Galmed Pharmaceuticals

Galmed Pharmaceuticals Completes Analysis of a Pharmacokinetic Study of Aramchol in Healthy Volunteers

-- Results Confirm Favorable Safety Profile of Two High Doses of Aramchol --

TEL AVIV, Israel, Dec. 1, 2014 /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, today announced the completion of the statistical analysis of a pharmacokinetic (PK) study of three doses, including two high doses (400 mg and 600 mg), of its drug candidate, aramchol, in 66 healthy adult male volunteers. No Serious Adverse Events (SAEs) were observed in the study.

Galmed's Chief Medical Officer, Dr. Maya Halperin stated, "The completion of the analysis adds important data to the favorable safety profile of aramchol, which we've consistently observed in our earlier clinical trials, as well as in our long-term, high dose animal toxicology studies." Dr. Halperin continued, "The study results support Galmed's decision to administer the two higher doses of aramchol in its Phase IIb clinical trial in Non-Alcoholic Steato-Hepatitis (NASH) patients, which will be conducted in Israel, Latin America and Europe, as well as its Phase IIa clinical trial in cholesterol gallstone patients, which was initiated in Israel earlier this month."

The study was a single-site, randomized, partially double-blind, placebo-controlled study conducted in three parts. The first two parts of the study assessed PK, safety and tolerability of aramchol tablets administered in single doses of 200 mg, 400 mg and 600 mg either following a ten-hour overnight fast or a high-fat, high-calorie meal. The third part of the study assessed PK, safety and tolerability of aramchol tablets administered in the same three doses as the first two parts of the study for ten consecutive days, in each case within one hour after a light breakfast.

Although no SAEs were observed, a total of 27 adverse events were observed (26 mild and one moderate). Out of the 27 adverse events, 24 were considered as unrelated to aramchol and three as possibly related (all three of which were mild).

The PK data gathered by Galmed from the three parts of the study revealed that aramchol is appropriate for a once daily oral administration with food.

As previously disclosed, Galmed is currently prepared to initiate its Phase IIb trial of aramchol in NASH patients as scheduled, which, if successful, may serve as a basis for Phase III pivotal trials for the treatment of NASH to be conducted in the United States and Europe. Galmed expects to report interim results of this Phase IIb trial in the second half of 2015, and final results in the second half of 2016.

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 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.

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