Galmed Pharmaceuticals

Galmed Announces New Positive Data from Ongoing ARMOR Study Open Label Part Showing Clinically Significant Effect on Fibrosis Improvement

-- Updated liver histology data from first 20 patients show 60% fibrosis improvement by at least 1 stage as early as 24 weeks, data will be presented at AASLD Late Breaker Presentations --

-- Statistically significant reductions in biomarkers associated with liver fibrosis including ALT, AST, Fib-4 and ProC-3 was also observed in ~ 50 patients --

-- Results are an early indication that higher dose of Aramchol could provide statistically and clinically meaningful effect on fibrosis in the double-blind placebo controlled regulatory part for submission of an NDA under Sub-part H--

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 **Today @ 8.30am Eastern Time**

TEL AVIV, Israel, Nov. 8, 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 histology and biomarkers analyses in the ongoing Open-Label Part of the ARMOR Phase 3 study.

Galmed previously announced a substantial effect on fibrosis improvement based on histology, in the 16 first patients from the ongoing Open-Label Part of the ARMOR study. New analyses of biomarkers corroborate this effect showing statistically significant reductions in biomarkers associated with liver fibrosis including ALT, AST, Fib-4 and ProC-3. Reductions of a similar magnitude are seen in a cohort of the first 20 patients for which paired biopsy have been analyzed (Late breaker AASLD Cohort N=20) and a cohort of 50 patients for which biomarker data was analyzed (ARCON Cohort N=50) based on all available data (N=139). Aramchol continues to show excellent safety and tolerability profile. Data support that higher dose of Aramchol could provide statistically and clinically meaningful effect on fibrosis in the upcoming double-blind placebo controlled part for submission of the ARMOR study to support an NDA under Sub-part H.

Results support discussions with FDA to potentially allow a smaller and shorter double-blind placebo control histology-based part to support regulatory submission of an NDA.

A summary of the results is presented below:

		Late Breaker AASLD Cohort [1] (N=20)		**ARCON Cohort [2] (N~50)**	
	visit	**Change from baseline [3]**	**p value**	**Change from baseline [3]**	**p value**
ALT	week 24	-20.88	<.0001	-16.44	<.0001
	week 48	-20.05	<.0001	-17.43	<.0001
AST	week 24	-15.08	<.0001	-13.43	<.0001
	week 48	-14.74	<.0001	-13.28	<.0001
FIB-4	week 24	-0.22	0.0006	-0.27	<.0001
	week 48	-0.23	0.0012	-0.22	0.0006
PRO-C3	week 24	-8.83	0.0010	-9.68	<.0001
	week 48	-13.79	0.0005	-13.00	<.0001
PRO-C3 %	week 24	-15.89	0.0106	-13.84	0.0077
	week 48	-19.76	0.0294	-17.37	0.0192
≥1 point in fibrosis improvement		60%			

1. Number of subjects in the AASLD cohort at week 24 and week 48 respectively are; ALT 19 and 9, AST 19 and 9, FIB-4 19 and 9, PRO-C3 19 and 10

2. Number of subjects in the ACRON cohort with data at week 24 and week 48 respectively are; ALT 61 and 18, AST 61 and 18, FIB-4 56 and 18, PRO-C3 43 and 15

3. MMRM baseline adjusted analysis

4. ProC-3 were analyzed by Nordic Bioscience using an improved methodology with higher sensitivity and specificity. Mean Baseline 47.2 ug/L.

Prof. Vlad Ratziu, Professor of Hepatology, Sorbonne Université, the ARMOR study co-principal investigator commented: "this high rate of fibrosis reversal is very encouraging particularly since it was confirmed by a very stringent pathological review that includes 3 pathologists reading slides according to a predefined protocol. Moreover, it is backed by congruent changes in fibrosis biomarkers and by a biochemical response in aminotransferases already documented in the ARREST trial."

Allen Baharaff, President and CEO of Galmed commented "Aramchol's direct effect on fibrosis is translated to clinical efficacy on fibrosis improvement. Apparently, the magnitude of the statistical and clinical effects is dose related. Once elevating the dose, we are starting to see the full potential of Aramchol to reduce liver fibrosis. We believe Aramchol at a higher dose stands out as a leading compound for the treatment of liver fibrosis."

A late-breaking poster presentation covering liver histology data of the first 20 patients from the Open Label Part of the ARMOR study 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 from November 12-15, 2021.

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-blind controlled, placebo part, designed to evaluate the safety and efficacy 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.

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https://galmedpharma.investorroom.com/2021-11-08-Galmed-Announces-New-Positive-Data-from-Ongoing-ARMOR-Study-Open-Label-Part-Showing-Clinically-Significant-Effect-on-Fibrosis-Improvement