Galmed Pharmaceuticals

Galmed to add Open Label Part to ARMOR Study; First Read-out Expected in Q4 2021

New Phase 1 Data Confirm Aramchol Meglumine PK Parameters Similar to Aramchol Acid

TEL AVIV, Israel, Dec. 17, 2020 /PRNewswire/ --

- All patients currently enrolled in both arms of ARMOR will be given the opportunity to transition to the new open label part with 300mg BID Aramchol Acid, allowing a potential first readout of the kinetics of histological outcome measures and non-invasive tests (NITs) associated with NASH and fibrosis in Q4 2021.
- The new open label part will enroll a total of approximately 150 patients drawn from both current ARMOR patients and newly recruited patients.
- The Aramchol meglumine program provides an attractive new salt form of Aramchol and new data from first Phase 1 study show the pharmacokinetics (PK) have a similar plasma PK profile to Aramchol acid.
- A new patent on the low dose composition of Aramchol salts has been granted by the U.S. PTO (US patent no. 10,849,911 B2) with a term expiring in 2035.
- Plan to meet with FDA in Q2 2021 to discuss the introduction of Aramchol meglumine into the randomized, double-blind, placebo-controlled part of ARMOR by Q4 2021.

Galmed to conduct KOL event on January 26, 2021 to discuss these latest developments.

Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and inflammatory diseases announced today the addition of an open-label part to its ARMOR Phase 3 registrational study. All currently enrolled patients in both arms will be given the opportunity to transition to an active regimen of Aramchol. This is designed to evaluate treatment response kinetics, pharmacokinetics (PK) and safety of twice daily administration (BID) of Aramchol 300mg in approximately 150 subjects at various time points with the results of a second biopsy coming as early as 24 weeks after initiation of treatment. The 150 patients are expected to be comprised of both current ARMOR patients as well as new patients.

Separately, Galmed is announcing new data from a Phase 1, first in human (FIH) study that compared Aramchol meglumine to Aramchol acid. These initial results demonstrate that the new salt form of Aramchol meglumine has a plasma PK profile that is very similar to Aramchol acid. It also shows that the

administration of both forms results in the same form of Aramchol in the blood, regardless of which drug product is administered.

Allen Baharaff, Galmed co-founder and CEO commented "The addition of the open-label part to our ARMOR study will give us an important early readout of twice daily Aramchol 300mg, which in a previously reported PK study significantly increased plasma levels, as well as provide us with other important data in support of the ARMOR registrational study. Furthermore, over the last few years, Galmed has been in the process of developing a new product, Aramchol meglumine, which is a salt form of Aramchol free acid. We have now shown with our first in human PK data that Aramchol meglumine and Aramchol free acid, the drug substance that is currently being evaluated in our ARMOR Phase 3 study, circulate in the blood as Aramchol regardless of which drug product is administered. The markedly higher solubility of Aramchol meglumine results in lower variability which is a significant added benefit. By developing a salt version of Aramchol, we are able to take the important step towards gaining patent protection on the drug until 2035. We plan to submit these results along with other supportive data to the FDA and discuss with the FDA a plan to introduce Aramchol meglumine into the randomized placebo-controlled part of the ARMOR Phase 3 study. This is all part of our overall strategy to optimize our clinical development program towards a Sub-part H filing and approval."

All subjects enrolled into the open-label part of ARMOR will receive 300mg of Aramchol BID. Patients will be randomized (1:1:1) into 3 groups with post-baseline liver biopsy being performed at 24 weeks, 48 weeks, or 72 weeks, respectively. The first data milestone is expected when approximately one-third of the study population (~ 50 subjects) has completed 24 weeks of treatment, followed shortly by a second data milestone after one-third of the population has completed the on-treatment liver biopsy.

The new open label part will enroll a broader study population than the initial ARMOR protocol defined, including subjects with NASH and liver fibrosis stage 1-3, subjects with NASH who may or may not be overweight, and subjects with NASH who may or may not have type 2 diabetes (T2DM) or be pre-diabetic.

