Galectin Therapeutics Reports Fiscal 2019 Financial Results and Provides Business Update

March 16, 2020

Addition of Pol F. Boudes, M.D. as Chief Medical Officer strengthens executive team for launch of Galectin's NASH-RX trial for the prevention of esophageal varices in patients with NASH cirrhosis

NORCROSS, Ga., March 16, 2020 (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 year ended December 31, 2019. These results are included in the Company's Annual Report on Form 10-K, 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 focus of the past few months has been on finalizing the refinements to our planned NASH-RX trial based on feedback from the U.S. Food and Drug Administration (FDA). Our Adaptive-Designed Phase 2b/3 trial protocol is nearly complete, and we anticipate initiating the trial in the second quarter of 2020. We have been very successful working with our partners to modify our initial trial design, incorporating a new biostatistics element to verify the rate of varices development and accordingly adjust trial sizing to help assure a key assumption related to the rate of varices development is met. Most recently, we strengthened our executive team with the addition of Dr. Pol F. Boudes, a Chief Medical Officer who has experience running NASH drug trials. In addition, as a result of the modifications to our trial, our clinical research organization Covance has been able to identify additional international clinical trial sites. Drug manufacturing capacity has been established to meet the needs of the entire trial. Belapectin (formerly known as GR-MD-02) is the first drug that has been shown to prevent the development of esophageal varices in patients with compensated NASH cirrhosis. If confirmed, these results would constitute a significant benefit for patients."

Richard E. Uihlein, Chairman of the Board, added, "I am extremely pleased with the progress achieved over the past few months. We are now in the final stages of finalizing our NASH-RX trial, which improves the likelihood of showing belapectin's effects. And, with the recent addition of Dr. Boudes as Chief Medical Officer, we have a strong executive with extensive experience conducting trials of this nature. As always, our goal is to provide a therapy for the growing NASH epidemic around the world."

NASH-RX Trial Update

The NASH-RX trial is planned to use an adaptive design, confirm dose selection and reaffirm the efficacy data observed in the NASH-CX trial and, with pre-planned adaptations, inform the larger Phase 3 trial component. The adaptive design being considered allows pre-planned adjustments of the trial that may include, amongst other factors, optimization of dose selection, confirmation of efficacy and proof of concept observed in the NASH-CX trial, optimized sizing and statistical powering of the Phase 3 component, and possible inclusion of more advanced cirrhotic patients. We believe that these adaptations taken together should optimize conduct of the NASH-RX trial giving belapectin (GR-MD-02) the best opportunity to show a positive therapeutic effect. If the results of the NASH-RX trial are compelling, there could be the potential for accelerated FDA approval and/or partnership opportunity with a large pharmaceutical company.

The trial protocol is based on feedback from several interactions with the FDA during the last few months of 2019, including the November 14, 2019, telephone conference which included the FDA and Company representatives along with its co-primary investigators, biostatistical experts and other experts at Covance. In this meeting, the FDA indicated the new design was reasonable (subject to review of the protocol), and FDA indicated that they were still supportive of the surrogate end-point concepts originally proposed.

We believe the study design potentially could improve the likelihood of showing drug efficacy because:

- It clarifies and reaffirms NASH-CX efficacy and safety at two distinct drug doses supported by robust pharmacokinetic analysis
- It provides for appropriate selection of optimal dose – e.g., single dose (2 or 4 mg/kg) for Phase 3 component
- A separate Hepatic Impairment study may allow inclusion of more severe patients who are believed to have a much higher rate of esophageal varices progression and bleeding and other decompensating events
- Reduced frequency of esophagogastroduodenoscopys (EGD), elimination of biopsy endpoints and elimination of hepatic venous pressure gradient (HVPG) testing may make it easier to enroll trial patients and retain these patients during the duration of the trial
- Adaptation to size and power calculations based on sample size re-estimation and the interim analysis will allow better estimates of Phase 3 cohort sizing and of statistical power
- A planned interim analysis after 18 months of completed treatment will assess affirmation of Phase 2 efficacy and safety results, help select a single optimal dosage, and inform the Phase 3 stage of the study, including its size

In the Phase 3 component of this trial, the primary endpoint is development of new esophageal varices. Patients already enrolled for the Phase 2b component of the trial will continue on the selected single dose into the Phase 3 component of the trial. Patient selection for both Phase 2b and 3 components will be based on routine clinical signs of portal hypertension, including, amongst others, the presence or absence of varices, depressed platelet count (thrombocytopenia), enlargement of the spleen size and evidence of collateral blood vessels by imaging. The current study design and protocol are subject to modification after review by FDA.

