Galectin Therapeutics Reports Q1 2019 Financial Results and Provides Business Update

May 10, 2019

Subscription rights to purchase Galectin Therapeutics, Inc. common shares, with accompanying warrants, mailed to Holders of Record as of April 29.
Rights expire at 5:00 PM Eastern on May 23, 2019

Portion of the Net Proceeds of Rights Offering to be used for Phase 3 clinical trial of belapectin, the first drug to show positive results in a clinical trial in patients with compensated NASH cirrhosis

NORCROSS, Ga., May 10, 2019 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results and provided a business update for the three months ended March 31, 2019. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the U.S. Securities and Exchange Commission and is available at **www.sec.gov**.

Harold H. Shlevin, Ph.D., President and Chief Executive Officer of Galectin Therapeutics, said, “The past quarter we continued to prepare for a Phase 3 clinical trial program with our proprietary compound, belapectin (formerly known as GR-MD-02), the first drug to show positive results in a clinical trial in patients with compensated NASH cirrhosis without esophageal varices. We further announced our Rights Offering as the means chosen to raise equity capital in a cost-effective manner, which also provides all of our existing stockholders the opportunity to participate. We intend to use the net proceeds from this offering for general working capital purposes and for a portion of the cost of our NASH-RX Phase 3 clinical trial evaluating the efficacy of our drug candidate belapectin for the treatment of NASH cirrhosis patients without esophageal varices.

“We are making progress with our preparations for the Phase 3 trial. A Clinical Research Organization (CRO) to run the clinical trial has been selected and engaged, and we are also in the latter stages of a process that would enlarge and strengthen our management team. Beyond our NASH trial, there have been encouraging developments in other paths forward for belapectin, as illustrated by a presentation made at the Keystone Symposia on Molecular and Cellular Biology, where Dr. Sturgill, a researcher at Providence Portland Medical Center, discussed the effects belapectin had when combined with various T-cell targeting immunotherapies, including both aOX40 and Pembrolizumab (KEYTRUDA®). The trial involving belapectin and KEYTRUDA at Providence Portland reported a favorable Objective Response Rate (ORR) in the first 3 cohorts.”

Richard E. Uihlein, Chairman of the Board, added, “I was originally drawn to Galectin Therapeutics as an investor for its goal to save and change lives, as well as its potential return. Now that we prepare to commence our NASH-RX Phase 3 clinical trial, under my board leadership we are changing our lead strategy for equity raises. As the critical first step in the financial plan to fund the trial, we have commenced our Rights Offering through which we will turn first to our stockholder base for additional funding. This will give all of our stockholders, large and small, the ability to maintain their *pro-rata* ownership or increase their ownership percentage if they so choose to oversubscribe, and I invite my co-investors to invest along side of me.

“My intention is to personally subscribe $20 million dollars in this offering, which alone will be a significant portion of the total we hope to raise in this round. I hope this Rights Offering will be viewed as equitable and fair by our stockholder base, many of whom have been invested in our company for many years, and by others who invest with us in the future.”

Summary of Key Development Programs and Updates

- Filed a Registration Statement on Form S-3 with the U.S. Securities and Exchange Commission (SEC) with regards to a planned Rights Offering of common stock and warrants to its stockholders and certain warrant holders. The offering states that the company seeks to raise $50 million to $70 million. The Registration Statement is now effective, and the Rights Offering has commenced.

- Released an open letter to stockholders written by Richard E. Uihlein, Board Chair. In the letter, Mr. Uihlein states that he intends to personally subscribe $20 million in the Company’s Rights Offering.

- The official nonproprietary, generic name for GR-MD-02 is now belapectin. The United States Adopted Names (USAN) Council is responsible for selecting simple, informative and unique nonproprietary (generic) drug names. Recently the USAN assigned the name belapectin to GR-MD-02.

Scientific Presentations and Conferences

- Dr. Elizabeth Sturgill of Providence Cancer Institute presented findings on belapectin at the 2019 Keystone Symposia on Molecular and Cellular Biology, March 25 in Keystone, Colorado. In the oral presentation titled “Galectin-3 Inhibition with GR-MD-02 Synergizes with T Cell-Targeting Immunotherapy, Leading to Reduced Immune Suppression and Improved Overall Survival,” Dr. Sturgill discussed the effects belapectin had when combined with various T-cell targeting immunotherapies, including both aOX40 and Pembrolizumab (KEYTRUDA). Dr. Sturgill also gave a poster presentation titled “Galectin-3 inhibition with belapectin synergizes with agonist anti-OX40 mAb therapy leading to reduced immune suppression and improved overall survival.”

