Galectin Therapeutics Reports 2021 Financial Results and Provides Business Update

March 31, 2022

NORCROSS, Ga., March 31, 2022 (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, 2021. 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**.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said: “Reiterating my comments from our shareholders meeting in December, I am proud of our team and their accomplishments during 2021. It was a challenging year for many companies, particularly in biotech and drug development. Our experienced new team coalesced in identifying and addressing pertinent issues with a prescience that was indicative of their accumulated experience and extensive backgrounds. While we are always cognizant of the ultimate goal of registering a new drug, our primary focus throughout 2021 and now continues to be the enrollment of our adaptively designed Phase 2b/3 NAVIGATE trial for the prevention of esophageal varices in patients with NASH cirrhosis. Many clinical trials in the past two years have experienced difficulties in enrollment, and we have been no exception. For several reasons, the pandemic makes enrolling patients for the NAVIGATE trial more challenging than most trials. Patients eligible for the NAVIGATE trial have liver cirrhosis and, as such, are at a greater health risk of complications from COVID-19. Additionally, our patient population tends to display other comorbidities, including diabetes and obesity. It is also important to consider the safety of our candidate participants first, as cirrhotic patients with portal hypertension are immunocompromised. We believe that as we continue to emerge from the COVID-19 pandemic, site recruitment and patient enrollment will accelerate and we have experienced increases in enrollment, particularly in the U.S and Mexico. However, we have not seen the enrollment in Europe that we anticipated, and conditions there remain uncertain. Consequently, we have activated multiple sites in Latin America and believe this will overcome our challenges in Europe. This decision was made in advance of current conditions. At this time, while we continue to target enrollment completion for June 30, 2022, ultimately it may require an additional quarter to complete.”

Mr. Lewis continued, “Late in 2021, we engaged three noted physicians – Dr. Chetan Bettegowda, from Johns Hopkins, and Dr. Nishant Agrawal and Dr. Ari Rosenberg, both from University of Chicago Medical Center – as consultants to help define the path forward in oncology. In consultation with our oncology experts, we have now selected the treatment of recurrent or metastatic head and neck cancer as the lead indication to pursue for belapectin in combination with Keytruda, an immune checkpoint inhibitor. The decision is notably based on the lack of available treatments for these patients, the low response rates of monotherapy, the limited number of therapies in development, and the resulting very high medical need. We are currently working to compile an Investigational New Drug (IND) package, including the development of a phase 2 trial protocol, with the objective for the Company to file an IND with the FDA oncology division.”

Dr. Pol Boudes, Chief Medical Officer stated: “I continue to be confident that the NAVIGATE trial will be fully enrolled despite the challenges we have seen related to the COVID-19 pandemic. Additionally, I am pleased to report we recently completed enrollment in a Hepatic Impairment Study, a very important study to include in our New Drug Application (NDA) dossier. The Hepatic Impairment Study was being conducted at four sites and involved 38 subjects (divided amongst normal healthy volunteers, and patients with mild, moderate, and severe hepatic impairment). Each subject received a single infusion of belapectin (4 mg/kg LBM) and their serum belapectin levels were monitored for up to approximately two weeks to define the effects of various stages of cirrhosis on belapectin pharmacokinetics. The tolerance and safety of belapectin are also being evaluated.”

Financial Results

For the year ended December 31, 2021, the Company reported a net loss applicable to common stockholders of $30.7 million, or ($0.52) per share, compared to a net loss applicable to common stockholders of $23.6 million, or ($0.41) per share for the year ended December 31, 2020. The increase is largely due to an increase in 2021 research and development expenses related to the Company’s NAVIGATE trial.

Research and development expenses for the year ended December 31, 2021, was $23.8 million compared with $18.0 million for the year ended December 31, 2020. The increase was primarily due to costs related to our NAVIGATE clinical trial and other supportive activities. General and administrative expenses for the year ended December 31, 2021, were $6.4 million, compared to $5.5 million for the year ended December 31, 2020. The increase was primarily due to non-cash stock-based compensation expense and insurance expense.

As of December 31, 2021, the Company had $39.6 million of cash and cash equivalents. On December 20, 2021, the Company received $10 million in proceeds from an unsecured convertible promissory note from its Board Chairman, Richard E. Uihlein. The Company received a total of $30 million in unsecured promissory notes from Mr. Uihlein in 2021. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through at least March 31, 2023.

The Company expects that it will require more cash to fund operations after March 31, 2023, and believes it will be able to obtain additional financing as needed. Currently, we expect to require an additional approximately $45-$50 million to cover costs of the NAVIGATE trial to reach the planned interim analysis estimated to occur around the end of the first quarter of 2024, along with drug manufacturing and other research and development activities and general and administrative costs. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us.

About Belapectin

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs, including fibrotic disorders of the liver, lung, kidney, heart and vascular system. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis, and these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial (www.NAVIGATEnash.com), titled “A Seamless Adaptive Phase 2b/3, Double-Blind,

Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis," began enrolling patients in June 2020, and is posted on www.clinicaltrials.gov (NCT04365868). Galectin-3 has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Company-sponsored Phase 2 development program, which the company is exploring.

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis

Non-alcoholic steatohepatitis (NASH) has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is the only curative treatment available. Approximately 9,000 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

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 current 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 continue to impact 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, 2021, 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,	
	2021	**2020**
Operating expenses:		
Research and development	$ 23,818	$ 17,976
General and administrative	6,361	5,468
Total operating expenses	30,179	23,444
Total operating loss	(30,179)	(23,444)
Other income (expense):		
Interest income	3	66

Interest expense	(489)	(87)
Change in fair value of derivatives	138	
Total other income	(348)	(21)
Net loss	$ (30,527)	$ (23,465)
Preferred stock dividends	(171)	(137)
Net loss applicable to common stock	$ (30,698)	$ (23,602)
Basic and diluted net loss per share	$ (0.52)	$ (0.41)
Shares used in computing basic and diluted net loss per share	58,527	57,029

Condensed Consolidated Balance Sheet Data

	December 31, 2021	December 31, 2020
	(in thousands)	
Cash and cash equivalents	$ 39,648	$ 27,142
Total assets	41,827	29,600
Total current liabilities	9,033	5,399
Total liabilities	39,211	5,407
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 893	$ 22,470