

Acasti Reports Successful CaPre(R) Phase II TRIFECTA Results Proving Statistically Significant Improvements in Triglycerides & Non-HDL-C

CaPre(R) Met All Primary and Key Secondary Endpoints

- *Statistically significant mean placebo-adjusted reduction of triglycerides of 36.4% at 1 gram and 38.6% at 2 gram daily doses of CaPre®*
- *Statistically significant reduction of 5.3% in non-HDL-C using 2 grams of CaPre® daily (considered the most accurate risk marker for cardiovascular disease)*
- *No increases in LDL-C (bad cholesterol) and slight increases in HDL-C (good cholesterol)*
- *Clinically meaningful mean placebo-adjusted reduction in VLDL-C of 10.9% and 13.5% at 1 gram and 2 gram daily doses CaPre®, respectively (VLDL-C is considered a highly significant predictor of cardiovascular disease)*
- *Statistically significant dose dependent improvement in Omega-3 Index (a risk factor for coronary heart disease)*
- *CaPre® shown to be safe, well tolerated and effective*

LAVAL, Quebec, Sept. 29, 2014 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("**Acasti**" or the "**Corporation**") (Nasdaq:ACST) (TSX-V:APO), an emerging biopharmaceutical company, announces successful top-line results for its Phase II double blind, placebo controlled trial (TRIFECTA) assessing the safety and efficacy of CaPre® for the treatment of patients with hypertriglyceridemia. CaPre®, Acasti's investigational new drug candidate, is composed of a patent-protected highly concentrated novel omega-3 phospholipid for the prevention and treatment of certain cardiometabolic disorders.

"These positive results further indicate that CaPre® may be an important treatment option to safely and effectively reduce triglycerides," highlighted Andre Godin, Acasti's Interim President and Chief Executive Officer. "High plasma triglyceride concentrations have been identified as an independent risk factor for cardiovascular disease."

"Not only did we see a highly statistically significant reduction in triglycerides on patients taking daily doses of 1 gram or 2 grams of CaPre®, we also observed a significant reduction in non-HDL-C," added Dr. Harlan W. Waksal, M.D., a member of Acasti's Board of Directors. "The results are even more notable when you consider that the majority of patients had mild to moderate hypertriglyceridemia. Based on omega-3 published clinical data and results from our previously completed Phase II Open Label (COLT) study, greater benefits could be achieved in patients with severe hypertriglyceridemia, using higher dosages of CaPre®, including 4 grams."

Trial Design

TRIFECTA was a randomized, placebo-controlled, double-blind, dose-ranging trial designed to evaluate the safety and efficacy of CaPre® in reducing triglyceride levels in patients with mild-to-severe hypertriglyceridemia, using daily doses of 1 gram or 2 grams of CaPre® or placebo over a 12-week period. Placebo consisted of microcrystalline cellulose, a well-known inert substance not absorbed into the bloodstream. Demographic and baseline characteristics of the patient population were balanced. A total of 387 patients were randomized and 365 patients completed the 12-week study, in line with the targeted number of evaluable patients. From this patient population, approximately 90% had mild to moderate hypertriglyceridemia with baseline triglycerides between 200 and 499 mg/dL (2.28 to 5.69 mmol/L). The remainder had very high baseline triglycerides between 500 and 877 mg/dL (> 5.7 and < 10 mmol/L). Approximately 30% of patients were on lipid lowering medications, such as statins, and approximately 10% were diabetic.

A Statistically Significant Reduction in Triglycerides

CaPre® successfully met the trial's primary endpoint achieving a statistically significant ($p < 0.001$) mean placebo-adjusted decrease in triglycerides from baseline to week-12, with reductions of 36.4% for 1 gram and 38.6% for 2 grams.

Benefits in Other Key Cholesterol Markers

Along with material triglyceride reductions, all key secondary endpoints were met. This is a notable achievement as the trial was not designed to show a statistical significance on any other lipid than triglycerides. Nevertheless, there was a statistically significant decrease in non-HDL-C versus placebo ($p=0.038$), with the 2 gram per day CaPre® group decreasing by 5.3% from baseline versus placebo over the 12-week period. Non-HDL is considered the most accurate risk marker for cardiovascular disease.

CaPre® was also shown to have a slight increase in HDL-C (good cholesterol) at both the 1 gram and 2 gram levels and decrease in LDL-C (bad cholesterol) at 2 grams. As well, there was a clinically meaningful mean placebo-adjusted reduction in VLDL-C of 10.9% and 13.5% at 1 gram and 2 gram daily doses of CaPre®, respectively. VLDL-C is considered a highly significant predictor of coronary artery disease.

