

Galectin Therapeutics Reports Third Quarter 2014 Financial Results and Provides Update on Company's Development Program

NORCROSS, Ga., Nov. 10, 2014 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today reported its financial results for the third quarter and nine months ended September 30, 2014. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the Securities and Exchange Commission. The Company also provided an update on its development program.

According to Peter Traber, M.D., Chief Executive Officer, President and Chief Medical Officer, Galectin Therapeutics, "In the past three months, we have continued progress in our development program. We were pleased to have data from cohorts 1 and 2, as well as, interim data from nine completed patients from cohort 3 of our Phase 1 clinical trial of GR-MD-02, our patent-protected proprietary galectin inhibitor, in patients with NASH with advanced fibrosis presented at the American Association for the Study of Liver Diseases meeting (The Liver Meeting) on November 9, 2014. We were gratified to have the data presented at this forum, which represents the largest and most prestigious liver meeting in the world, attended by thousands of physicians, scientists and researchers from around the globe."

"The presentation at AASLD's The Liver Meeting was delivered by Stephen A. Harrison, M.D., Chief of Hepatology at Brooke Army Medical Center in Fort Sam Houston," continued Dr. Traber. "Dr. Harrison represented an outstanding group of principal investigators at leading medical institutions in the U.S., many of whom have authored seminal publications in liver disease, and NASH in particular. For example, Dr. Arun Sanyal was the first author on the PIVENS clinical trial (N Engl J Med 2010;362:1675-85), which represents a model for the conduct of clinical trials in NASH. Dr. Brent Neuschwander-Tetri was the first author on the recently published FLINT clinical trial (Lancet 2014 doi:10.1016/S0140-6736(14)61933-4). These are only two examples of the many contributions made by this group to the science and clinical care of patients with NASH. Galectin Therapeutics is greatly appreciative of all their efforts related to this Phase 1 clinical trial."

The overall objective of the Phase 1 study was to evaluate safety and pharmacokinetics of GR-MD-02 to provide information and support to design a Phase 2 clinical program to assess efficacy of GR-MD-02 in patients with NASH with advanced fibrosis and cirrhosis. Specifically, this Phase 1 first-in-man study evaluated the safety, tolerability, and pharmacokinetics and explored potential serum biomarkers for single and multiple doses of GR-MD-02 when administered to patients with fatty liver disease with advanced fibrosis.

The information presented by Dr. Harrison, as provided in the presentation released simultaneously with this announcement of the Company's third quarter financial results, covered a number of important areas:

- **Pre-clinical data.** Published pre-clinical data on efficacy of GR-MD-02 was reviewed as a basis for the human clinical development program. The positive effect of GR-MD-02 on advanced fibrosis and cirrhosis in animal models was highlighted.
- **Cohorts 1, 2 and 3.** Previously-reported results from the ongoing Phase 1 clinical trial including completed cohorts 1 and 2 were presented and, for the first time, interim data from completed patients from cohort 3. In the three-cohort design, eight patients (6 active drug and 2 placebo) completed cohort 1 at the 2 mg/kg dosage; nine patients (7 active drug and 2 placebo) completed cohort 2 at the 4 mg/kg dosage; and nine patients (6 active drug and 3 placebo) have so far completed cohort 3 at the 8 mg/kg dosage. Therefore, there was a similar number of patients from each of the cohorts for comparison purposes.
- **Phase 1 results.** The data showed that administration of 2, 4 and 8 mg/kg lean body weight of GR-MD-02 intravenously for four doses over 6 weeks was safe and well tolerated. Thus, the primary endpoint of the study has been met. There were no serious adverse events reported in any of the three cohorts and the mild (grade 1) adverse events possibly related to study drug were found in 3 placebo patients and only 2 patients receiving active drug.
- **Phase 1 pharmacokinetics.** In cohorts 1 and 2, pharmacokinetic data demonstrated a proportional increase in total drug exposure with doubling of the dose of GR-MD-02 with no accumulation after four doses. In newly released data from cohort 3, Dr. Harrison reported that pharmacokinetic analysis of GR-MD-02 plasma levels for the 8 mg/kg dose provides drug coverage in the upper portion of the targeted therapeutic range derived from NASH animal model studies.
- **Phase 1 biomarkers.** While there are no validated serum biomarkers for evaluation of potential therapeutic changes over time in NASH or fibrosis, a panel of serum tests were evaluated to explore potential biomarkers for use in future studies. For a test to be useful for evaluating disease activity, it is necessary that the tests have reasonably low variability over time in patients that are treated with placebo. Unfortunately, most of the putative biomarkers showed high variability within the same individual in placebo and GR-MD-02 patients, rendering them not useful as reliable biomarkers in this short-term clinical trial. Earlier results in this patient population that suggested changes in certain biomarkers were

not evident with increased numbers of placebo patients for comparison after cohort 3.

