

July 9, 2014



Acasti Completes Phase II Double Blind (TRIFECTA) and Pharmacokinetic Trials

LAVAL, Quebec, July 9, 2014 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (**Acasti** or the **"Corporation"**) (Nasdaq:ACST) (TSX-V:APO), 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, announces the completion of two trials, the Phase II double-blind, placebo-controlled (TRIFECTA) study and the Pharmacokinetic (PK) trial.

"The conclusion of the clinical studies is a key milestone in our drug development program and we look forward to obtaining results for the two trials," said Andre Godin, Interim President and Chief Executive Officer of Acasti. The results of the Phase II and PK trials are an important part of Acasti's on-going discussions with the US Food and Drug Administration (FDA) to obtain approval to conduct a Phase III trial in the USA.

Phase II TRIFECTA Trial

The primary objective of the TRIFECTA trial is to evaluate the safety and efficacy of CaPre® in reducing triglyceride levels in patients with mild to severe hypertriglyceridemia. Upon reaching the number of targeted patients, a planned second blinded interim analysis indicated a significant clinical signal, without any safety concerns. Given that the stopping threshold had been met, the data review committee members recommended that there was sufficient evidence of a treatment effect that warranted the termination of the study. The Corporation intends to unblind the study and top-line results are expected by the end of September 2014, with full data coming out in the following quarter.

In Acasti's previously completed Phase II open-label (COLT) trial, CaPre® was found to be safe and effective in reducing triglyceride levels in patients with hypertriglyceridemia. Triglyceride lowering activity was seen at all doses tested. As well, CaPre® also had a positive impact on multiple lipoproteins, including high-density lipoprotein (HDL – good cholesterol) and non-HDL, and no significant deleterious effect on low-density lipoprotein (LDL – bad cholesterol). "If this lipid efficacy is maintained throughout our clinical trials, it could be a key differentiator from other omega-3 prescription drugs currently on the market," highlighted Mr. Pierre Lemieux, PhD, Chief Operating Officer of Acasti.

Pharmacokinetic Trial

Acasti's Pharmacokinetic trial is designed to evaluate blood profiles and bioavailability in healthy human volunteers taking single and multiple doses of Capre®. Top-line results are expected to be available by the end of September 2014, with full data coming out in the following quarter.

The PK study marks an important step in Acasti's pivotal US strategy to secure regulatory approval to distribute and market CaPre® as a prescription drug in the US.

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

Certain statements included in this press release may be considered forward-looking information within the meaning of Canadian securities laws and forward-looking statements within the meaning of U.S. federal securities laws, both of which we refer to as forward-looking statements. 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 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. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by Acasti in its public securities filings available at www.sedar.com and www.sec.gov/edgar.shtml, actual events may differ materially from current expectations. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.

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CONTACT: Acasti Contact:
Andre Godin
Interim President & CEO
Interim CFO Acasti
+1.450.687.2262

a.godin@neptunebiotech.com
acastipharma.com

John Ripplinger
Investor Relations
+1.450.687.2262
j.ripplinger@acastipharma.com
acastipharma.com

Source: Acasti Pharma Inc.