

November 13, 2012

# **Tekmira Provides Corporate Update and Announces Third Quarter 2012 Results**

## Conference Call at 7:30 am Eastern Time Today

VANCOUVER, British Columbia, Nov. 13, 2012 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, announced today its financial and operating results for the third quarter ended September 30, 2012 and provided a corporate update.

On November 12, 2012, Tekmira announced that it entered into a settlement agreement with Alnylam Pharmaceuticals, Inc. that resolves all litigation between the companies, and signed a new licensing agreement that restructures the relationship and provides clarity on all intellectual property and licensing issues between the companies. As a result of the restructuring and new agreements, Tekmira will receive \$65 million within 10 days and is eligible to receive \$10 million in near-term milestone payments expected to be received in 2013. For more information, please refer to Tekmira's news release dated November 12, 2012.

"The settlement and restructuring announced yesterday gives us, and the entire RNAi field, clarity around the intellectual property that protects our lipid nanoparticle (LNP) technology. Building upon our strong balance sheet and accomplishments to date, we are confident that we can continue to create significant, sustainable value for our shareholders. With our cash runway now extending into 2015, we are excited about our plans to aggressively advance multiple products into human clinical trials," said Dr. Mark J. Murray, Tekmira's President and CEO.

"We recognize that the primary value driver for Tekmira will be the clear demonstration of the clinical value of our own pipeline of RNAi products in a range of therapeutically important, commercially attractive markets. We expect that our lead oncology product, TKM-PLK1, will enter a Phase 2 trial in 2013; we continue to advance our TKM-Ebola product in collaboration with the U.S. Department of Defense's TMT program; and, we continue to generate data to support near-term decisions around further development of other product candidates within our pipeline. In addition, we are entitled to future royalty payments based on sales of Margibo, which was recently approved by the FDA," added Dr. Murray.

#### **Tekmira's Products**

#### TKM-PLK1

In December 2010, Tekmira announced the initiation of patient dosing in a Phase 1 human clinical trial for TKM-PLK1 in patients with advanced solid tumors. The Phase 1 clinical trial, conducted at oncology centers in the United States, is an open label, multi-dose, dose escalation study designed to evaluate the safety, tolerability and pharmacokinetics of TKM-PLK1 as well as determine the maximum tolerated dose. Secondary objectives of the trial are to measure tumor response and the pharmacodynamic effects of TKM-PLK1 in patients providing biopsies.

To date, TKM-PLK1 has been administered to 23 patients with a total of 128 doses administered. On August 14, 2012, Tekmira released interim results from the TKM-PLK1 Phase 1 study, which employs a unique LNP developed for oncology applications, showing that TKM-PLK1 was generally well tolerated. TKM-PLK1 has shown drug activity to date, including one patient with a partial response and another patient who attained stable disease. Based on these interim data, patient enrollment is continuing at 0.75 mg/kg. Once complete, results from the Phase 1 clinical trial, including additional measures of drug activity, will be presented at a forthcoming scientific meeting. Tekmira anticipates initiating a Phase 2 clinical trial in 2013.

## TKM-Ebola Update

On August 6, 2012, Tekmira announced that it had received a temporary stop-work order from the U.S. Department of Defense (DoD) with respect to Tekmira's TKM-Ebola program, which is funded under the Transformational Medical Technologies (TMT) Program. On October 2, 2012, Tekmira disclosed that the temporary stop-work order was lifted by the United States DoD and work will continue on development of the TKM-Ebola product.

Tekmira has submitted a modification request to the existing contract to the U.S. DoD in order to integrate recent advancements in LNP formulation and manufacturing technology in the TKM-Ebola development program. The program will

utilize an LNP formulation that is more than 10-fold more potent than previous formulations and more potent than all other LNP formulations currently being evaluated in clinical trials. Tekmira has initiated pre-clinical and chemistry, manufacturing and control studies that support the use of these improvements in the program. This development strategy will be accommodated by modifications to the existing contract, allowing both Tekmira and TMT to benefit from the significant advancements in LNP formulation technology made by Tekmira since the commencement of the TMT-funded program in July 2010. It is expected that the LNP formulation work will be completed and submitted to the FDA in the second half of 2013 in order to initiate a new Phase 1 clinical trial.