- **FibroTest[®]**. One test did indicate that there was an effect of the drug on a disease associated biomarker. FibroTest[®], a composite score that has been correlated with the extent of liver fibrosis, was significantly reduced by GR-MD-02 treatment in cohort 3. This change was attributable to a reduction in serum alpha-2 macroglobulin, a protein long studied in liver disease. This reduction was only evident at the 8 mg/kg dose, and indicates some dose-dependent pharmacodynamic effect of GR-MD-02.

"Based on the robust pre-clinical efficacy and positive safety, tolerability and pharmacokinetics in the Phase 1 clinical trial and a pharmacodynamic effect, the Company is in a position to design a strong Phase 2 clinical trial to assess potential surrogate endpoints that are closely associated with clinical-related outcomes in patients with cirrhosis, including hepatic venous pressure gradient (HVPG) and morphometric analysis of collagen on liver biopsies," continued Dr. Traber. "To this end, the Company recently met with the U.S. Food and Drug Administration (FDA) to discuss a proposed design of a Phase 2 clinical trial and other activities in support of a Phase 2 trial. The company has determined its Phase 2 trial will be in NASH patients with cirrhosis with evaluation of portal hypertension (hepatic venous pressure gradient) as the primary endpoint and the amount of collagen as a key secondary endpoint. Further details of the clinical trial will be announced prior to initiation. We are finalizing the clinical plans and expect to begin a Phase 2 clinical trial in the second quarter of 2015. We are extremely pleased with the progress of the GR-MD-02 development program and continue to believe firmly that a galectin inhibitor such as our GR-MD-02 has a potential role to play in treatment of liver fibrosis."

"Based on the positive results of the Phase 1 clinical trial, there is adequate data to proceed with a phase 2 program," noted Dr. Traber. "For this reason, we will terminate the enrollment of additional patients in the Phase 1 trial and complete the additional 4 patients that are currently undergoing treatment, providing a total of 13 patients in cohort 3."

Dr. Traber added, "We also significantly enhanced our patent portfolio recently with the issuance of U.S. Patent No. 8,828,971 entitled Galactose-Pronged Carbohydrate Compounds for the Treatment of Diabetic Nephropathy and Associated Disorders. Also, we received a notice of allowance for patent application number 13/573,442 titled "Composition of Novel Carbohydrate Drug for Treatment of Human Diseases." This patent covers composition and chemical structural claims for compounds that includes the Company's lead galectin inhibitor compound GR-MD-02 and will not expire until December 2031; and an additional notice of allowance which further broadens the Companies intellectual property protection for patent application number 14/456,644 titled "Composition of Novel Carbohydrate Drug for Treatment of Human Diseases" which amongst other items, covers processes of making our lead compound from a variety of various pectin sources and will not expire until 2031. Finally, we recently announced a significant addition to our board of directors in the election of Gilbert S. Omenn, M.D., Ph.D. Dr. Omenn's wealth of experience and knowledge will be an outstanding resource for the company."

"Following our announcement of the second cohort results of our Phase 1 clinical trial of GR-MD-02, a number of shareholder lawsuits were filed against Galectin Therapeutics and certain of its directors and officers alleging breaches of fiduciary duties and/or violations of the federal securities laws," noted Dr. Traber. "We dispute the allegations underlying these complaints, which are primarily based on misinterpretations of the GR-MD-02 Phase 1 second cohort results and erroneous allegations relating to Galectin Therapeutics' engagement of outside firms to promote the Company. We intend to vigorously defend against these allegations and claims and intend to seek dismissal of the litigation. We have filed motions requesting that the litigation be transferred from Nevada to Georgia, where the Company is headquartered. We expect that the costs we incur defending against this litigation will be covered by directors' and officers' liability insurance, subject to the applicable policy retention. For more information on the litigation, see our litigation disclosure in our September 30, 2014 Form 10-Q."

