Galmed Pharmaceuticals

Galmed and Gannex Expand Development Programs For NASH Through Research Collaboration of Aramchol and ASC41 (THR-beta Agonist)

TEL-AVIV, Israel and SHANGHAI, Sept. 10, 2020 /PRNewswire/ -- Gannex Pharma Co., Ltd., a wholly owned company of Ascletis Pharma Inc. (HKEX: 1672) and Galmed Pharmaceuticals Ltd. (NASDAQ: GLMD) announces today 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). The financial details of this transaction are not disclosed.

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.

Aramchol is a novel synthetic small molecule, a conjugate of cholic acid and arachidic acid, linked by a stable amide group. Aramchol exerts its anti-steatotic and anti-fibrotic effects via inhibition of SCD 1 expression in hepatocytes and hepatic stellate cells (HSCs). In hepatocytes, 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 a favorable safety and tolerability profile. Aramchol is currently in a 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.

"There is a significant medical need and a large potential pharmaceutical market for NASH treatment. There are currently no drugs licensed for the treatment of NASH in US, Europe and China. ASC41 is a THR-beta agonist that improves steatosis, inflammation and fibrosis, and Aramchol, a SCD 1 inhibitor, reduces glycemic index and fibrosis. Therefore, combination therapy of the two drug candidates could result in synergistic effect for the treatment of NASH," said Dr. Jinzi J. Wu, Founder, Chairman and CEO of Ascletis.

"It is clear today that NASH is a chronic condition with multiple liver pathologies. Among all pathologies, excessive liver fat, high glycemic index and fibrosis are major treatment challenges. By combining ASC41, THR-beta agonist, which is clinically proven to rapidly reduce liver fat and improved blood lipids profile, with Aramchol, SCD 1 inhibitor, which is clinically proven to reduce glycemic index and fibrosis, physicians will have good and solid toolbox and will be able to normalize NASH patients for life and control the disease," said Allen Baharaff, President and CEO of Galmed. "We believe that combining these two distinct and selective compounds with complementary mechanisms will provide a perfect treatment for NASH."

About NASH

NASH is the progressive form of non-alcoholic fatty liver disease (NAFLD), which is characterized by the accumulation of fat in the liver, inflammation and fibrosis (scarring), and can eventually lead to cirrhosis and liver failure. NASH is a major cause of liver disease worldwide and the leading cause of liver transplants for people under 50 in the US. There are currently no approved treatments for NASH.

About Ascletis

Ascletis is an innovative R&D driven biotech and listed on Hong Kong Stock Exchange (Ascletis, 1672.HK). Ascletis is committed to developing and commercializing innovative drugs of viral hepatitis, NASH and HIV/AIDS, for unmet medical needs in China and globally. Led by a management team with deep expertise and a proven track record, Ascletis has developed into a fully integrated platform covering the entire value chain from discovery and development to manufacturing and commercialization. Ascletis has three marketed products and eleven R&D pipeline drug candidates (seven of them developed in house). 1. Viral hepatitis: (i) marketed all oral HCV regimen of Asclevir® and Ganovo® combination (RDV/DNV regimen) and ASC18 fixed dose combination (FDC), with bridging study finished, is an upgraded version of RDV/DNV regimen. ASC18FDC will further enhance the competitiveness of Ascletis ' hepatitis C products. (ii) marketed Pegasys® for HBV clinical cure; (iii) breakthrough therapies for HBV clinical cure. 2. NASH: global development of novel drug candidates against three different targets – FASN, THR-beta and FXR, which are expected to be used alone or in combination. NASH is a global disease, Ascletis conducts global clinical research in Europe, America and China. 3. HIV/AIDS: ASC09F is a FDC treatment of HIV targeting protease. The clinical trial application of ASC09F has been approved. For more information, please visit www.ascletis.com.

About Galmed Pharmaceuticals

About Galmed Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases. Its lead compound, Aramchol™, a backbone drug candidate for the treatment of NASH and fibrosis is currently in a Phase III registrational study.

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