



August 13, 2014

## **Tekmira Provides Corporate Update and Announces Second Quarter 2014 Results**

### **Conference Call at 5:00 pm Eastern Time Today**

VANCOUVER, British Columbia, Aug. 13, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today announced its financial and operating results for the second quarter ended June 30, 2014 and provided a corporate update.

"We continue to monitor the tragic Ebola virus outbreak very closely. The current outbreak underscores the critical need for an effective therapeutic agent to treat the Ebola virus," said Dr. Mark J. Murray, Tekmira's President and CEO.

"We remain sharply focused on our clinical programs and the key milestones to be reached by year end. Importantly, our Hepatitis B program continues to advance, with the goal of filing an IND, or equivalent, for our TKM-HBV program in the second half of 2014. Within our TKM-PLK1 oncology platform, we expect to present Phase IIa interim data from our clinical trial with GI-NET and ACC patients before the end of this year, and we have begun enrollment in an additional Phase I/II trial targeting HCC patients," stated Dr. Murray.

### **Corporate Update**

- For the second quarter ended June 30, 2014 we had cash, cash equivalents and investments of \$129.5 million. The company has 22.1 million common shares issued and outstanding, and 24.6 million shares on a fully diluted basis.
- The single ascending dose portion of the TKM-Ebola Phase I clinical trial has been successfully completed in healthy human volunteers. As per the protocol maximum tolerated dose (MTD) was established to be 0.3 mg/kg for healthy subjects without steroid premedication.
- In July, we received notice from the U.S. Food & Drug Administration (FDA) that our TKM-Ebola program was on clinical hold. Subsequently, the company received written notice from the FDA modifying the clinical hold to a "partial clinical hold," allowing for the potential use of TKM-Ebola in individuals who have a confirmed or suspected Ebola infection. The company remains on clinical hold as it relates to the multiple-ascending dose portion of the Phase I clinical study in healthy volunteers with TKM-Ebola. The company expects this matter to be resolved by Q4 2014.
- Our therapeutic, TKM-Ebola, is currently an unapproved agent and the regulatory framework to support its use in Africa has not yet been established. Given the severity of the situation, we are carefully evaluating options for use of our investigational drug within accepted clinical and regulatory protocols. This includes discussions with government agencies and NGO's, including the WHO, in various countries on the potential use of TKM-Ebola to treat Ebola virus infected individuals. There can be no assurance that an appropriate framework for the use of this product will be found. We will continue to provide updates as necessary when clinical and regulatory pathways become confirmed.
- Within our TKM-PLK1 clinical trial targeting GI-NET and ACC patients, we saw an additional RECIST qualifying Partial Response (PR), defined as a greater than 30 percent reduction in target tumor lesions. This patient is continuing on therapy and has achieved a 44 percent reduction in their target tumor mass, located outside of the liver. Furthermore, scans of the target tumor lesions demonstrate signs of necrosis, indicative of anti-tumor activity.
- We have initiated a Phase I/II clinical study of TKM-PLK1 in patients with Hepatocellular Carcinoma (HCC).
- We intend to file an Investigational New Drug (IND) application, or equivalent, in the second half of 2014, in order to advance our TKM-HBV program into a Phase I clinical study, with initial data available in 2015.
- We received an additional \$1.5 million payment from Monsanto following completion of specified program developments.

### **Financial Results**

#### **Net loss**

The net loss for Q2 2014 was \$6.1 million (\$0.28 per common share) as compared to a net loss of \$3.0 million (\$0.21 per common share) for Q2 2013. This increased loss largely reflects expense increases of \$5.3 million offset by other income gains of \$3.1 million, relating to foreign exchange and warrant revaluation. The net loss for the first half 2014 was \$24.1 million (\$1.15 per common share) as compared to a net loss of \$5.6 million (\$0.39 per common share) for the first half of 2013. This increased loss largely reflects expense increases of \$10.6 million and other income losses of \$9.3 million relating to foreign exchange losses and warrant revaluation.

## **Revenue**

Revenue was \$1.8 million for Q2 2014 as compared to \$2.8 million for Q2 2013. Under the DoD contract to develop TKM-Ebola, Tekmira is being reimbursed for costs incurred, including an allocation of overheads, and is being paid an incentive fee. For this contract, Tekmira recorded \$0.9 million in revenue in Q2 2014 as compared to \$2.5 million in Q2 2013.

Tekmira also recorded revenue from Monsanto for research services and the use of the Company's technology. In June, Tekmira received \$1.5 million from Monsanto following the completion of specified program developments. Most of the revenue recorded under this contract is being amortized over the contract period, which was determined to be four years at inception. Monsanto revenue in Q2 was \$0.9 million.

