

Galmed Pharmaceuticals Announces First Administration of Aramchol in its Phase IIa Trial for the Treatment of Cholesterol Gallstones

TEL AVIV, Israel, Nov. 13, 2014 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed"), a clinical-stage biopharmaceutical company focused on the development and commercialization of a once-daily, oral medication for the treatment of liver diseases and cholesterol gallstones, announced today the first administration of its drug candidate, aramchol, in its proof-of-concept Phase IIa clinical trial for the treatment of newly formed cholesterol gallstones following bariatric surgery.

The Phase IIa trial is being conducted at the Assuta Medical Center in Tel Aviv, Israel and is a single center, randomized, double blind, placebo controlled study, designed to evaluate the efficacy and safety of a once-daily dose of aramchol for three months in 36 adult patients. The primary endpoint of the trial is a complete dissolution of newly formed cholesterol gallstones following bariatric surgery. Secondary endpoints include a decrease of more than 50% in the number of newly formed gallstones, prevention of the formation of additional gallstones during the trial period and dissolution of biliary sludge. The Company anticipates reporting top line results in the first half of 2015. Approximately 5% of the general population in most countries develops cholesterol gallstones and the current standard of care is surgery, either laparoscopic or open cholecystectomy.

About Galmed Pharmaceuticals Ltd.

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 Non-Alcoholic Steato-Hepatitis, or NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need.

Cautionary Note on 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 U.S. 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.

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Josh Blacher, Galmed Pharmaceuticals Ltd., +972-3-693-8448, josh@galmedgroup.com, Andrew McDonald, LifeSci Advisors, LLC, +1-646-597-6987, andrew@lifesciadvisors.com

<https://galmedpharma.investorroom.com/2014-11-13-Galmed-Pharmaceuticals-Announces-First-Administration-of-Aramchol-in-its-Phase-IIa-Trial-for-the-Treatment-of-Cholesterol-Gallstones>