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Tekmira Provides Update on TKM-PLK1 Phase I/II Clinical Study in Patients With Advanced Gastrointestinal Neuroendocrine Tumors and Adrenocortical Carcinoma

VANCOUVER, British Columbia, Dec. 31, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today provided a status update on the Phase I/II clinical study in patients with advanced Gastrointestinal Neuroendocrine Tumors (GI-NET) and Adrenocortical Carcinoma (ACC).

Tekmira today reported that:

- Enrolment of the target patient numbers in these Phase I/II studies has been completed;
- To date, 55 patients, in the both the Phase I and Phase I/II studies have been treated at doses of ≥ 0.6 mg/kg, considered to be in the efficacious dose range based on preclinical studies. Of these, 31 patients comprise the target population of GI-NET or ACC patients;
- Nine GI-NET and ACC patients remain actively on treatment, and data collection is ongoing;
- The Company continues to see evidence of anti-tumor activity in some treated subjects, including one ACC patient with an almost complete resolution of their disease;
- Final data from these studies is expected in mid-2015.

"Having completed enrolment in these studies, we will follow these patients to measure the responses observed with TKM-PLK1 in patient groups where there are very few, if any, treatment options," said Dr. Mark J. Murray, Tekmira's President and CEO. "We are on track to report complete study results and determine the TKM-PLK1 development path forward next year."

About Gastrointestinal Neuroendocrine Tumors (GI-NET)

Neuroendocrine tumors (NETs) refer to a group of unusual and complex cancers that affect neuroendocrine cells, with those arising in the gastrointestinal tract referred to as GI-NET. A Surveillance Epidemiology and End Results (SEER) database analysis demonstrates a dramatic five-fold increase in the incidence of neuroendocrine tumors from 1973 to 2004. Incidence of GI-NET is predicted to continue to rise at a faster rate than other malignant tumors.

Each year an estimated 8,000 people in the United States are diagnosed with a neuroendocrine tumor that starts in the gastrointestinal tract, which includes the stomach, intestine, appendix, colon, or rectum. There is a poor prognosis for advanced metastatic NETs, with survival rates for GI-NET ranging from five to 56 months. (Source: American Cancer Society, and www.neuroendocrinetumor.com)

About Adrenocortical Carcinoma (ACC)

Adrenocortical Carcinoma is a rare cancer that forms in the outer layer of tissue of the adrenal gland (a small organ on top of each kidney that makes steroid hormones, adrenaline, and noradrenaline to control heart rate, blood pressure, and other body functions). Adult adrenocortical carcinoma tumors are aggressive with a very poor prognosis. Between 60%-70% of patients at the time of diagnosis are found to have stage III or IV disease. These patients have a survival rate of 40%, or less, with a known recurrence rate between 70% and 90%.

As adrenocortical carcinomas are so rare, there has been only limited prospective evaluation of treatment strategies. Very few, if any, universally accepted treatment standards have been identified. (Source: American Cancer Society)

About TKM-PLK1 Phase I/II Clinical Trial Targeting GI-NET/ACC

This ongoing TKM-PLK1 Phase I/II clinical trial is currently targeting two indications: GI-NET and ACC. This trial is a multi-center, single arm, open label study designed to measure efficacy using Response Evaluation Criteria in Solid Tumors and tumor biomarkers for GI-NET patients, as well as to evaluate TKM-PLK1's safety, tolerability and pharmacokinetics. TKM-PLK1, which employs a unique lipid nanoparticle (LNP) formulation for oncology applications, is administered weekly with each four-week cycle consisting of three once-weekly doses followed by a rest week. Tekmira has achieved its target enrolment for the Phase I/II trials of TKM-PLK1.

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 (ribonucleic acid interference) product development programs; and the development of TKM-PLK1 for the treatment of two therapeutic oncology indications: advanced Gastrointestinal Neuroendocrine Tumors (GI-NET) and Adrenocortical Carcinoma (ACC); and a status report of the Phase I/II clinical study with TKM-PLK1 in patients with GI-NET or ACC.

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. 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: TKM-PLK1 may not prove to be effective in the treatment of GI-NET or ACC; complete study results in the second half of 2015, may not generate results that permit advancing the product into further clinical studies; Tekmira's products may not prove to be effective or as potent as currently believed; the FDA may refuse to approve Tekmira's products, or place restrictions on Tekmira's ability to commercialize its products; 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; 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; and economic and capital market conditions.

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 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.

CONTACT: Investors

Julie P. Rezler

Director, Investor Relations

Phone: 604-419-3200

Email: jrezler@tekmira.com

Media

Please direct all media inquiries to media@tekmira.com