The focus and goal of the therapeutic program is to prevent the development of large esophageal varices, which are strongly correlated with patient

mortality due to sudden and severe bleeding. Based on the results of the NASH-CX trial, the clinical program will focus on patients who are at increased risk of developing varices, i.e. patients who have clinical signs of portal hypertension, such as low platelet counts or increased spleen size (splenomegaly).

The key milestones and associated target dates for the NASH-RX trial will be announced as elements of design of the trial are finalized based on the recent FDA feedback. However, we currently expect the first patient to be initiated in the second quarter of 2020. The study overall will likely involve approximately 130 sites in 11 countries in North America, Europe, Asia, and Australia.

Other Updates

- Announced that Pol F. Boudes, M.D. has been appointed Chief Medical Officer - a key development for the company as it nears launch of its NASH-RX trial, an adaptively-designed Phase 3 trial in NASH cirrhosis. Dr. Boudes' diverse background in drug development, especially his experience in NASH and other liver diseases, bolsters Galectin's global advanced clinical development of belapectin for NASH cirrhosis.

Peer-reviewed publication, Scientific Presentations and Conferences

- *Gastroenterology,* a prominent journal in the field of gastrointestinal disease, published a peer reviewed paper titled, *"Effects of Belapectin, an Inhibitor of Galectin-3, in Patients with Nonalcoholic Steatohepatitis with Cirrhosis and Portal Hypertension,"* highlighting the potential prevention of esophageal varices of its NASH-CX Phase 2 clinical trial in NASH cirrhosis. We were greatly honored that such a prestigious, peer-reviewed publication felt the quality of our science merited the industry-wide attention they provide.

- Initial results of the efforts at Galectin Sciences LLC (our majority-owned subsidiary) were presented by Dr. E. Zomer, Ph.D., Vice President, Discovery Research and Product Development, at the 3rd Annual Anti-Fibrotic Drug Development (AFDD) Summit regarding Galectin's discovery program of its next generation of oral galectin-3 inhibitors. The presentation entitled *"Therapeutic Integrin Inhibition,"* discussed the next generation of galectin-3 inhibitors, as well as the discovery of functional allosteric inhibitors.

Financial Results

For the year ended December 31, 2019, the Company reported a net loss applicable to common stockholders of $13.6 million, or ($0.26) per share, compared to a net loss applicable to common stockholders of $15.0 million, or ($0.38) per share for the full year 2018. The decrease is largely due a decrease in general and administrative expenses, primarily stock-based compensation, and preferred stock dividends, somewhat offset by an increase in research and development expense.

Research and development expense for 2019 was $7.5 million compared with $6.5 million for 2018. The increase was primarily due to costs related to our NASH-RX clinical trial planning and site start-up and qualification processes globally, along with preparations and some preclinical activities incurred in support of the planned clinical program, such as development and reproductive toxicity studies, clinical supplies and other supportive activities, somewhat offset by lower non-cash stock compensation expenses. General and administrative expenses for 2019 were $6.0 million, down from $7.1 million for the full year 2018, primarily due to a decrease in non-cash stock-based compensation expenses.

As of December 31, 2019, the Company had $47.5 million of cash and cash equivalents. During 2019, the company effected a Rights Offering which, together with other common stock and warrants issued, raised $50.5 million in net proceeds. 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 September 30, 2021.

The Company expects that it will require more cash to fund operations after September 30, 2021 and believes it will be able to obtain additional financing as needed. The total cost to obtain the interim efficacy data of the planned trial, including general overhead, is currently estimated to be approximately $125 million; however, the costs and timing of such trial are not yet completely finalized. These costs will require additional funding. There can be no assurance that we will be successful in obtaining financing to support our operations beyond September 30, 2021, or, if available, that any such financing will be on terms acceptable to us.

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 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 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 trial endpoints required by the FDA may not be achieved; 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 as modified to meet the requirements of the FDA may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be 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 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. Global factors such as coronavirus may limit access to NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. 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, 2019, 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

	Year Ended December 31, 2019	2018
Operating expenses:		
Research and development	$ 7,467	$ 6,471
General and administrative	5,971	7,131
Total operating expenses	13,438	13,602
Total operating loss	(13,438)	(13,602)
Other income (expense):		
Interest income	231	38
Interest expense	(87)	(336)
Total other income	144	(298)
Net loss	$ (13,294)	$ (13,900)
Preferred stock dividends	(263)	(1,147)
Warrant modification	(6,622)	-
Net loss applicable to common stock	$ (20,179)	$ (15,047)
Basic and diluted net loss per share	$ (0.39)	$ (0.38)
Shares used in computing basic and diluted net loss per share	52,238	39,414

Condensed Consolidated Balance Sheet Data

	December 31, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	$ 47,480	$ 8,253
Total assets	48,467	9,006
Total current liabilities	2,820	2,108
Total liabilities	2,872	2,108
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 43,872	$ 5,175

Source: Galectin Therapeutics Inc.