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# GR-MD-02 Demonstrates Clinically Significant Effect in Patients with Severe and Refractory Atopic Dermatitis (Eczema)

NORCROSS, Ga., March 14, 2017 (GLOBE NEWSWIRE) -- **Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, today announced preliminary results for severe and refractory atopic dermatitis from a small, open label, investigator-initiated study with GR-MD-02 that has enrolled 3 patients. There were no serious adverse events observed. All three patients showed clinical response as determined by reduction of the Eczema Area and Severity Index (EASI) score at week 12 having received 6 every other week doses, with two patients achieving a 64% and 74% reduction in EASI, respectively, at six weeks after receiving only 3 doses of GR-MD-02 (see graph below). These findings are believed to demonstrate a clinically significant effect of this novel investigational drug in this patient population. More information and commentary on these findings can be found in a simultaneously released CEO Perspective: http://perspectives.galectintherapeutics.com/galectin-inhibitor-therapy-effective-severe-atopic-dermatitis-eczema/.

A photo accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/254ebcff-519a-41b0-8f1a-e9c9be2b09ee

Simon A. Ritchie, M.D., FAAD, lead investigator and staff dermatologist, San Antonio Military Health System, Fort Sam Houston, TX, said "There is a lack of effective therapy currently on the market for patients with severe, refractory atopic dermatitis. As a galectin-3 inhibitor, GR-MD-02, represents a novel mechanism for treatment in patients with severe atopic dermatitis that have failed standard of care. The significant clinical effect we have seen from preliminary results in this investigator-initiated protocol is encouraging and warrants a phase 2 controlled trial with various doses and regimens to further explore the drug's potential."

Photo

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The small, open label, investigator-initiated protocol treated three adult patients with severe atopic dermatitis. All three patients had failed a number of systemic therapies and would be classified as refractory, meaning that they have not responded to medical treatment beyond topical steroids. The disease severity was determined using EASI, an objective scoring system in common use for atopic dermatitis studies. GR-MD-02 was given intravenously at a starting dose of 8 mg/kg at baseline and then every other week for 10 weeks (6 infusions) and then increased to 12 mg/kg every other week for an additional 7 infusions. All three patients experienced improvement in their atopic dermatitis, with patient 1 achieving a 64% reduction in EASI at 24 weeks, the time of his 13$^{th}$ infusion. While patient 1 has completed the full 13 infusions, patients 2 and 3 have just started the higher dose of 12 mg/kg. It should be noted that patient 1 has elected to remain on 24 additional weeks of therapy because of the positive effect on his clinical symptoms.

"We are pleased by the results of this study demonstrating the safety and clinically significant effect in patients with severe atopic dermatitis, although because of the potential of a placebo effect in this disease, confirmation of the magnitude of the effect will require placebo-controlled trials," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer, Galectin Therapeutics. "Moreover, the activity of GR-MD-02 in these patients compares favorably with other drugs currently in development, and with minimal side effects as demonstrated by nearly 3,000 doses of our compound being administered in multiple completed and ongoing clinical trials with no severe adverse effects attributed to the drug."

**About Atopic Dermatitis**
Atopic dermatitis, commonly called eczema, is a chronic inflammatory condition of the skin of caused by multiple factors that usually arises in early childhood, often in infancy. While it usually resolves by early teenage years, approximately 5-10% of patients have the disease extend into adulthood. Classic symptoms are itching and burning of the skin, resulting in thickening of the skin in response to the scratching. In some adults, it can be severe with debilitating itching, inability to sleep, and social stigmatization due to skin damage and thickening, often on the face.

Surveys suggest that up to 18% of the population have atopic dermatitis, up to 37% of those people seek medical care, and over 70% of those seeking care have mild disease that is handled by primary care physicians. Approximately 20% with mild and 2% with severe disease are referred to specialists. The national estimated cost of treatment is as high as $3.8 billion,

as of 2012.

**About GR-MD-02**
GR-MD-02 is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease 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. The drug binds to galectin proteins and disrupts their function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis.

**About Galectin Therapeutics**
Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver and skin diseases and cancer. Galectin's lead drug (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. 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. 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, and use words such as "may," "estimate," "could," "believe", "expect" and others. They are based on 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 a therapy for the treatment of atopic dermatitis, psoriasis and other skin diseases, as well as fibrotic and cancer. 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. 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 complete its current trials or further develop and/or fund further 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.

Contacts:

Jack Callicutt, Chief Financial Officer

(678) 620-3186

ir@galectintherapeutics.com

Primary Logo

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