



Galectin Therapeutics Update on the Impact of COVID-19

April 2, 2020

NORCROSS, Ga., April 02, 2020 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins today provided an update on the impact of the COVID-19 pandemic on the Company and its clinical trial activities.

As the global COVID-19 pandemic continues to quickly evolve, we have put measures in place intended to safeguard the health of our employees in line with many other companies. In doing so, we aim to do our part to help slow the spread of COVID-19 in our communities and protect our employees and their families, all while continuing the critical work necessary to initiate and conduct our NASH-RX clinical trial for patients with NASH cirrhosis.

In accordance with guidance issued by the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO) and local authorities, our employees are working remotely from home. We are now leveraging digital communication technologies to continue important interactions with healthcare professionals, patients and other stakeholders. We remain committed to completing and filing the NASH-RX protocol with the US Food and Drug Administration (FDA) in the near term. To date, we have suffered no significant financial hardships, delays or loss of any employees or contractors related to COVID-19.

The COVID-19 pandemic has substantially impacted the global healthcare delivery system including the conduct of clinical trials. As appropriate, many healthcare systems and providers have understandably prioritized caring for those suffering from COVID-19 and redirected resources in support of the broader community currently. This burden on the healthcare system has also impaired the ability of many clinical research centers to start new studies, enroll new patients and/or continue ongoing clinical trials. Most importantly, we must consider the risk to the patients of asking them to leave their homes and travel in an environment governmental authorities have deemed unsafe. At this time and as previously communicated, we plan to initiate the NASH-RX trial during the second quarter of 2020; however, this may be impacted by the COVID-19 pandemic.

Galectin Therapeutics Inc. has developed several overarching principles to guide its conduct of clinical research in light of COVID-19. Number one among these is the safety of patients, site personnel and our own employees. In addition, several health authorities have provided guidance for the conduct of clinical trials during this pandemic and suggestions related to assuring study integrity and the value of the data. Following this guidance, we can report the following actions and developments:

Galectin Therapeutics and the team at Covance, our CRO, are focused on those activities that we can directly control. For example, these include the completion of protocol and associated documents for new clinical trials and filing of protocols and associated documents with regulatory agencies, both in the US and internationally. This also includes numerous activities in conjunction with Covance and external vendors to ensure all internal systems such as study databases, adjudication systems, laboratory systems, data monitoring committee charters and the like are fully ready when trial sites are willing to restart their clinical research activities.

Clinical supply distribution and related activities with our external vendors are so far only minimally impacted. However, this could change in the coming weeks and months. Fortunately, we currently have an adequate supply of belapectin. External activities directed toward specific site start-up activities such as pre-study visits (using virtual techniques) by Covance employees, site contracting activities, training activities and site-directed ethic committee submissions will continue moving forward in conjunction with the site principal investigators and site coordinators, as well as with managers of the NASH site-specific network we are using.

We remain strongly committed to initiating our adaptive Phase 3 trial as soon as reasonably possible considering COVID-19. We are doing everything we can to minimize disruption and delays in site-related activities and patient enrollment and striving to do so in a safe and considerate manner. Further information will be forthcoming as we all navigate this situation.

Our hearts and thoughts go out to everyone whose lives have been seriously affected by COVID-19, and to our medical professionals on the front lines who are combating the virus.

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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Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc. Belapectin is the USAN assigned name for Galectin Therapeutics' galectin-3 inhibitor GR-MD-02



Source: Galectin Therapeutics Inc.