Galmed Pharmaceuticals

# Galmed Pharmaceuticals Announces the Beginning of Enrollment in its Phase IIb ARREST Trial for the Treatment of NASH, as well as the Expansion of the Study to the United States

TEL AVIV, Israel, March 9, 2015 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed"), a clinical-stage biopharmaceutical company focused on the development and commercialization of a once-daily, oral therapy for the treatment of liver diseases and cholesterol gallstones, announced today the beginning of enrollment in its Phase IIb clinical trial, or our ARREST Study, of aramchol in patients with Non-Alcoholic Steato-Hepatitis, or NASH, who also suffer from obesity and insulin resistance.

Galmed has commenced its multinational ARREST Study of aramchol, which is expected to take place in more than 70 centers in 12 countries, including the United States. Dr. Maya Halpern, Galmed's Chief Medical Officer, commented, "We are pleased that Professor Vlad Ratziu, from the University Pierre et Marie Curie in Paris, an internationally acclaimed key opinion leader, is the ARREST Study's global principal investigator, and Professor Rohit Loomba, from the University of California San Diego School of Medicine, is the ARREST Study's U.S.-based principal investigator."

Galmed's ARREST Study is a multi-center, randomized, double-blind, placebo-controlled, dose-ranging Phase IIb clinical trial of aramchol. The trial's primary end-point is a statistically significant reduction of liver fat content measured by Magnetic Resonance Spectroscopy, or MRS, and the trial's secondary end-point is the complete resolution of NASH, as measured by two biopsies (at the beginning and at the end of the ARREST Study), and improvement of the NAFLD Activity Score (NAS), as well as an improvement in the markers of liver inflammation and various metabolic biomarkers.

In addition, Galmed today announced that it has also expanded its clinical activities to include patient recruitment for the ARREST Study in the United States. Allen Baharaff, Galmed's Chief Executive Officer, stated, "We believe that U.S.-based patient recruitment will shorten the recruitment time for our ARREST Study, as well as improve the study's breadth and relevance." Galmed currently expects to release interim results of the ARREST Study in the first half of 2016, later than originally planned, due to our revised geographic strategy of enrollment on the Study. Galmed further reaffirmed that it expects to release top-line data by the end of 2016.

Mr. Baharaff concluded, "While the alignment and coordination of the study's geographic expansion caused a slight delay, we believe we're much better off for adding robust clinical operations in the United States and look forward to the interim results."

**About Galmed**

Galmed is a clinical-stage biopharmaceutical company focused on the development and commercialization of a novel, once-daily, oral therapy for the treatment of liver diseases and cholesterol gallstones 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.

***Forward-Looking Statements***

*This press release includes forward-looking statements. Such forward-looking statements 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 those identified under the heading "Risk Factors" included in the registration statement on Form F-1 (File No. 333 -193792), initially filed with the Securities and Exchange Commission, or the SEC, on February 6, 2014 and declared effective by the SEC on March 12, 2014, 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 reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update any forward-looking statements.*

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/galmed-pharmaceuticals-announces-the-beginning-of-enrollment-in-its-phase-iib-arrest-trial-for-the-treatment-of-nash-as-well-as-the-expansion-of-the-study-to-the-united-states-300047122.html

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Investor Contact: Josh Blacher, CFO, Galmed Pharmaceuticals Ltd., josh@galmedpharma.com, +1.646.780.7605

---