At September 30, 2014, the Company had \$31.2 million of non-restricted cash and cash equivalents which it believes will be sufficient to fund currently planned future operations, research and development through mid-2016.

For the quarter ended September 30, 2014, the Company reported a net loss applicable to common stock of \$3.8 million, or (\$0.17) per share, basic and diluted, compared with a net loss applicable to common stock of \$3.7 million or (\$0.22) per share, basic and diluted, for quarter ended September 30, 2013.

Research and development expense for the third quarter of 2014 was \$2.0 million, compared with \$1.2 million for third quarter of 2013. The increase in research and development expense in the second quarter of 2014 over 2013 primarily relates to increased costs for our Phase 1 clinical trial and pre-clinical costs related to preparation for a planned Phase 2 clinical trial.

General and administrative expense for the third quarter of 2014 was \$1.4 million, compared with \$2.4 million for the second quarter of 2013. The primary reason for the decrease was a \$0.9 million non-cash stock-based compensation due to the modification recorded in September 2013 of certain vested options held by a former board member to extend the contractual exercise period to the original expiration dates as opposed to 90 days after service on the board ended.

About Galectin Therapeutics

Galectin Therapeutics (Nasdaq:GALT) is developing promising carbohydrate-based therapies for the treatment of fibrotic liver

disease and cancer based on the Company's unique understanding of galectin proteins, key mediators of biologic function. We are leveraging extensive scientific and development expertise as well as established relationships with external sources to achieve cost effective and efficient development. We are pursuing a clear development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

Forward Looking Statements

This press release contains, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as "may," "estimate," "could," "expect" and others. They are based on our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements. These statements include those regarding our plans, expectations and goals regarding clinical trials, including our expectation that final clinical data from the third cohort should be available in January 2015, plans regarding a Phase 2 clinical trial, and plans regarding future funding alternatives and the sufficiency of cash on hand to fund future operations and planned research and development through mid-2016. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that our plans, expectations and goals regarding any clinical trial or any future trials are subject to factors beyond our control and there is no guarantee that we will avoid delays in the development of our drug products or receive FDA approval for any of our drugs in development. Any current clinical trials and any future trials may not produce positive results in a timely fashion, if at all, and any necessary changes during the course of a trial could prove time consuming and costly. We may have difficulty in enrolling candidates for testing, which would impact our estimates regarding timing, and we may not be able to achieve the desired results. Upon receipt of FDA approval, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse impact on our ability to achieve revenues from any proposed indications. Plans regarding development, approval and marketing of any of our drugs, including GR-MD-02, are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. To date, we have incurred operating losses since our inception, and our ability to successfully develop and market drugs may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2013, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc.

Condensed Consolidated Statements of Operations

	Quarter Ended		Nine Months	
	September 30,		Ended September 30,	
	2014	2013	2014	2013

(in thousands, except per share data)

Operating expenses:

Research and development	\$ 1,979	\$ 1,192	\$ 6,345	\$ 4,293
General and administrative	1,498	2,353	5,351	5,007
Total operating expenses	3,477	3,545	11,696	9,300
Total operating loss	(3,477)	(3,545)	(11,696)	(9,300)

Other income (expense):

Interest and other	12	3	29	11
Loss from equity method investment	(53)	--	(390)	--
Total other income (expense)	(41)	3	(361)	11

Net loss	<u>\$(3,518)</u>	<u>\$(3,542)</u>	<u>\$(12,057)</u>	<u>\$(9,289)</u>
Preferred stock dividends and accretion costs	(335)	(181)	(935)	(784)
Warrant modification	--	--	--	(8,763)
Net loss applicable to common stock	<u>\$(3,853)</u>	<u>\$(3,723)</u>	<u>\$(12,992)</u>	<u>\$(18,836)</u>
Basic and diluted net loss per share	\$ (0.17)	\$ (0.22)	\$ (0.60)	\$ (1.15)
Shares used in computing basic and diluted net loss per share	22,051	16,988	21,732	16,438

Condensed Consolidated Balance Sheet Data

September 30, December 31,

2014 2013

(in thousands)

Cash and cash equivalents	\$ 31,201	\$ 10,489
Total assets	31,319	10,713
Total current liabilities	1,380	2,486
Total liabilities	1,380	2,486
Total redeemable, convertible preferred stock	6,722	6,746
Total stockholders' equity	\$ 23,217	\$ 1,481

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