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Galectin Therapeutics Reports Second Quarter 2016 Financial Results and Provides Business Update

Top-line data from NASH-FX trial in NASH patients with advanced fibrosis expected to be reported by the end of September

Australian patent allowance strengthens global intellectual property franchise

NORCROSS, Ga., Aug. 09, 2016 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today reported financial results for the three and six months ended June 30, 2016. These results are included in the Company's Form 10-Q, which has been filed with the U.S. Securities and Exchange Commission and is available at www.sec.gov.

Summary of Key Development Programs, Updates and Anticipated Milestones

- 1 Completed recruitment in a Phase 2 clinical trial with GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with cirrhosis (stage 4) (the NASH-CX trial), wherein patient recruitment was completed slightly ahead of our original expectations
- 1 Completed enrollment in Phase 2 clinical trial with GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with advanced fibrosis (stage 3) (the NASH-FX trial)
- 1 Positive preclinical results were presented at the American Thoracic Society (ATS) 2016 International Conference in which GR-MD-02 had shown a positive effect on vascular remodeling in an animal model of pulmonary arterial hypertension (PAH)
- 1 Presented interim results from an exploratory, open-label, Phase 2a clinical trial with GR-MD-02 in patients with moderate-to-severe plaque psoriasis in which patients showed significant improvement in their plaque psoriasis

Management Commentary

"We are very pleased with the significant progress achieved this quarter completing enrollment in two important clinical trials, gaining further global protection of our intellectual property, and presenting further evidence of the positive effects of GR-MD-02 in new and exciting applications," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "Most immediately, with enrollment in our NASH-FX trial in NASH patients with advanced fibrosis (stage 3) having been completed on schedule in May, we are on pace to report top-line data assessing the efficacy of GR-MD-02 by the end of September. And, with recruitment also completed for our Phase 2 NASH-CX trial, we will be able to assess the efficacy of GR-MD-02 in up to 156 patients with non-alcoholic steatohepatitis (NASH) with cirrhosis. Patient recruitment for this trial was completed slightly ahead of our original expectations and we anticipate to report top line results in December 2017, as previously planned."

With its NASH trials investigating liver applications, Galectin is also exploring other applications of its lead compound. This quarter, the Company received encouraging results on two early stage studies. In an early stage investigation of applicability to vascular remodeling in pulmonary arterial hypertension (PAH), investigators from the Vascular Biology Center and the Department of Pharmacology and Toxicology at Augusta University presented data at the American Thoracic Society (ATS) 2016 International Conference, in which GR-MD-02 had shown a positive effect in an animal model of PAH. David Fulton, Ph.D., director of the Vascular Biology Center at Augusta University, noted that the alterations in cardiopulmonary function and vascular proliferation, as well as in fibrosis were significantly attenuated by in vivo treatment with specific gal-3 inhibitors, with our lead compound obviously being a gal-3 inhibitor.

Separately, interim results from an exploratory, open-label, Phase 2a clinical trial with GR-MD-02 in patients with moderate-to-severe plaque psoriasis, in which four patients who received 12 weeks of therapy had significant improvement in their plaque psoriasis, led to the extension of the treatment duration to 24 weeks. These interim results demonstrate a potentially important clinical effect of GR-MD-02 in clearing moderate-to-severe plaque psoriasis.

In the quarter, the Company also received Notice of Allowance from the Australian Government Patent Office for patent application for "Composition of Novel Carbohydrate Drug for Treatment of Human Diseases" that, from the date they are issued and through 2032, will extend coverage of GR-MD-02 to Australia to treat patients at risk of non-alcoholic steatohepatitis (NASH), fibrosis, inflammatory and autoimmune disorders in which galectins are at least in part involved. The allowance of these claims further strengthens the protection of the intellectual property behind GR-MD-02. This is but one of more than 50 patent applications the Company has pending in 10 foreign countries, all of which are viewed as significant

markets for the active pharmaceutical ingredient (API) or the manufacture of the API. When issued, this patent will augment Galectin's current intellectual property portfolio for treatment of liver fibrosis, kidney fibrosis, lung fibrosis or heart fibrosis.