Finally, a statistically significant dose response increase in the Omega-3 Index for patients on 1 gram and 2 grams of CaPre® versus placebo was noted. The Omega-3 Index reflects the percentage of EPA and DHA in red blood cell fatty acids. The risk of cardiovascular disease is considered to be lower as the Omega-3 Index increases.

CaPre® Well Tolerated with No Safety Concern

CaPre® was found to be safe and well tolerated at all doses tested, with no serious adverse events that were considered treatment related. Out of 387 randomized patients, a total of 7 (1.8%) were discontinued as a result of adverse events, three were on placebo, two were on 1 gram of CaPre® and two were on 2 grams of CaPre®. The predominant incidence was gastrointestinal related, with no difference between CaPre® and placebo. The safety profiles of patients on CaPre® and placebo were similar.

"These results are very encouraging and mark an important milestone in the development of CaPre®," said Dr. Jacques Genest, MD FRCP(C), Cardiologist and the McGill University Novartis Chair in Medicine at the McGill University Health Center/Royal Victoria Hospital and a member of Acasti's Scientific Advisory Board and Principal Investigator of the trial. "CaPre® has an interesting metabolic profile for the treatment of hypertriglyceridemia, a medical condition afflicting a large number of adults and for which treatment options are often limited. With this achievement, Acasti is now moving one step closer to the potential commercialization of CaPre®."

Next Steps

Acasti continues to expect full TRIFECTA results by the end of calendar 2014. Once available, the Corporation will finalize its next steps including its on-going discussions with the US Food and Drug Administration (FDA). Acasti remains committed to moving forward with its pivotal Phase III clinical trial of CaPre® in patients with severe hypertriglyceridemia and to achieving full regulatory approval of CaPre®.

"These results further substantiate the positive findings of our Open Label Clinical Trial (COLT) announced in August 2013," concluded Mr. Godin. "We will continue along our path of value creation as we expand our clinical program to evaluate the safety and efficacy of CaPre®." Considerable medical needs remain in the multi-billion dollar hypertriglyceridemia market. Market participants, including the American Heart Association, have estimated that one-third of the US population has elevated levels of triglycerides.

Hypertriglyceridemia

Hypertriglyceridemia is a condition characterized by abnormally high levels of triglycerides, which are fats carried in the bloodstream. According to the American Heart Association, the prevalence of hypertriglyceridemia is increasing in the United States and globally, correlating to the increasing incidence of obesity and diabetes. Market participants, including the American Heart Association, have estimated that one-third of the population in the United States has elevated levels of triglycerides, including over 40 million people diagnosed with mild to moderate hypertriglyceridemia and over 4 million people diagnosed with severe hypertriglyceridemia. According to The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease (2011), triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low HDL-C and elevated levels of LDL-C. Lowering triglyceride levels is one of the primary goals to reduce a patient's risk of atherosclerotic cardiovascular disease. Hypertriglyceridemia is due to both genetic and environmental factors, including obesity, sedentary lifestyle and high-calorie diets.

[About Acasti Pharma Inc.](#)

Acasti is an emerging biopharmaceutical company focused on the research, development and commercialization of new krill oil-based forms of omega-3 phospholipid therapies for the treatment and prevention of certain cardiometabolic disorders, in particular abnormalities in blood lipids, also known as dyslipidemia. Because krill feeds on phytoplankton (diatoms and dinoflagellates), it is a major source of phospholipids and polyunsaturated fatty acids ("PUFAs"), mainly eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA"), which are two types of omega-3 fatty acids well known to be beneficial for human health. CaPre®,

currently Acasti's only prescription drug candidate, is a highly purified omega-3 phospholipid concentrate derived from krill oil and is being developed to help prevent and treat hypertriglyceridemia, which is a condition characterized by abnormally high levels of triglycerides in the bloodstream. ONEMIA®, a medical food and currently Acasti's only commercialized product, is a purified omega-3 phospholipid concentrate derived from krill oil with lower levels of phospholipids, EPA and DHA content than CaPre®.

Forward Looking Statements

Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. securities laws and Canadian securities laws. Such forward-looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "will," or "plans" to be uncertain and forward-looking. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

The forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement and the "Cautionary Note Regarding Forward-Looking Information" section contained in Acasti's latest Annual Information Form, which also forms part of Acasti's latest annual report on Form 20-F, and which is available on SEDAR at www.sedar.com, on EDGAR at www.sec.gov/edgar.shtml and on the investor section of Acasti's website at acastipharma.com (the "AIF"). All forward-looking statements in this press release are made as of the date of this press release. Acasti does not undertake to update any such forward-looking statements whether as a result of new information, future events or otherwise, except as required by law. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in Acasti's public securities filings with the Securities and Exchange Commission and the Canadian securities commissions. Additional information about these assumptions and risks and uncertainties is contained in the AIF under "Risk Factors".

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