Galmed Pharmaceuticals

Results of Galmed's Phase 2b ARREST Trial of Aramchol Published in Nature Medicine

- Data add to the growing body of clinical and scientific evidence demonstrating the therapeutic potential of Aramchol, a stearoyl CoA desaturase (SCD 1) down regulator, for the treatment of NASH and Fibrosis

- A Phase 3 program is currently ongoing with a higher daily Aramchol dose

TEL AVIV, Israel, October 11, 2021 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and inflammatory diseases announced today that the one-year results of the global Phase 2b randomized placebo-controlled ARREST Trial of Aramchol in patients with NASH have been published in *Nature Medicine* (https://www.nature.com/articles/s41591-021-01495-3).

The ARREST Phase 2b study randomized 247 patients with NASH confirmed by liver biopsy. Patients were randomized 2:2:1 to receive Aramchol 400mg, 600mg or placebo once daily. The manuscript describes the complete data analyses including reduction in liver fat by imaging, improvements in liver histology and liver enzymes as well as the very good safety profile of Aramchol.

Aramchol is the most advanced down regulator of SCD 1 in clinical development. Aramchol, by targeting this single receptor, an important metabolic master switch, induces cascade of events that leads to two main changes: in hepatocytes, Aramchol elevates the fatty acids oxidation (or in other words – fat burn) and influences AMPK, which results also in reducing glycemic parameters; and in hepatic stellate cells, Aramchol down regulates collagen production (i.e. fibrosis). Data from the ARREST Phase 2b study published in this paper demonstrate how the mechanism of action of Aramchol translates into clinical performance.

This published study, in addition to mechanistic studies demonstrated and published thus far, provided the rationale for the continued development of Aramchol for patients with NASH and fibrosis and a potential to further improved efficacy using higher drug exposure (>50% higher).

The ARMOR study - a Phase 3, multinational, multicenter, randomized, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of Aramchol 300mg twice daily in subjects with NASH with an open-label part to evaluate the safety, PK and treatment response kinetics of Aramchol is currently ongoing (NCT04104321).

Prof. Vlad Ratziu, Professor of Hepatology, Sorbonne Université, the paper's lead author and the ARMOR study co-principal investigator commented "The publication of the detailed results of the ARREST trial in a prestigious general medical journal such as Nature Medicine speaks to the interest of the scientific

community towards this molecule with an innovative mode of action and its potential for treating fibrotic NASH. We look forward to seeing the impact of an optimized Aramchol exposure in NASH patients from the Phase 3 ARMOR trial"

"The publication of these data in Nature Medicine speaks to the strong interest from the clinical community in this unmet need area. We are grateful to all the patients and clinical sites that participated in the study around the world", said Allen Baharaff, President and Chief Executive Officer of Galmed. "Coupled with new recent publications elucidating Aramchol's MoA and particularly its direct effect on fibrosis, these results underscore the significant potential of Aramchol as a therapeutic option for patients diagnosed with NASH and Fibrosis. We are committed to evaluating the safety and efficacy of Aramchol in patients diagnosed with NASH and Fibrosis in our ongoing ARMOR Phase 3 study."

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. There are currently no approved therapies for NASH.

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.

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 18, 2021, 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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