 months, the reduction along the same lines was by 5 mm and 2 mm, accordingly. In addition in the former group there was a significant reduction of ALT by 6 U/L, while in the control it was only by 3 U/L.

Ivan M. Petyaev, Pavel Y. Dovgalevsky, Natalia E. Chalyk, Victor A. Klochkov, Nigel H. Kyle, and Yuriy K. Bashmakov - Reduction of Liver Span and Parameters of Inflammation in Nonalcoholic Fatty Liver Disease Patients Treated with Lycosome Formulation of Phosphatidylcholine. International Journal of Chronic Diseases (2018), Article ID 4549614.

Pancreatic Steatosis - Clinical Trial Proof-of-concept Phase IIa

In a randomised, examiner-blinded clinical study on 7 patients with Pancreatic Steatosis it was demonstrated that 4 months of administration of PTCL (daily dose 450 mg PTC and 7 mg *trans*-lycopene), resulted in a dramatic reduction of pancreatic steatosis (MRI), from a 21.7% fat/water ratio to 5.9%, fig. 1. There were no detectable changes in the control PTC group.



baseline PTCL after 4 months

Alcohol Liver Impact - Clinical Trial Proof-of-concept – Phase IIa

A crossover double blind, placebo controlled clinical trial on 10 healthy volunteers was carried out in order to compare the possible liver protective effect of PTCL and the control PTC after a single intake of a moderate amount of ethanol.

It was observed that administration of PTCL (450 mg PTC and 7 mg *trans*-lycopene) 1 hour before intake of ethanol resulted in better clearance in the serum of the toxic metabolite, acetaldehyde, than in the control PTC and placebo experiment. In addition, the PTCL was more active than the control PTC in preventing a decline of the serum antioxidant activity, increase in ox-LDL caused by ethanol ingestion.

Ivan M. Petyaev, Marina P. Chernyshova, Dmitry V. Pristensky, Natalia E. Chalyk, Victor A. Klochkov, Nigel H. Kyle, and Yuriy K. Bashmakov - Effect of Lycosome-Formulated Phosphatidylcholine on Parameters of Biological Oxidation after Single Intake of Moderate Amount of Alcohol. Advances in Preventive Medicine (2018), Article ID 5840451.

Next Step

The main objective of Lycotec is to find funding and/or partner to take PTC Lycosome to a Phase II clinical trial programme to assess further its impact on NAFLD/NASH, steatosis of the pancreas and the mitigating therapeutic effect of different toxic impacts on these essential metabolic organs.

Regulatory

All molecules comprising PTC Lycosome are safe for humans and do not require FDA or other countries' regulatory body approval for oral administration in their therapeutic dose-range.

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