### Other Preclinical Candidates

Tekmira has a number of other preclinical candidates in its pipeline addressing a wide range of therapeutic needs such as alcohol dependence and additional oncology targets. The research team at Tekmira will continue to generate data to support the advancement of the most promising of these targets and expects to be in a position to nominate the next product candidate for development in the coming months.

#### **Partners' Products**

As dictated by the terms in the new licensing agreement announced yesterday, Alnylam has a license to use Tekmira's LNP technology to advance RNAi therapeutic products, and Tekmira remains eligible to receive milestones and royalties as Alnylam's LNP enabled products are developed and commercialized.

- ALN-TTR: Tekmira is entitled to receive a \$5 million milestone payment when ALN-TTR02 enters a pivotal or Phase 3
  clinical trial, which is expected to occur in 2013. Tekmira is eligible to receive royalty payments based on commercial
  sales of ALN-TTR.
- ALN-VSP: Tekmira is entitled to receive a \$5 million milestone payment related to the initiation of clinical trials for ALN-VSP in China, which is expected to occur in 2013. Tekmira is eligible to receive royalty payments based on commercial sales of ALN-VSP.
- ALN-PCS: Tekmira is eligible to receive royalty payments based on commercial sales of ALN-PCS.
- Other LNP-Enabled Products: Tekmira is eligible to receive up to an aggregate of \$16 million in milestones and royalties
  for each additional LNP-based product developed by Alnylam.

Tekmira has a number of legacy license agreements that provide potential milestone and royalty payments. Marqibo, which is a liposomal formulation of the chemotherapy drug vincristine — along with two other liposomal chemotherapy products, Alocrest and Brakiva — were licensed from Tekmira to Talon Therapeutics, Inc. in 2006. Talon is responsible for all future development of these products. On August 9, 2012, Tekmira disclosed that Talon received accelerated approval from the FDA for Marqibo® (vinCRIStine sulfate LIPOSOME injection) for the treatment of adult patients with Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. Tekmira received a US\$1 million milestone payment based on the FDA approval of Marqibo and is eligible to receive royalty payments based on Marqibo's commercial sales.

#### **Financial Results**

#### **Net Loss**

For the first nine months of 2012 (year-to-date (YTD) 2012) the Company's net loss was \$8.5 million (\$0.63 per common share) as compared to a net loss of \$8.1 million (\$0.73 per common share) for YTD 2011. For Q3 2012, net loss was \$3.4 million (\$0.25 per common share) as compared to a Q3 2011 net loss of \$1.5 million (\$0.12 per common share).

#### Revenue

Revenue was \$3.0 million in Q3 2012 as compared to \$4.2 million in Q3 2011.

On July 14, 2010, Tekmira signed a contract with the United States Government to advance an RNAi therapeutic utilizing the Tekmira's LNP technology to treat Ebola virus infection. Under the contract Tekmira is being reimbursed for costs incurred, including an allocation of overheads, and is being paid an incentive fee. U.S. Government revenue was \$1.9 million in Q3 2012 as compared to \$2.0 million in Q3 2011.

On August 6, 2012, the Company announced that it had received a temporary stop-work order from the U.S. Government in respect of its TKM-Ebola contract. On October 2, 2012, Tekmira announced that the stop-work order had been lifted and work was to be resumed. As a result of the stop-work order, U.S. Government revenue was lower than the Company had forecasted for Q3 2012 and YTD 2012.

In Q3 2012, the Company earned a US\$1.0 million milestone payment from Talon Therapeutics, Inc. based on the FDA

approval of Marqibo and will receive royalty payments based on Marqibo's commercial sales.

### Research, development, collaborations and contracts expenses

Research, development, collaborations and contracts expenses were \$3.1 million in Q3 2012 as compared to \$4.4 million in Q3 2011.

Third-party expenses on the TKM-Ebola program and Alnylam manufacturing were considerably lower in Q3 2012 as compared to Q3 2011.

Spending on Tekmira's internal research programs was reduced as the Company focused on TKM-Ebola, TKM-PLK1 and its litigation against Alnylam and AlCana.

## General and administrative expenses

General and administrative expenses were \$1.5 million in Q3 2012 as compared to \$1.2 million in Q3 2011.

The increase in Q3 2012 largely relates to legal fees incurred in respect of Tekmira's lawsuit against Alnylam and AlCana.

