Galmed Pharmaceuticals

Galmed Pharmaceuticals Completes Patient Recruitment for ARREST Phase IIb NASH study

TEL AVIV, Israel,, Jan 9, 2017 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of Aramchol, a once-daily, oral therapy for the treatment of liver diseases including Non-Alcoholic Steato-Hepatitis (NASH), announced today that it has completed recruitment for its Phase IIb ARREST study ("ARREST Study").

The ARREST Study is a global, multi-center, randomized, double blind, placebo-controlled, Phase IIb clinical trial evaluating the treatment effects and safety of Aramchol in 240 patients with biopsy proven NASH who are overweight or obese, and who are pre-diabetic or type-II-diabetic. The ARREST Study duration is 52 weeks with 12 weeks' follow-up period. Results are anticipated to be announced in Q2 2018.

The ARREST Study primary endpoint, previously demonstrated in a Phase IIa study, is reduction in liver fat content measured by magnetic resonance spectroscopy (MRS). The secondary histological endpoints include improvement of fibrosis, two-point improvement in NAS (NAFLD Activity Score) and resolution of NASH. The ARREST Study will also evaluate surrogate metabolic endpoints.

Patients enrolled in the ARREST Study have advanced NASH with more than 60% having fibrosis in stages 2 (19%) and 3 (42%) and a mean NAS score of 5.

"ARREST is a global NASH study, operating across four continents includingNorth America, Europe, LatAm and China. "The design of the study took advantage of lessons learned from other large Phase II studies by enrolling a population at increased risk for disease progression." stated Allen Baharaff President and chief executive officer of Galmed.

"The ARREST study is the largest study to date to incorporate both MRI and histology endpoints. I expect that Aramchol will demonstrate the effects seen in pre-clinical and clinical studies on the three pathologies of NASH: steatosis, inflammation and fibrosis", commented Professor Vlad Ratziu, the ARREST Study's global principal investigator. Professor Ratziu continued, "The ARREST Study is a fully global outreach trial with spectacular rates of inclusion from numerous investigators. This speaks to the excitement for testing Aramchol and generating a large set of data on invasive and non-invasive assessments that will move the field of liver diseases forward, but also, more generally, to the potential of conducting large clinical trials globally which will be the key to further phase III developments".

About Aramchol and Non-alcoholic Steatohepatitis (NASH)

Aramchol (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, causing beneficial modulation of intra-hepatic lipid metabolism. Aramchol's ability to modulate hepatic lipid metabolism was discovered and validated in numerous animal species and models by leading Israeli and European research groups led by the Company's founder, the late Prof. Tuvia Gilat. Recently, anti-inflammatory and anti- fibrotic effects were observed in mice treated with Aramchol using a methionine-choline deficient (MCD) diet treatment model and rats' prevention thioacetamide (TAA) model.

To date, over 400 subjects have been dosed with Aramchol in five Clinical trials, including the ARREST Study. Our Phase IIa Study with 60 nonalcoholic fatty liver disease (NAFLD) and NASH patients demonstrated that Aramchol 300mg per day significantly reduced liver fat content after 12 weeks of treatment.

The FDA granted Fast Track designation status to Aramchol for the treatment of NASH.

NASH is an emerging health crisis impacting 3% to 5% of the U.S. population and 2% to 4% globally. It is the fastest growing cause of liver cancer and liver transplant in the U.S., due to the rise in obesity. 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.

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 nonalcoholic steatohepatitis, or NASH and liver diseases utilizing its proprietary first-in-class family of synthetic fatty-acid/bile-acid conjugates, or FABACs. 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. Galmed also sponsors the ARRIVE Study, a proof-of-concept Phase IIa clinical trial designed to evaluate the safety and efficacy of Aramachol in up to 50 patients with HIV-associated NAFLD and lipodystrophy. The ARRIVE Study is an investigator-initiated trial, conducted at the University of California San Diego by Professor Rohit Loomba. More information about the ARREST Study and the ARRIVE Study may be found on ClinicalTrials.gov identifieries: NCT02279524 and NCT02684591, respectively.

Forward-Looking Statements:
This press release may include forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to Galmed's objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that Galmed intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are

based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Applicable risks and uncertainties include risks and uncertainties associated with the initiation, timing, progress and results of the Company's research, preclinical studies and clinical trials as well as risks and uncertainties identified under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission, or the SEC, on March 22, 2016, and in other filings that Galmed has made and may make with the SEC in the future. The forward-looking statements contained in this press release are made as of the date of this press release and reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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