Galmed Pharmaceuticals

Galmed Pharmaceuticals Announces Dosing of First Subject in First in Human Phase 1 Trial of Amilo-5MER

Amilo-5MER is believed to have significant effect in the treatment of chronic inflammation

TEL AVIV, Israel, March 16, 2021 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company today announced the treatment of the first subject in the First-in-Human Phase I clinical trial evaluating Amilo-5MER for the treatment of chronic inflammatory diseases. Additional subjects enrollment to the study is ongoing. Amilo-5MER is an investigational first-in-class, specific, penta peptide, designed to interfere with Serum Amyloid A (SAA) polymerization and aggregation resulting in significant reduction of pro inflammatory cytokine secretion.

"Initiating the Phase 1 trial represents an important milestone in the development of our pipeline product candidate, Amilo-5MER, for patients with chronic inflammatory diseases mainly IBD and Rheumatoid Arthritis. Based on encouraging preclinical data of Amilo-5MER, we believe Amilo-5MER, with its novel mechanism of action, has the potential to provide a significant treatment option for patients suffering from auto-immune and chronic inflammatory diseases," said Allen Baharaff, CEO of Galmed Pharmaceutical. "We are excited to bring Amilo-5MER into the clinical phase and look forward to advancing our product pipeline to address additional important indications for the benefit of patients around the world."

Amilo-5MER's Phase I trial is a three-part, single center, double-blind, randomized, placebo-controlled first in human study of single ascending doses (Part 1) and multiple doses (Part 2) of Amilo-5MER in young healthy male subjects and a single dose cohort in healthy elderly male and female subjects (Part 3). The study plans to enroll up to 64 healthy male and female subjects (56 young male and 8 elderly male and female). The primary objectives of the trial are to evaluate the safety, tolerability, and pharmacokinetics of Amilo-5MER.

"The first subject dosed in the Amilo-5MER clinical trial marks a significant milestone toward delivering a new mechanism of action for potential medicines to treat autoimmune and chronic inflammatory diseases such as Crohn's Disease, Ulcerative Colitis, Rheumatoid Arthritis and Multiple Sclerosis, all of which share the pro-inflammatory cytokine SAA. Other life-threatening maladies associated with SAA-induced 'cytokine storm' such as Sepsis or COVID-19 infection, may be also suppressed by Amilo5MER," said Prof. David Naor, Hebrew University Lautenberg Center for Immunology and Cancer Research and the inventor of Amilo-5MER.

About Amilo-5MER

Amilo-5MER is a specific penta peptide, a highly potent inhibitor of chronic inflammation currently under development for IBD.

In preclinical studies, Amilo-5MER demonstrated interference with SAA polymerization and aggregation resulting in significant reduction of chronic inflammation in multiple animal models. Amilo-5MER has a unique mode of action up stream to all pro inflammatory cytokine production which are currently being used and in clinical trials. Amilo-5MER down regulates multiple pro inflammatory cytokine secretion.

In LPS induced inflammation in mice, the animal model for systemic inflammation, Amilo-5MER reduced IL-6, TNF a, IFN g and IL-1b levels in the serum. Elevated levels of these pro inflammatory cytokine are the hallmark of acute and chronic inflammatory conditions and are symptomatic also among COVID-19 patients.

About 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 specific penta peptide and recently initiated a first in human study.

Research of Amilo-5Mer is currently being conducted under a research and option agreement with Yissum, the tech transfer company of the Hebrew University. Under the agreement, Galmed has been granted an exclusive option to negotiate and enter into a definitive license agreement with Yissum for Amilo-5Mer upon certain pre-agreed upon terms and such other terms to be agreed upon. Galmed plans to exercise its option if the first-in-human study is successful, however there can be no assurance that Galmed will enter into a definitive license agreement or that it will be on terms favorable to Galmed. If Galmed does not enter into a definitive license agreement, then Galmed will not have the ability to continue the development and potential commercialization of Amilo-5Mer.

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 coronavirus outbreak; 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.

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