Galmed Pharmaceuticals

Phase II Aramchol Clinical Trial Results

Galmed Phase II Aramchol Clinical Trial Successfully Demonstrates Safety and Positive Short-Term Effects for Treating Fatty Liver Disease

Encouraging results confirm that Aramchol is a suitable candidate for treating Non-Alcoholic Fatty liver Disease (NAFLD), a major public health problem in western countries that affects at least 100 million people in the US alone

Galmed Medical Research Ltd. announced today that Phase-II randomized, double blind trial results of its novel drug Aramchol for treating Fatty Liver Disease (NAFLD) has successfully confirmed the novel drug's suitability for treating this disease.

The double blind, randomized placebo controlled phase-II trial was carried out in twelve medical centers in Israel. The study assessed the safety, pharmacokinetics and short-term effects of two doses of Aramchol (300 and 100 mg) in male and female patients suffering from NAFLD or NASH. Non-alcoholic fatty liver disease (NAFLD) is a wide spectrum of liver diseases, ranging from fatty liver (steatosis), to nonalcoholic steatohepatitis (NASH) and can ultimately lead to cirrhosis, or advanced scarring of the liver. NAFLD is caused by the accumulation of fat in the liver and is part of the metabolic syndrome.

Aramchol, developed by Prof. Tuvia Gilat, is a novel synthetic small molecule that reduces fat in the liver by inhibiting Stearoyl-CoA desaturase1 (SCD1), a key enzyme in the metabolism of fats in the liver. Aramchol is a member of the Fatty Acid Bile Acid Conjugate (FABAC) family, which has demonstrated the ability to lower liver lipids, particularly triglycerides, in pre-established fatty liver disease in several animal species.

The changes in liver fat content in 57 patients treated with the Aramchol, versus the placebo arm, were evaluated following 3 months of treatment by Nuclear Magnetic Resonance Spectroscopy (NMRS). Secondly, the study evaluated changes in serum liver enzymes, markers of endothelial dysfunction, insulin resistance and lipid levels, as well as SCD1 activity and cholesterol synthesis.

Therapeutic dose response

A statistically significant dose response was observed in the relative change in liver fat content between the three groups (300 mg, 100 mg, and placebo). Patients treated with 300 mg Aramchol had a significant reduction of 12.6% in liver fat content, compared to an increase of +6.4% in the placebo group and a non-significant change of -3.0% in the 100 mg group. Therapeutically positive trends were also seen in several secondary endpoints. For example, Serum adiponectin levels increased only in the high 300 mg dose Aramchol group (1.8 µg/ml) and reduced in the low dose (-3.4 µg/ml) and placebo groups (-7.1 µg/ml). Endothelial function increased by 63% in the high 300 mg dose group, by 23% in the low 100 mg dose group and by 34% in the placebo group. In patients receiving 300 mg there were non-significant

reductions in serum ALT, HOMA, insulin levels and body weight, while no such changes were observed in the 100 mg or placebo groups. No significant difference between the three groups was observed in reduction of serum levels of cholesterol, triglyceride and HbA1c levels. Detailed results will be presented for the first time at the International Liver Congress EASL 2012, in Barcelona, Spain, April 18-22, 2012.

Demonstrated safety

No severe drug related adverse events (“AE”) were observed during the 3-month treatment period and subsequent recovery period. Adverse events were mild or moderate and transient, and did not differ between the groups. No patient discontinued treatment due to AEs.

Once daily dosage suitability

Pharmacokinetics studies confirmed Aramchol’s suitability for once daily oral administration. The study demonstrated dose proportional increases in plasma levels with constant steady state levels throughout the study period and a long elimination half-life.

“NAFLD is prevalent among the western population and affects at least 100 million people in the US. This disease may advance to chronic liver disease and is associated with metabolic syndrome and cardiovascular morbidity and mortality. There are currently no efficient medical treatments to solve this major public health problem. These very encouraging clinical study results confirm that Aramchol is a suitable candidate for this purpose,” said Prof. Ran Oren from Hadassah Medical Center, Principal Investigator for the study.

About Fatty Liver Disease

NAFLD refers to a wide spectrum of liver disease ranging from fatty liver (steatosis), to nonalcoholic steatohepatitis (NASH), to cirrhosis (advanced scarring of the liver). In recent years, NAFLD emerged as the world’s most common liver disease and a major contributing factor of Chronic Liver Disease (CLD), one of the major causes of morbidity and mortality worldwide. It is estimated that NAFLD affects up to 33 percent of adults and over 5 percent of children. The prevalence of NASH is between 4 and 6 percent of the general population. The prevalence of NAFLD and NASH is rising rapidly across the globe, in parallel with obesity and diabetes. It is estimated that about two-thirds of obese adults and one-half of obese children may suffer from NAFLD.

About Galmed Medical Research, Ltd

Galmed Medical Research, Ltd (www.galmedpharma.com) is a biopharmaceutical company that develops innovative, proprietary drugs for the treatment of cholesterol and liver diseases. The Company discovered a series of proprietary fatty acid bile-acid conjugates (FABACs) which selectively affect several pathways in lipid metabolism.

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