December 17, 2012

Acasti Pharma Provides an Insight of Its Current Clinical Trials Results

LAVAL, Quebec, Dec. 17, 2012 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("**Acasti**") (TSX-V:APO), a Neptune Technologies & Bioressources Inc. ("**Neptune**") subsidiary, announces a clinical study update and announces the first ever human data of safety and efficacy of its patented prescription drug candidate CaPre®.

Acasti has achieved significant progress in the two presently ongoing clinical studies. The registrational phase II double blind placebo controlled clinical study has completed its first of two interim analysis. The review committee assembled to evaluate the progress of the study reviewed the interim analysis relative to drug safety and efficacy, and agreed, unanimously, that the study should continue as planned. All committee members were convinced that there are no concerning toxicity issues and that the signals of possible CaPre® therapeutic effect, noted as reduction of triglyceride in the groups evaluated, were reassuring and clinically significant to allow the further continuation of the study. As it is customary, the data was provided to the committee members blind, meaning that the identity of the three groups was not revealed. Since the data showed no safety concerns and a strong clinical signal the decision was made, by the committee, that it is safe to continue the study and that there is no need to unblind the data.

The second phase II open label clinical study should be completed by the end of the first quarter of 2013. It has been delayed due to the need for further patient recruitment after the approved clinical trial amendment to add an additional 4g/day CaPre® treatment group, following a FDA recommendation to evaluate the effect of a 4g dose. Acasti was able to obtain completed clinical data from a cohort of patients that completed an eight-week treatment with 2g CaPre® per day, which will not be included in the primary analysis under the amended protocol. Test results of 23 patients were analysed of whom 19 had baseline triglyceride levels between 204 and 476mg/dl. The data showed a statistically significant 25% ($p<0.05$) reduction in triglycerides after eight weeks of treatment. Besides the important decrease in triglycerides, CaPre® also decreased Low Density Lipoprotein (LDL), Very Low Density Lipoprotein (VLDL) and non-HDL lipids and increased High Density Lipoprotein (HDL).

"We are pleased with the progress of our clinical efforts. Most notably, we are very satisfied with the significant impact on triglyceride even in this hard to treat population of patients in the lower strata of hypertriglyceridemia. Achieving statistical significance with such a low number of patients and only after a short eight-week treatment period definitely encourages us to push our strategy forward towards US clinical studies and validation during the upcoming year" said Harlan Waksal, M.D., Executive Vice-President, Business and Scientific affairs. "The Management's enthusiasm remains strong. We are moving forward to finalize plans for the filing of a US IND for Phase III clinical study in 2013" Dr. Waksal concluded.

"This snapshot of clinical data has given us a first look at the safety and clinical efficacy of

this very interesting drug candidate. Even within a small cohort, CaPre® has demonstrated its ability to be a valuable alternative in the control of triglycerides. This early look at data is in line with our expectation of the safety and clinical promise of this patented novel omega-3 entity" stated Dr. Jean Davignon, chairman of the review committee and Emeritus Researcher, Clinical Research Institute of Montreal (IRCM). "The lipidologists community is markedly interested in lipid residual risk reduction in the post-statin era and is always looking for effective drugs" he added.

About Acasti Pharma Inc.

Acasti Pharma is developing a product portfolio of proprietary novel long-chain omega-3 phospholipids. Phospholipids are the major component of cell membranes and are essential for all vital cell processes. They are one of the principal constituents of High Density Lipoprotein (good cholesterol) and, as such, play an important role in modulating cholesterol efflux. Acasti Pharma's proprietary novel phospholipids carry and functionalize the polyunsaturated omega-3 fatty acids EPA and DHA, which have been shown to have substantial health benefits and which are stabilized by potent antioxidants. Acasti Pharma is focusing initially on treatments for chronic cardiovascular and cardiometabolic conditions within the over-the-counter, medical food and prescription drug markets.

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Source: Acasti Pharma Inc.