- Dr. Elizabeth Sturgill's talk described how combination therapies with belapectin have been shown to improve the survival rate of tumor-bearing mice, reducing the percentage of suppressive myeloid cells (MDSC) as well as diminishing the cells' suppressive capabilities. Belapectin acts as an inhibitor of galectin-3, a molecule found in many tumors and associated with poor prognosis because it depresses immune response to the tumor. Under the direction of Brendan D. Curti, M.D., Member and Director, Providence Melanoma Program and Cytokine and Adoptive Immunotherapy Program, Phase 1 human trials at Providence Cancer Institute using KEYTRUDA in combination with belapectin have borne out the preclinical results, with patients in the trial showing stronger responses than expected with KEYTRUDA alone. Recent analysis confirms the preliminary findings and suggests that reduced M-MDSCs may serve as a potential biomarker for response to treatment.

- Dr. Harold Shlevin presented at the H.C. Wainwright Global Life Sciences Conference, held at the Grosvenor House in London on April 9.

- Dr. Harold Shlevin participated in the Roth Capital Partners Battle of the NASH Thrones Investor Conference, held on March 28 in New York City.

Dr. Shlevin concluded, "We are very excited to be embarking on a Phase 3 program using belapectin in treatment of compensated NASH cirrhotic patients. We look forward to the continued support of our stockholders in this undertaking. In particular, Mr. Uihlein has been a staunch supporter of the Company and his efforts have been instrumental in helping us advance our development programs targeted to assisting patients with NASH cirrhosis."

Financial Results

For the three months ended March 31, 2019, the Company reported a net loss applicable to common stockholders of $9.1 million, or $0.20 per share, compared to a net loss applicable to common stockholders of $4.5 million, or $0.12 per share, for the three months ended March 31, 2018. The increase was caused by a one-time, non-cash $6.6 million charge related to extending the life of warrants held by the holder of the Company's Series B preferred stock in connection with the conversion of all the Series B preferred stock into common stock. Results also reflect lower preclinical, clinical and non-cash stock-based compensation expenses in the current period compared to the year ago period.

Research and development expense for the three months ended March 31, 2019, was $0.6 million compared with $2.3 million for the three months ended March 31, 2018. The decrease primarily relates to a reduction in costs for the NASH-CX Phase 2 clinical trial as it wound down, and lower preclinical costs. General and administrative expense for the three months ended March 31, 2019, were $1.7 million, compared to $1.9 million for the three months ended March 31, 2018, primarily due to a decrease in non-cash stock-based compensation expenses somewhat offset by higher legal costs.

As of March 31, 2019, the Company had $7.0 million of cash and cash equivalents. The Company also has a $10 million unsecured line of credit, under which no borrowings have been made to date. The Company believes it has sufficient cash, including availability under the line of credit, to fund currently planned operations and research and development activities through at least March 31, 2020. The currently planned operations do not include costs related to a planned Phase 3 clinical trial. While the costs of the trial and general overhead during the Phase 3 trial are expected to be approximately $100 million, the costs and timing of such trial are not yet finalized. The Company has not made commitments for such trial that cannot be covered with available cash.

About Galectin Therapeutics

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug belapectin (formerly known as GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein which is directly involved in multiple inflammatory, fibrotic, and malignant diseases for which it has Fast Track designation by the U.S. Food and Drug Administration. The lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis, and in combination immunotherapy for advanced melanoma and other malignancies; advancement of these additional clinical programs is largely dependent on finding a suitable partner. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. Additional information is available at **www.galectintherapeutics.com**.

Forward Looking Statements

This press release contains 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 management's current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin's development program for belapectin will lead to the first therapy for the treatment of fatty liver disease with cirrhosis and those regarding the hope that our lead compounds will be successful in the treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis and in cancer immunotherapy and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company's currently planned clinical trial and any future clinical studies may not produce positive results in a timely fashion, if at all, and could prove time consuming and costly; plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies; regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital, including in its

Rights Offering, that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report on Form 10-K for the year ended December 31, 2018, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2019	**2018**
	(in thousands, except per share data)	
Operating expenses:		
Research and development	$ 646	$ 2,298
General and administrative	1,721	1,880
Total operating expenses	2,367	4,178
Total operating loss	(2,367)	(4,178)
Other income (expense):		
Interest and other	(8)	(80)
Total other income	(8)	(80)
Net loss	(2,375)	(4,258)
Preferred stock dividends	(96)	(285)
Non-cash charge related to warrant modification	(6,622)	--
Net loss applicable to common stock	$ (9,093)	$ (4,543)
Basic and diluted net loss per share	$ (0.20)	$ (0.12)
Shares used in computing basic and diluted net loss per share	44,975	37,284

Condensed Consolidated Balance Sheet Data

	March 31, 2019	**December 31, 2018**
	(in thousands)	
Cash and cash equivalents	$ 6,972	$ 8,253
Total assets	7,830	9,006
Total current liabilities	907	2,108
Total liabilities	988	2,108
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 5,119	$ 5,175

Source: Galectin Therapeutics Inc.