The open label part of ARMOR will also provide information about the utility of state-of-the-art non-invasive tests (including ProC3 and ELF) and imaging that may be able to provide early predictions for histology responses to Aramchol and long-term safety data to support the planned histology-based Sub-part H submission to the FDA for regulatory approval.

The open label part will be conducted in a smaller subset of the ARMOR sites; approximately 50 selected sites in the U.S., and around the world which have been less affected by the COVID-19 pandemic. The Company is expecting the first of the planned 150 patients to be enrolled in the first quarter of 2021 and expects the first histology data to be reported by the fourth quarter of 2021.

In light of the rapid development of the Aramchol meglumine program and due to the delays resulting from the COVID-19 pandemic, randomization of new patients into the double-blind, placebo-controlled histology-based registrational part of ARMOR will be temporarily suspended as currently enrolled patients are transitioned to open label. This will allow the capture and reporting of important data from ARMOR much earlier than previously expected. It will also help to ensure a seamless introduction of the new Aramchol meglumine into the double-blind, placebo-controlled part of ARMOR, which is expected to resume by the fourth quarter of 2021.

Prof. Vlad Ratziu, Professor of Hepatology, Sorbonne Université, and Hospital Pitié Salpêtrière,Paris, France and the ARMOR study co-principal investigator commented "the open-label part aims to help bridge the gap between current histology-based trials and future real-world practice where biomarkers will be extensively used to assess candidates for therapy and treatment response. It also addresses an important practical question which is to determine the individual dynamics of treatment response; this is expected to provide evidence-based knowledge with the prospect of optimizing the benefit of Aramchol 300mg BID and other future NASH therapies."

About Aramchol and Non-alcoholic Steatohepatitis (NASH)

Aramchol (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, liver targeted SCD1 modulator, developed as an oral therapy for the treatment of nonalcoholic steatohepatitis ("NASH") and fibrosis. Aramchol's ability to modulate hepatic lipid metabolism was discovered and validated in animal models, demonstrating downregulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol on fibrosis is mediated by downregulation of steatosis and directly on human collagen producing cells. Aramchol has been granted Fast Track Designation status by the FDA for the treatment of NASH.

NASH is an emerging world crisis impacting an estimated 3% to 5% of the U.S. population and an estimated 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 non-alcoholic fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality.

Galmed Pharmaceuticals Ltd.

Galmed Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases. Our lead compound, Aramchol™, a backbone drug candidate for the treatment of NASH and fibrosis is currently in a Phase 3 registrational study. We are also collaborating with the Hebrew University in the development of Amilo-5MER, a 5 amino acid synthetic peptide and plan to initiate a first in human study by the first quarter of 2021.

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. Many factors could cause Galmed's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the timing and cost of Galmed's pivotal Phase 3 ARMOR trial, or the ARMOR Study or any other pre-clinical or clinical trials; completion and receiving favorable results of the ARMOR Study for Aramchol or any other pre-clinical or clinical trial; the impact of the COVID-19 pandemic; regulatory action with respect to Aramchol or any other product candidate by the FDA or the EMA; the commercial launch and future sales of Aramchol or any other future products or product candidates; Galmed's ability to comply with all applicable post-market regulatory requirements for Aramchol or any other product candidate in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol or any other product candidate; Galmed's expectations regarding the commercial market for NASH patients or any other indication; third-party payor reimbursement for Aramchol or any other product candidate; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol or any other product candidate by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol or any other product candidate; the development and approval of the use of Aramchol or any other product candidate for additional indications or in combination therapy; and Galmed's expectations regarding licensing, acquisitions and strategic operations. More detailed information about the risks and uncertainties affecting Galmed is contained under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the SEC on March 12, 2020, 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.

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Guy Nehemya, Chief Operating Officer, Galmed Pharmaceuticals Ltd., investor.relations@galmedpharma.com, +972-3-693-8448

Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2020-12-17-Galmed-to-add-Open-Label-Part-to-ARMOR-Study-First-Read-out-Expected-in-Q4-2021