Galmed Pharmaceuticals

# Galmed Pharmaceuticals Announces FDA Clearance of IND of Aramachol™ for the Treatment of Patients with HIV-Associated Lipodystrophy and Nonalcoholic Fatty Liver Disease

TEL AVIV, Israel, Dec. 1, 2015 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of a once-daily, oral therapy for the treatment of liver diseases, announced today that the U.S. Food and Drug Administration (FDA) has cleared Galmed's Investigational New Drug (IND) application for the ARRIVE Study (**AR**amchol™ for the **R**eversal of H**IV**-Associat**E**d Lipodystrophy and NAFLD), a proof-of-concept clinical trial that will evaluate the safety and efficacy of Aramachol™ in up to 50 patients with HIV-associated lipodystrophy and nonalcoholic fatty liver disease, or NAFLD.

"In patients with human immunodeficiency virus (HIV) infection, liver disease is among the leading causes of death," stated Galmed Chief Medical Officer, Dr. Maya Halpern. Dr. Halpern continued, "Nearly half of the HIV infected patients without viral hepatitis that undergo evaluation for unexplained liver test abnormalities are found to have NAFLD. The prevalence of NAFLD is higher in individuals with HIV infection than in the general population. To date, there are no therapies for the treatment of HIV-associated NAFLD – like NASH – and clinical trials in this area have been few."

The ARRIVE Study is a randomized, double-blinded, allocation-concealed, placebo-controlled, proof-of-concept Phase IIa clinical trial, which is an investigator-initiated study, and will be conducted at the University of California San Diego by Professor Rohit Loomba. The study will evaluate up to 50 patients with HIV-Associated Lipodystrophy and NAFLD, with either Aramchol™ at 600 mg or placebo for 12 weeks. Pre- and post-treatment MRI-measured liver fat content and total body fat via dual energy x-rayabsorptiometry (DEXA) will be compared. The primary end point of successful therapy will be an improvement in hepatic steatosis as measured by MRI. Secondary endpoints will be an improvement in total body fat, metabolic profile, and liver biochemistry.

Professor Loomba and his team of collaborators, including Professor Sirlin at UCSD, have pioneered the development of MRI-based assessment of treatment response in NAFLD, and will be using advanced imaging methods to assess treatment response in patients with HIV-associated NAFLD and lipodystrophy. "At the NAFLD Research Center, UCSD, our approach is to apply innovative clinical trial design by collaborating across disciplines to find solutions for clinical problems for patients suffering from liver diseases, and the ARRIVE Study is a prime example of this innovative team science approach as it brings together clinicians working on liver disease, MR imaging, body composition and HIV to help solve the understudied and under-appreciated issue of HIV-associated NAFLD and lipodystrophy," said Professor Loomba, Director, NAFLD Research Center, UCSD.

"As we've discussed, we believe the commercial potential for Aramchol™ extends beyond the treatment for nonalcoholic steatohepatitis, or NASH," stated Galmed President and Chief Executive Officer, Allen Baharaff. Mr. Baharaff continued, "Importantly, today's announcement of a Phase IIa trial, serves two strategic purposes:  (1) It marks the first step in potentially extrapolating additional commercial value with our existing assets, and (2) it signifies the beginning of our execution of a de-risking strategy through more potential applications and end markets for our product." Mr. Baharaff concluded, "The ARRIVE Study is the beginning of executing this strategy and we expect to pursue additional opportunities."

**About HIV-Associated Lipodystrophy and Nonalcoholic Fatty Liver Disease**

Human Immunodeficiency Virus (HIV) is a major global health issue, with 35.3 million people living with the disease worldwide, 2-3 million of which are in the United States, and Western and Central Europe. While effective combination antiretroviral therapy (cART) has resulted in a major reduction in acquired immunodeficiency syndrome (AIDS)-related mortality overall, liver disease is now the second leading cause of death in patients with HIV, accounting for nearly 7-14% of all deaths in this population. Although viral hepatitis is still the leading cause of liver related morbidity and mortality in this population, nearly half of the HIV-infected patients without viral hepatitis that undergo evaluation for unexplained liver test abnormalities are found to have NAFLD. The prevalence of NAFLD is higher in individuals with HIV infection than in the general population. In a recently conducted clinical trial at the University of California San Diego by Professor Rohit Loomba, the largest such study to-date, which compared age and sex matched patients with primary NAFLD, with patients with HIV-associated NAFLD, patients with HIV-associated NAFLD had significantly higher rates of definite steatohepatitis (63% vs. 37%, P = 0.04), and more features of liver injury, including lobular inflammation (<0.001) and acidophil bodies (<0.001).

**About Nonalcoholic Fatty Liver Disease and Nonalcoholic Steatohepatitis**

Nonalcoholic fatty liver disease (NAFLD) is the most common cause of chronic liver disease inthe United States and it affects almost 30% of adults in Western countries. With climbing obesity rates and more sedentary patient populations, the prevalence of NAFLD is increasing worldwide and is becoming the predominant cause of chronic liver disease in parts of the world. NAFLD represents a spectrum of diseases ranging from simple excess liver fat, or steatosis, to nonalcoholic steatohepatitis (NASH). NASH is the progressive form of fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality in persons who drink little or no alcohol. NASH represents the more severe end of this spectrum and is characterized by steatosis, ballooning degeneration and lobular inflammation with or without fibrosis. Long-term risks of NASH include cardiovascular disease, cirrhosis, hepatocellular carcinoma and end stage liver disease requiring liver transplantation.

**About Galmed Pharmaceuticals Ltd.**

Galmed is a clinical-stage biopharmaceutical company focused on the development of a novel, once-daily, oral therapy for the treatment of liver diseases utilizing its proprietary first-in-class family of

synthetic fatty-acid/bile-acid conjugates, or FABACs. Galmed believes that its product candidate, Aramchol™, has the potential to be a disease modifying treatment for fatty liver disorders, including NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need, and HIV-associated lipodystrophy and NAFLD. Galmed is currently conducting the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol™ in subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. More information about the ARREST Study may be found on ClinicalTrials.gov identifier: NCT02279524.

***Forward-Looking Statements***

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