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ASIA EDITION

Gannex, Galmed enter into research agreement for NASH treatment

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ASC41 is an oral thyroid hormone receptor beta agonist which received IND approval from China's NMPA

China-based Gannex Pharma Co. Ltd., a wholly-owned company of Ascletis Pharma Inc. and Galmed Pharmaceuticals Ltd. in Israel have recently announced that they have entered into a research agreement aiming at combination therapy of ASC41 (THR-beta agonist) and Aramchol (SCD 1 inhibitor) for the treatment of non-alcoholic steatohepatitis (NASH).

ASC41 is an oral thyroid hormone receptor beta (THR-beta) agonist which recently received IND approval from China's National Medical Products Administration (NMPA) to conduct clinical trials for NASH indication. Topline data of Phase I safety, PK and preliminary efficacy (LDL-C) in healthy volunteers with LDL-C > 110 mg/dL is expected to be available by the end of 2020.

ASC41's active moiety selectively activates THR-beta resulting in the improvement of steatosis/lipotoxicity, inflammation, ballooning, fibrosis in both direct and indirect manner. In two NASH animal models, ASC41 demonstrated the same improvement in liver steatosis, inflammation and fibrosis at 1/10 dose of Resmetirom (MGL-3196), another THR-beta agonist currently in Phase III clinical trial.

In hepatocytes, the reduction of SCD 1 results in elevation of AMPK, FA oxidation and Glutathione ratio. In HSC's inhibition of SCD 1 results in specific up regulation of PPAR Y which blocks collagen production. In Phase II clinical trials for NASH, Aramchol significantly reduced liver fat, improved liver histology i.e., ballooning and fibrosis, hepatic biochemistry and glycemic parameters with favorable safety and tolerability profile.

Aramchol is currently in Phase III registrational study for NASH and fibrosis (ARMOR) and has been granted Fast Track designation status by the FDA for the treatment of NASH.