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Tekmira Initiating Phase I/II Clinical Trial in Patients with Hepatocellular Carcinoma

VANCOUVER, British Columbia, May 27, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today announced they have met all regulatory requirements to initiate a Phase I/II clinical trial of TKM-PLK1 in patients with Hepatocellular Carcinoma (HCC). Tekmira is also conducting a separate Phase I/II clinical trial evaluating TKM-PLK1 in patients with Gastrointestinal Neuroendocrine Tumors (GI-NET) or Adrenocortical Carcinoma (ACC).

"Hepatocellular carcinoma is associated with one of the poorest survival rates in oncology, and clearly new therapies are needed. We are encouraged with the positive data from our GI-NET and ACC clinical studies with TKM-PLK1 and there is sound rationale for evaluating this agent in HCC," said Dr. Mark J. Murray, Tekmira's President and CEO.

"We are excited about reaching another important milestone for Tekmira by launching this new clinical trial, and also remain on track to share results from our GI-NET/ACC trial in the second half of this year," added Dr. Murray.

This trial is an open-label, multi-center, Phase I/II dose escalation study in patients with advanced hepatocellular carcinoma. The study is designed to determine the safety, tolerability and clinical benefit of TKM-PLK1. The study will be conducted at sites in North America and Asia.

About Hepatocellular Carcinoma (HCC)

Hepatocellular carcinoma (HCC) is one of the most common cancers worldwide and the third most common cause of cancer-related death worldwide. HCC is overwhelmingly related to chronic liver disease, particularly hepatitis B and [hepatitis C](#). Patients with HCC usually are asymptomatic until later stages. The prognosis of HCC generally is very poor, with a median survival of six to 20 months and less than five percent of symptomatic patients surviving more than two years. 350,000 to 1 million cases of HCC occur every year worldwide. (source: www.clinicalkey.com)

About TKM-PLK1

Tekmira's lead oncology product candidate, TKM-PLK1, targets polo-like kinase 1 (PLK1), a protein involved in tumor cell proliferation and a validated oncology target. Inhibition of PLK1 expression prevents the tumor cell from completing cell division, resulting in cell cycle arrest and death of the cancer cell. PLK1 has been a target of interest for years, and evidence that patients with elevated levels of PLK1 in their tumors exhibit poorer prognosis and survival rates has been documented in the medical literature. By using an RNAi approach and exploiting its naturally occurring mechanism of action, Tekmira can potentially overcome the limitations of other approaches and effectively silence PLK1.

About RNAi and Tekmira's LNP

RNAi therapeutics have the potential to treat a broad 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 therapeutics, such as "siRNAs," require delivery technology to be effective systemically. Tekmira believes its LNP technology represents the most widely adopted delivery technology for the systemic delivery of RNAi therapeutics. Tekmira's LNP platform is being utilized in multiple clinical trials by both Tekmira and its partners. Tekmira's LNP technology (formerly referred to as stable nucleic acid-lipid particles or SNALP) encapsulates siRNAs with high efficiency in uniform lipid nanoparticles that are effective in delivering RNAi therapeutics to disease sites in numerous preclinical models. 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 FDA divisions 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 delivery technology to pharmaceutical partners. Tekmira has been working in the field of nucleic acid delivery for over a decade and has broad intellectual property covering LNPs. Further information about Tekmira

can be found at www.tekmirapharm.com. Tekmira is based in Vancouver, B.C.

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 the initiation of a Phase I/II Clinical Trial with TKM-PLK1 in patients with HCC; a separate Phase I/II Clinical Trial with TKM-PLK1 evaluating TKM-PLK1 in patients with GI-NET or ACC and expected results of this trial in the second half of this year; the effectiveness of Tekmira's products over other approaches in silencing PLK1; and Tekmira's strategy, future operations, clinical trials, prospects and the plans of management; RNAi (ribonucleic acid interference) product development programs.

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 Tekmira's products as therapeutic treatments for diseases; and mRNA is efficiently delivered using Tekmira's LNP. 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: the Phase I/II Clinical Trial with TKM-PLK1 in patients with HCC may not complete as expected, or at all; the Phase I/II Clinical Trial with TKM-PLK1 evaluating TKM-PLK1 in patients with GI-NET or ACC may not complete as expected, or at all; Tekmira's products may not prove to be effective as therapeutic treatments for diseases; Tekmira's LNP may not be as efficient of a delivery system for mRNA as currently believed; Tekmira may not obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; Tekmira may face competition from other pharmaceutical or biotechnology companies and the possibility that other organizations have made advancements in RNAi delivery technology that Tekmira is not aware of; pre-clinical and clinical trials may be more costly or take longer to complete than anticipated and may not generate results that warrant future development of the tested drug candidate; Tekmira's development partners and licensees conducting clinical trial, development programs and joint venture strategic alliances may not result in expected results on a timely basis, or at all; future operating results are uncertain and likely to fluctuate; economic and capital market conditions; Tekmira may become subject to product liability or other legal claims for which Tekmira has made no accrual in its financial statements; 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 for the year ended December 31, 2013 (Annual Report), as well as Tekmira's continuous disclosure filings, which are available at www.sedar.com or at 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.

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