Galmed Pharmaceuticals

Galmed Announces Positive Results from First 16 Patients in Open-Label Part of ARMOR Study

-- Treatment with Aramchol 300mg BID reduced fibrosis progression measured by histology in 15 out of the 16 patients completed as of data cutoff --

-- 50% of the 16 patients showed fibrosis improvement by ≥1 stage, seen as early as 24 weeks --

--Data demonstrates that treatment with Aramchol 300mg BID resulted in clinically significant greater histological improvement than observed previously with Aramchol 600mg QD --

-- Data add to body of evidence from prior studies demonstrating the benefit of Aramchol for patients with histologically confirmed NASH and fibrosis and provides clinical support for the hypothesis that a higher daily dose will result in improved clinical benefit --

-- Data will be presented at a late-breaking poster presentation at The Liver Meeting Digital Experience 2021, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), which will be held from November 12-15, 2021 --

Galmed's management team will host a conference call and webcast to provide an update on current developments with respect to its clinical programs for Aramchol including NASH Expert Insights on the ongoing Open-Label Part of the ARMOR study, and to discuss financial results for the quarter ended September 30, 2021 on November 8th @ 8.30am Eastern Time

TEL AVIV, Israel, Nov. 1, 2021 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company for liver, metabolic and inflammatory diseases announced today results from the first 16 patients in the Open-Label Part of the ARMOR Phase 3 study who underwent a scheduled post-baseline biopsy.

End of treatment biopsies were performed for 8 patients at 24 weeks, 6 at 48 weeks and 2 at 72 weeks. Altogether treatment with Aramchol reduced fibrosis progression in 15 out of the 16 patients. 8 out of the 16 patients (50%) showed fibrosis improvement by ≥1 stage (4 of 8 after 24 weeks, 3 of 6 after 48 weeks and 1 of 2 after 72 weeks). In 3 patients (19%), fibrosis was reduced by 2 points. In 7 of 16 (44%) patients there was fibrosis improvement without worsening of NASH. Aramchol continues to show good safety and tolerability.

A late-breaking poster presentation that includes this new data from Galmed's ARMOR Phase 3 Open-Label Part will be presented at The Liver Meeting Digital Experience™ 2021, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), which will be held form November 12-15, 2021. The abstract covering this new data will also be featured in the December issue of the scientific journal Hepatology and is available on the website of the AASLD.

Prof. Scott Friedman MD, Dean for Therapeutic Discovery, Fishberg Professor of Medicine and Pharmacologic Sciences at Mount Sinai commented: "These most recent findings add to the growing evidence of likely efficacy of Aramchol in NASH. Combined with the previous results indicating a direct

antifibrotic activity of this agent towards fibrogenic cells, these new data are cause for optimism as we await further Phase 3 results. "

Allen Baharaff, President and CEO of Galmed commented: "The data we present today provides initial clinical support for our hypothesis that higher Aramchol exposure results in improved clinical benefit and that a direct anti-fibrotic effect of Aramchol may be manifested as early as 24 weeks." Mr. Baharaff continued: "The findings are a direct outcome of the drug development optimization work we have carried since the completion of the Phase 2b ARREST study in our mission to de-risk our Phase 3 study and bring to the market a leading drug for NASH and fibrosis."

Conference Call & Webcast:

Monday November 8, 2021, 8:30 AM ET

Toll Free: 1-877-425-9470
Toll/International: 1-201-389-0878
Israel Toll Free: 1 809 406 247
Conference ID: 13724243
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1511856&tp_key=e9490761d4

Replay Dial-In Numbers

Toll Free: 1-844-512-2921
Toll/International: 1-412-317-6671
Replay Pin Number: 13724243
Replay Start: Monday November 8, 2021, 11:30 AM ET
Replay Expiry: Monday November 22, 2021, 11:59 PM ET

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.

About ARMOR Study

ARMOR is a Phase 3 study comprised of two-parts, an open-label part and a randomized, double-controlled, placebo part, designed to evaluate the safety and efficiacy of Aramchol in approximately 200 sites in the U.S., Europe and Latin America.

The first part, an open-label study, is designed to evaluate treatment response kinetics, pharmacokinetics and safety of twice daily administration of Aramchol 300mg in approximately 150 subjects with NASH and liver fibrosis stage 1-3 (F1 capped at 30 subjects), subjects with NASH who may or may not be overweight, and subjects with NASH who may or may not have type 2 diabetes or be pre-diabetic. Patients are randomized (1:1:1) into three groups with post-baseline liver biopsy being performed at 24 weeks, 48 weeks, or 72 weeks, respectively. A second post-baseline liver biopsy will be conducted after one year for subjects whose post-baseline liver biopsy at week 24, 48 or 72 does not show at least one stage improvement in fibrosis. The open label part is being conducted at approximately 50 selected sites in the U.S., and around the world which have been less affected by the COVID-19 pandemic.

The second part, a randomized, double-blind, placebo-controlled study, is designed to evaluate the safety and efficacy of twice daily administration of Aramchol 300 mg to support regulatory approval, with both a histology-based phase and a clinically-based phase. As currently designed, a total of 2000 subjects with NASH and liver fibrosis stage 2 and 3 who are overweight and are either pre-diabetic or have type 2 diabetes are expected to be randomized 2:1 to receive Aramchol 300mg BID or matching placebo. In the histology-based phase, we intend to treat 1000 subjects with Aramchol or matching placebo for 72 weeks until the second biopsy. The histology-based data is intended to serve as the basis for the submission of a Sub-part H marketing authorization application under regulatory provisions of accelerated/conditional approval. The primary histology-based endpoint is NASH resolution without worsening of fibrosis or fibrosis improvement without NASH worsening. In the clinically-based phase, all subjects will continue with the same treatment assignment for up to seven years until study completion to confirm clinical efficacy. We may announce end-of-study at the time when a total of 380 subjects have experienced at least one pre-specified clinical event or at five years from last subject randomization, whichever comes first. The primary clinically-based endpoint is expected to be based on clinical events including all-cause mortality, histological progression to cirrhosis, MELD score >15, and hepatic decompensation events (e.g., hepatic encephalopathy, variceal bleeding, ascites).

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.

Logo - http://mma.prnewswire.com/media/595923/Galmed_Pharmaceuticals_Ltd_Logo.jpg

SOURCE Galmed Pharmaceuticals Ltd.

For further information: For further information: Investor Contact: 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/2021-11-01-Galmed-Announces-Positive-Results-from-First-16-Patients-in-Open-Label-Part-of-ARMOR-Study