In addition, Tekmira recorded royalty revenue from Spectrum for the commercial sales of Marqibo® during Q2 2014.

## **Research, development, collaborations and contracts expenses**

Research, development, collaborations and contracts expenses were \$9.3 million in Q2 2014 as compared to \$4.9 million in Q2 2013.

TKM-HBV expenses increased as Tekmira prepares to file an IND (or equivalent) in the second half of 2014 and TKM-PLK1 expenses increased with the expansion in the number of clinical trial sites and set-up for the HCC trial. In addition, Tekmira increased research activities related to the collaboration with Monsanto in the agricultural field.

## **General and administrative**

General and administrative expenses were \$1.8 million in Q2 2014 as compared to \$0.8 million in Q2 2013. The increase in general and administrative expense was due to an increase in compensation expense with the growth in employee base to support the expanded portfolio of product candidates.

## **Other income (losses)**

In Q2 2014, Tekmira recorded a foreign exchange loss of \$2.7 million related to the depreciation in value of U.S. dollar funds, as compared to a foreign exchange loss of \$0.06 million in Q2 2013.

The decrease in value of Tekmira's common share purchase warrants was \$5.8 million in Q2 2014 as compared to an increase in the value of common share purchase warrants outstanding of \$0.03 million in Q2 2013. The change in value is a direct result of the change in the Company's share price between reporting periods.

## **Conference Call Information**

Tekmira will hold a conference call and webcast today (Wednesday, August 13, 2014) at 2 p.m. Pacific Time (5 p.m. Eastern Time) to provide a corporate update and report financial results for the second quarter ended June 30, 2014. A live webcast of the call can be accessed through the Investor section of Tekmira's website at [www.tekmira.com](http://www.tekmira.com). Or, alternatively, to access the conference call, please dial 914-495-8556 or 1-866-393-1607.

An archived webcast will be available on the Tekmira website approximately two hours after the event. Alternatively, you may access a replay of the conference call by calling 404-537-3406 or 1-855-859-2056 and referencing conference ID 76477548.

## **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 (LNP) 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.tekmira.com](http://www.tekmira.com). Tekmira is based in Vancouver, B.C. Canada.

## 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; key milestones to be reached by year end; the filing of an IND, or equivalent, for the TKM-HBV program in the second half of 2014 in order to advance the TKM-HBV program into a Phase I clinical study, with initial data available in 2015; the presentation of Phase IIa interim data from Tekmira's clinical trial with GI-NET and ACC patients before the end of 2014; the enrollment in an additional Phase I/II trial targeting HCC patients; the partial clinical hold on TKM-Ebola by the FDA, Tekmira's response to the partial clinical hold and expectations of resolving the matter by the fourth quarter of 2014; the potential for use of TKM-Ebola in individuals who have a confirmed or suspected Ebola infection; discussions with government agencies and NGO's (including the WHO) in various countries on the potential use of TKM-Ebola to treat Ebola virus infected individuals; the appropriate framework for the use of TKM-Ebola; the initiation of a Phase I/II clinical study of TKM-PLK1 in patients with HCC; and statements with respect to revenue and expense fluctuation and guidance.

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; Tekmira's research and development capabilities and resources; the effectiveness of Tekmira's products as a treatment for cancer, chronic Hepatitis B infection, infectious disease, alcohol use disorder, or other diseases; the timing and quantum of payments to be received under contracts with Tekmira's partners including Alnylam, Spectrum, Monsanto and the DoD; and Tekmira's financial position and its ability to execute its business strategy. 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: Tekmira may not meet the milestones outlined in this news release as currently expected, or at all; the FDA may not lift the partial clinical hold placed on the TKM-Ebola program as currently anticipated, or at all, or may impose additional restrictions on the program that delay or prevent commercialization; TKM-Ebola may never be used as a treatment for Ebola; Tekmira's products may not prove to be effective or as potent as currently believed; anticipated studies and submissions to the FDA may not occur as currently anticipated, or at all; 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; Tekmira may not receive the necessary regulatory approvals for the clinical development of Tekmira's products; anticipated payments under contracts with Tekmira's collaborative partners may not be received by Tekmira on a timely basis, or at all, or in the quantum expected by Tekmira; payments received from third parties may not be sufficient to fund Tekmira's continued business plan as currently anticipated; future operating results are uncertain and likely to fluctuate; Tekmira may not be able to raise additional financing required to fund further research and development, clinical studies, and obtain regulatory approvals, on commercially acceptable terms or at all; economic and capital market conditions; and Tekmira may become subject to product liability or other legal claims for which Tekmira has made no accrual in its financial statements.

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](http://www.sedar.com) or at [www.sec.gov](http://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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Media

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