As at September 30, 2012, the Company had a contingent obligation to Orrick, Herrington and Sutcliffe LLP (Orrick), lead legal counsel for the lawsuit against Alnylam and AlCana of \$15,620,961 (US\$15,887,877). As a result of the settlement of the litigation between Tekmira and Alnylam on November 12, 2012 this amount, plus costs incurred after September 30, 2012, are now payable to Orrick and will be recorded in Q4 2012.

### Other income (losses) - change in fair value of warrant liability

In conjunction with equity and debt financing transactions in 2011 and an equity private placement that closed on February 29, 2012, Tekmira has issued common share purchase warrants. Under Tekmira's accounting policy, at each balance sheet date, the warrants are revalued using the Black-Scholes model and the change in value is recorded in the consolidated statement of operations and comprehensive loss. The aggregate increase in value of Tekmira's common share purchase warrants in Q3 2012 was \$1.7 million. The increase is largely a result of the increase in the Company's share price from the previous balance sheet date of June 30, 2012.

## Financial guidance

Tekmira believes that current funds on hand, plus expected income, including payments to be received from Alnylam in Q4 2012 and other funds from collaborative partners and the U.S. Government, will be sufficient to continue product development into 2015.

## **Conference Call Information**

Tekmira will hold a conference call and webcast today (Tuesday, November 13, 2012) at 4:30 am Pacific Time (7:30 am Eastern Time) to discuss its third quarter 2012 results and a corporate update, including the settlement announced yesterday. A live webcast of the call can be accessed through the Investor section of Tekmira's website at <a href="https://www.tekmirapharm.com">www.tekmirapharm.com</a>. Or, alternatively, to dial into the conference call, please call 914-495-8556 or 1-866-393-1607 and reference conference ID 70796137.

An archived webcast of this conference call will be available on the Tekmira website approximately two hours after the event. Or alternatively, you may access a replay of the conference call by calling 404-537-3406 or 1-855-859-2056 and referencing conference ID 70796137.

## **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 Alnylam RNAi Technology**

Tekmira has licenses to Alnylam RNAi intellectual property for certain siRNA programs.

#### **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 <a href="https://www.tekmirapharm.com">www.tekmirapharm.com</a>. Tekmira is based in Vancouver, B.C.

The Tekmira Pharmaceuticals logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=8319

## **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 are generally identifiable by use of the words "believes," "may," "plans," "will," "anticipates," "intends," "budgets," "could," "estimates," "expects," "forecasts," "projects" and similar expressions, and the negative of such expressions. Forward-looking statements in this news release include statements about the settlement to resolve all litigation between Tekmira and Alnylam Pharmaceuticals, Inc. and AlCana Technologies, Inc; statements about the quantum and timing of Tekmira's expected payments related to the settlement agreement and new licensing agreement with Alnylam; statements about Tekmira's expected payments from the settlement and cash runway extending into 2015; Tekmira's plans to advance multiple products into human clinical trials; expected timing of Phase 2 clinical trials for TKM-PLK1; the development of other product candidates in Tekmira's pipeline, including the expected timing for the nomination of Tekmira's next product candidate; anticipated royalty payments based on sales of Margibo; the modification request to the existing TKM-Ebola contract with the DoD to integrate recent advancements in LNP formulation and manufacturing technology; expected timing of the completion and submission of the LNP formulation work to the FDA and the initiation of a new Phase 1 clinical trial; the quantum and timing of funding that may be provided to Tekmira pursuant to the TKM-Ebola contract with the DoD; the quantum and timing of future milestone royalty payments expected from the ALN-TTR02. ALN-VSP, ALN-PCS and other LNP-enabled product development programs of Alnylam: the timing of an ALN-TTR02 pivotal or Phase 3 clinical trial; the timing of ALN-VSP clinical trials in China; milestones and royalty payments from Alnylam's LNPenabled products; Tekmira's expectations of entering into a cross license agreement with AlCana, which includes anticipated milestone and royalty payments and an expected agreement for AlCana not to compete in the RNAi field for five years; licenses for the discovery, development and commercialization of RNAi products directed to thirteen gene targets; expected royalty payments from commercial sales of Tekmira's product development partners; and Tekmira's strategy, future operations, clinical trials, prospects and the plans of management; RNAi (ribonucleic acid interference) product development programs; estimates of the number of clinical development programs to be undertaken by Tekmira and its product development partners; selection of additional product candidates; timing of release of clinical data; the effects of Tekmira's products on the treatment of cancer and infectious disease; statements and details of the TKM-PLK1 and TKM-Ebola Phase 1 human clinical trials; the quantum and timing of potential funding; use of lipid nanoparticle (LNP) technology by Tekmira's licensees; Tekmira's expectations with respect to existing and future agreements with third parties; and estimates of the length of time Tekmira's business will be funded by its anticipated financial resources.

