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Tekmira Initiates Phase I Clinical Trial of TKM-HBV

TKM-HBV, a Leading RNAi Approach to Reduce Hepatitis B Surface Antigen, Has the Potential to Play a Central Role in the Cure of Chronic Hepatitis B Virus Infection

VANCOUVER, British Columbia, Jan. 21, 2015 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, announced today that it has dosed the first subject in a Phase I clinical trial of TKM-HBV, a therapeutic agent designed to reduce hepatitis B surface antigen in patients chronically infected with hepatitis B virus (HBV).

"We are pleased to have reached this important milestone, initiation of phase I studies with TKM-HBV. Since TKM-HBV represents our most important development program, we are testing two LNP formulations, generations three and four, of the product in this study. We expect the results to determine which product formulation we will advance into chronically infected patients later this year," said Dr. Mark J. Murray, Tekmira's President and CEO.

The TKM-HBV Phase I clinical trial is a randomized, single-blind, placebo-controlled study, involving single ascending doses of TKM-HBV. The study will assess the safety, tolerability and pharmacokinetics of intravenous administration of two formulations of TKM-HBV in healthy adult subjects. For each formulation, there are five planned cohorts for a total of 20 subjects (40 in total for both formulations). Four subjects will be enrolled per cohort with three subjects receiving TKM-HBV, and one receiving placebo.

About TKM-HBV

The goal of TKM-HBV is to facilitate hepatitis B surface antigen (HBsAg) loss in patients with chronic hepatitis B. The continued presence of HBsAg in chronic HBV is believed to be responsible for disease pathogenesis and impairing the body's ability to clear the virus. Blocking HBsAg may lead to a functional cure by promoting immune-mediated clearance and control of HBV, potentially through HBsAg seroconversion. TKM-HBV is a novel lipid nanoparticle (LNP) formulated RNAi therapy that uniquely targets three highly conserved regions of the HBV viral genome. Targeting multiple sites on the HBV genome allows for potent reduction of multiple viral antigens, knockdown across a broad range of HBV genotypes, and a decrease in the probability of developing antiviral resistance. Preclinical studies with TKM-HBV have shown reductions of HBsAg and other important viral markers across the most prevalent HBV genotypes, demonstrating that TKM-HBV has the potential to treat patients with chronic HBV.

About HBV

The hepatitis B virus (HBV) is a DNA virus belonging to the Hepadnaviridae family of viruses. There are more than two billion people infected globally with HBV and 350 million have become chronically infected with HBV. In the United States there are approximately 1.4 million HBV chronically infected individuals. Almost 100,000 new people are infected with HBV annually and an estimated 5,000 Americans die each year from HBV and its complications. Current treatments are able to suppress HBV if taken indefinitely, but these do not typically lead to a functional cure, and viral rebound is observed upon treatment stoppage. (Source: WHO, CDC, Decision Resources)

About RNAi and Tekmira's LNP

RNAi therapeutics have the potential to treat a number of human diseases by "silencing" disease causing genes. The discoverers of RNAi, a gene silencing mechanism used by all cells, were awarded the 2006 Nobel Prize for Physiology or Medicine. RNAi trigger molecules often require delivery technology to be effective as therapeutics. Tekmira believes its LNP technology represents the most advanced and widely adopted delivery technology for the systemic delivery of RNAi triggers. Tekmira's LNP platform is being utilized in multiple clinical trials in various disease areas by Tekmira and its partners. Tekmira's LNP technology (formerly referred to as stable nucleic acid-lipid particles or SNALP) encapsulates RNAi triggers with high efficiency in uniform lipid nanoparticles that are effective in delivering these therapeutic compounds to disease sites. Tekmira's LNP formulations are manufactured by a proprietary method which is robust, scalable and highly reproducible, and LNP-based products have been reviewed by multiple regulatory agencies for use in clinical trials. LNP formulations comprise several lipid components that can be adjusted to suit the specific application.