The investigator-sponsored trials utilizing GR-MD-02 in combination with checkpoint inhibitors being conducted by Galectin's partners at the Providence Portland Cancer Center, who are also funding the studies, continue to advance. The study of GR-MD-02 in combination with Yervoy® and Keytruda® in two separate Phase 1b trials in patients with metastatic melanoma is expected to yield data from the Yervoy combination trial by the end of the year."

Galectin Therapeutics is exhibiting a steady pattern of progress throughout and across the organization not only with its primary investigations, but in new and evolving applications as well. As such, its addressable market increases from the still very large \$35 billion, understood to be available just from the treatment of NASH, to an even larger sum when considering psoriasis, PAH and potentially other maladies. Each of these efforts is based on a very systematic approach to advancing development whereby Galectin is moving methodically along the development path while simultaneously branching out into adjacent and complementary markets whenever the science warrants a new investigation. Allied with very strong medical professionals who are conducting these trials and investigations, Galectin's management team is doing everything within its power to optimize the value of the organization, its intellectual property, and the other assets at its disposal.

Financial Results

For the three months ended June 30, 2016, the Company reported a net loss applicable to common stockholders of \$5.8 million, or \$0.20 per share, compared with a net loss applicable to common stockholders of \$4.9 million, or \$0.21 per share, for the three months ended June 30, 2015. The increase is largely due to higher research and development expenses primarily related to the Phase 2 clinical program in NASH.

Research and development expense for the three months ended June 30, 2016 was \$4.2 million, compared with \$2.6 million for the three months ended June 30, 2015. The increase primarily relates to costs for the Phase 2 clinical trials begun in 2015, partially offset by lower preclinical costs.

General and administrative expense for quarter was \$1.3 million, compared with \$2.1 million for the prior year, with the decrease being to severance and non-cash stock compensation and lower legal and accounting fees.

As of June 30, 2016, the Company had \$18.0 million of non-restricted cash and cash equivalents. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through June 30, 2017.

About Galectin Therapeutics

Galectin Therapeutics is developing promising therapies for the treatment of fibrotic liver disease and cancer based on the Company's unique understanding of galectin proteins, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. 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 GR-MD-02 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 connection with cancer immunotherapy. 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 GR-MD-02 or any of its other drugs in development; the Company's current 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 that would allow it to further develop and/or fund current or future 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, 2015, 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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Yervoy® is a registered trademark of Bristol-Myers Squibb

Keytruda® is a registered trademark of Merck & Co.

Condensed Consolidated Statements of Operations

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
	(in thousands, except per share data)			
Operating expenses:				
Research and development	\$ 4,226	\$ 2,600	\$ 8,603	\$ 5,736
General and administrative	1,305	2,057	3,742	3,761
Total operating expenses	5,531	4,657	12,345	9,497
Total operating loss	(5,531)	(4,657)	(12,345)	(9,497)
Other income:				
Interest and other	12	14	26	28
Total other income	12	14	26	28
Net loss	\$ (5,519)	\$ (4,643)	\$ (12,319)	\$ (9,469)
Preferred stock dividends and accretion costs	(308)	(288)	(518)	(536)
Net loss applicable to common stock	\$ (5,527)	\$ (4,931)	\$ (12,837)	\$ (10,005)
Basic and diluted net loss per share	\$ (0.20)	\$ (0.21)	\$ (0.44)	\$ (0.43)
Shares used in computing basic and diluted net loss per share	29,023	23,731	29,001	23,398

Condensed Consolidated Balance Sheet Data

	<u>June 30, 2016</u>		<u>December 31, 2015</u>	
	<u>(in thousands)</u>			
Cash and cash equivalents	\$	18,003	\$	25,846
Total assets		18,247		26,408
Total current liabilities		3,636		1,360
Total liabilities		3,636		1,360
Total redeemable, convertible preferred stock		7,124		7,008
Total stockholders' equity	\$	7,487	\$	18,040

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