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 a treatment for cancer or infectious disease; the developmental milestones and approvals required to trigger funding for TKM-Ebola from the TMT program; results in preclinical models are indicative of the potential effect in humans; Tekmira's research and development capabilities and resources; FDA approval with respect to commencing clinical trials; the timing and obtaining of regulatory approvals for Tekmira's products; the timing and results of clinical data releases and use of LNP technology by Tekmira's development partners and licensees; the time required to complete research and product development activities; the timing and quantum of payments to be received under contracts with Tekmira's partners including Alnylam, Talon, the DoD, and others; Tekmira's financial position and its ability to execute on its business strategy; and Tekmira's ability to protect its intellectual property rights and not to infringe on the intellectual property rights of others. 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: expected payments related to the settlement and licensing agreement between Tekmira and Alnylam may not be received in the quantum and on the timing currently anticipated, or at all; payments received from the settlement may not be sufficient to fund Tekmira's continued business plan as currently anticipated; TKM-PLK1 may never enter into Phase 2 clinical trials; Tekmira may never receive

milestones or royalty payments from Alnylam; Tekmira may not receive any additional non-exclusive licenses: the possibility that Tekmira does not enter into a cross license agreement with AlCana on the terms currently anticipated, or all; Tekmira's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; Tekmira's research and development capabilities and resources will not meet current or expected demand; Tekmira's development partners and licensees conducting clinical trial, development programs and joint venture strategic alliances will not result in expected results on a timely basis, or at all; 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; Tekmira's products may not prove to be effective in the treatment of cancer and infectious disease; the possibility that other organizations have made advancements in RNAi delivery technology that Tekmira is not aware of; the FDA will not approve the commencement of Tekmira's planned clinical trials or approve the use of Tekmira's products and generally, difficulties or delays in the progress, timing and results of clinical trials; the FDA may determine that the design and planned analysis of Tekmira's clinical trials do not adequately address the trial objectives in support of Tekmira's regulatory submissions; future operating results are uncertain and likely to fluctuate; competition from other pharmaceutical or biotechnology companies; Tekmira's ability 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; a pivotal trial for ALN-TTR02 may not start as currently anticipated, or at all; clinical trials for ALN-VSP may not commence as anticipated, or at all; anticipated payments under contracts with Tekmira's collaborative partners including the U.S. Government, Alnylam, and Talon will not be received by Tekmira on a timely basis, or at all, or in the quantum expected by Tekmira; the U.S. Government may reduce or cancel certain defense spending, including Tekmira's contract to develop TKM-Ebola: FDA may decide that TKM-Ebola "Animal Rule" data is insufficient for approval and require additional pre-clinical, clinical or other studies, refuse to approve TKM-Ebola, or place restrictions on our ability to commercialize TKM-Ebola; the release of data from the TKM-Ebola and TKM-PLK1 Phase 1 human clinical trials may not occur in the expected timeframe, or at all; the DoD may not accept the modification request to the existing TKM-Ebola to integrate recent advancements in LNP formulation and manufacturing technology; we may not complete the work necessary for the submission of the new LNP formulation to the FDA in the anticipate timeframe, or at all; we may not initiate a new TKM-Ebola Phase 1 clinical trial in the anticipated timeframe, or at all; pre-clinical and clinical trials may be more costly or take longer to complete than anticipated; pre-clinical or clinical trials may not generate results that warrant future development of the tested drug candidate; Tekmira's products may not prove to be effective in the treatment of cancer or infectious disease; Tekmira may become subject to product liability or other legal claims for which Tekmira has made no accrual in its financial statements; Tekmira's cash runway may not extend as far as anticipated, and may be substantially less than required to continue current operations; and the possibility that Tekmira has not 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 20-F for the year ended December 31, 2011 (Annual Report), which is available at <a href="https://www.sedar.com">www.sedar.com</a> or at <a href="https://www.sec.gov/edgar.shtml">www.sec.gov/edgar.shtml</a>. 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.

Marqibo is a U.S. registered trademark of Talon Therapeutics, Inc.

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