About Tekmira

Tekmira Pharmaceuticals Corporation is a biopharmaceutical company focused on advancing novel RNAi therapeutics and providing its leading lipid nanoparticle (LNP) delivery technology to pharmaceutical and biotechnology partners. Tekmira has been working in the field of nucleic acid delivery for over a decade, and has broad intellectual property covering its delivery technology. Further information about Tekmira can be found at www.tekmira.com. Tekmira is based in Vancouver, Canada and Seattle, USA.

Forward-Looking Statements and Information

This news release contains "forward-looking statements" or "forward-looking information" within the meaning of applicable securities laws (collectively, "forward-looking statements"). Forward-looking statements in this news release include statements about Tekmira's strategy, future operations, clinical trials, prospects and the plans of management; RNAi as a leading approach in the treatment of HBV; TKM-HBV representing a central role in the treatment and potential cure of HBV; initiation of the Phase I clinical study in human healthy volunteers with two formulations of TKM-HBV comprising a third generation LNP and a new fourth generation LNP, which contains novel lipid chemistry and has shown improved potency in certain pre-clinical studies; and to progress to chronically infected patients later in the year; the effects and potency of Tekmira's product TKM-HBV to reduce hepatitis B surface antigen in patients with chronic hepatitis B infection; and estimations of unmet demands for TKM-HBV.

With respect to the forward-looking statements contained in this news release, Tekmira has made numerous assumptions regarding, among other things: LNP's status as a leading RNAi delivery technology; the effectiveness of RNAi therapeutics in the treatment of hepatitis B virus; and the results of pre-clinical studies. While Tekmira considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Additionally, there are known and unknown risk factors which could cause Tekmira's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: RNAi based therapeutics may not prove to be effective in the treatment of hepatitis B virus as currently anticipated, compared to other therapeutics, or at all; TKM-HBV may not prove to have any significance in the treatment of HBV; a cure for HBV may never be discovered; Tekmira may not initiate all the clinical trials for TKM-HBV as currently anticipated, or at all; the FDA or other regulatory agencies may refuse to approve Tekmira's products, or place restrictions on Tekmira's ability to commercialize its products; anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; future operating results are uncertain and likely to fluctuate; economic and capital market conditions; and the possibility that Tekmira may not have sufficiently budgeted for expenditures necessary to carry out planned activities.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's Annual Report on Form 10-K and Tekmira's continuous disclosure filings, which are available at www.sedar.com and www.sec.gov. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Tekmira disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

Additional Information and Where to Find It

Tekmira plans to file with the Securities and Exchange Commission (the "SEC") and mail to its stockholders a proxy statement in connection with the proposed Merger. The proxy statement will contain important information about the proposed Merger and related matters. INVESTORS AND STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT CAREFULLY IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE. Investors and stockholders will be able to obtain free copies of the proxy statement and other documents filed with the SEC by Tekmira through the SEC's website at www.sec.gov and from Tekmira by contacting Investor Relations by telephone at (604) 419-3200 or upon written request addressed to our corporate secretary at Tekmira Pharmaceuticals Corporation, 100 - 8900 Glenlyon Parkway, Burnaby, BC, Canada, V5J 5J8 or by going to Tekmira's Investor section on its corporate web site at www.tekmira.com.

Tekmira and its executive officers and directors may be deemed to be participants in the solicitation of proxies from the stockholders of Tekmira in connection with the proposed Merger. Information regarding the interests of these executive officers and directors in the transaction described herein will be included in the proxy statement described above. Additional information regarding these executive officers and directors is also included in Tekmira's Annual Report on Form 10-K, which was filed with the SEC on March 28, 2014, and is supplemented by other public filings made, and to be made, with the SEC by Tekmira. The Annual Report on Form 10-K and other public filings are available free of charge through the SEC's website at www.sec.gov and from Tekmira by contacting Investor Relations by telephone at (604) 419-3200 or upon written request addressed to our corporate secretary at Tekmira Pharmaceuticals Corporation, Tekmira Pharmaceuticals Corporation, 100 -

8900 Glenlyon Parkway, Burnaby, BC, Canada, V5J 5J8 or by going to Tekmira's Investor section on its corporate web site at www.tekmira.com.

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