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# **Acasti Pharma Reports Last Patient Visit in TRILOGY 1 Phase 3 Trial of CaPre for the Treatment of Severe Hypertriglyceridemia**

## **On track to report topline results for TRILOGY 1 in December 2019 and TRILOGY 2 in January 2020**

LAVAL, Québec, Nov. 26, 2019 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti" or the "Company") (NASDAQ: ACST – TSX-V: ACST), a biopharmaceutical innovator focused on the research, development and commercialization of its prescription drug candidate CaPre<sup>®</sup> (omega-3 phospholipid) for the treatment of severe hypertriglyceridemia (triglyceride blood levels from 500 mg/dL to 1500 mg/dL), announced that the last patient completed their final visit in the Company's TRILOGY 1 pivotal Phase 3 trial of CaPre last week. Topline results for TRILOGY 1 are expected to be reported as planned in December 2019. The Company also expects the last patient to complete their final visit in TRILOGY 2 in early January 2020, with topline results expected towards the end of January 2020.

Topline results will include a readout of the primary endpoint, which is intended to show CaPre's overall impact on lowering triglycerides (TGs) after 12 weeks compared to placebo. Safety and tolerability (e.g. overall adverse events (AE) and serious AE rate, any discontinuation due to AEs, and AEs of special interest such as gastrointestinal events) will also be reported.

The Company currently expects that topline results will not include any secondary or exploratory endpoints. The important secondary and exploratory endpoint results are expected to be completed before the end of March 2020, and will include: 1) additional TG secondary endpoints, including TG reduction at Week 26, which is intended to show CaPre's persistence of effect, TG reduction in various subgroups to show consistency of effect (such as patients stratified with baseline qualifying TG levels of  $\leq 750$  mg/dL vs.  $> 750$  mg/dL), and a comparison of TG reduction in patients using and not using statins at baseline; 2) Non-HDL-C; 3) VLDL-C; 4) HDL-C; 5) LDL-C and HbA1c.

Pierre Lemieux, Ph.D., COO and CSO of Acasti, commented, "We are pleased to report our "last patient, last visit" in TRILOGY 1, and we are nearing completion of TRILOGY 2 with approximately 85% of randomized patients having completed TRILOGY 2. Data clean-up is now 97% and 75% completed for TRILOGY 1 and TRILOGY 2, respectively. As a result, we are on track to report topline results for TRILOGY 1 in December 2019 and TRILOGY 2 in January 2020. Assuming these results are positive, we intend to present the full data set at important scientific meetings in the first half of 2020, and file an NDA by mid-2020 to obtain regulatory approval for CaPre in the United States."

**About CaPre (omega-3 phospholipid)**

Acasti's prescription drug candidate, CaPre, is a highly purified omega-3 phospholipid concentrate derived from krill oil, and is being developed to treat severe hypertriglyceridemia, a metabolic condition that contributes to increased risk of cardiovascular disease and pancreatitis. Its omega-3s, principally EPA and DHA, are either "free" or bound to phospholipids, which allows for better absorption into the body. Acasti believes that EPA and DHA are more efficiently transported by phospholipids sourced from krill oil than the EPA and DHA contained in fish oil that are transported either by triglycerides (as in dietary supplements) or as ethyl esters in other prescription omega-3 drugs, which must then undergo additional digestion before they are ready for transport in the bloodstream. Clinically, the phospholipids may not only improve the absorption, distribution, and metabolism of omega-3s, but they may also decrease the synthesis of LDL cholesterol in the liver, impede or block cholesterol absorption, and stimulate lipid secretion from bile. In two Phase 2 studies, CaPre achieved a statistically significant reduction of triglycerides and non-HDL cholesterol levels in patients across the dyslipidemia spectrum from patients with mild to moderate hypertriglyceridemia (patients with TG blood levels between 200mg/dl and 500mg/dl) to patients with severe hypertriglyceridemia (those with TG levels above 500mg/dl). Furthermore, in the Phase 2 studies, CaPre demonstrated the potential to actually reduce LDL, or "bad cholesterol", as well as the potential to increase HDL, or "good cholesterol", especially at the therapeutic dose of 4 grams/day. The Phase 2 data also showed a significant reduction of HbA1c at a 4 gram dose, suggesting that due to its unique omega-3/phospholipid composition, CaPre may actually improve long-term glucose metabolism. Acasti's TRILOGY Phase 3 program is currently underway.

## **About Acasti Pharma**

Acasti Pharma is a biopharmaceutical innovator advancing a potentially best-in-class cardiovascular drug, CaPre<sup>®</sup> (omega-3 phospholipid), for the treatment of hypertriglyceridemia, a chronic condition affecting an estimated one third of the U.S. population. Since its founding in 2008, Acasti Pharma has focused on addressing a critical market need for an effective, safe and well-absorbing omega-3 therapeutic that can make a positive impact on the major blood lipids associated with cardiovascular disease risk. The company is developing CaPre in a Phase 3 clinical program in patients with severe hypertriglyceridemia, a market that includes 3 to 4 million patients in the U.S. The addressable market may expand significantly if omega-3s demonstrate long-term cardiovascular benefits in on-going third party outcomes studies. Acasti may need to conduct at least one additional clinical trial to support FDA approval of a supplemental New Drug Application to expand CaPre's indications to this segment. Acasti's strategy is to commercialize CaPre in the U.S. and the company is pursuing development and distribution partnerships to market CaPre in major countries around the world. For more information, visit [www.acastipharma.com](http://www.acastipharma.com).

## **Forward Looking Statements**

*Statements in this press release that are not statements of historical or current fact constitute "forward-looking information" within the meaning of Canadian securities laws and "forward-looking statements" within the meaning of U.S. federal securities laws (collectively, "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,” “potential,” “should,” “may,” “will,” “plans,” “continue”, “targeted” or other similar expressions 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. Forward-looking statements in this press release include, but are not limited to, information or statements about Acasti’s strategy, future operations, prospects and the plans of management; Acasti’s ability to conduct all required clinical and non-clinical trials for CaPre, including the timing and results of those trials; the timing and the outcome of licensing negotiations; CaPre’s potential to become the “best-in-class” cardiovascular drug for treating severe Hypertriglyceridemia (HTG), Acasti’s ability to commercially launch CaPre, CaPre’s potential to meet or exceed the target primary endpoint of reducing triglycerides by 20% compared to placebo, and Acasti’s ability to fund its continued operations.*

*The forward-looking statements contained in this press release are expressly qualified in their entirety by this cautionary statement, the “Cautionary Note Regarding Forward-Looking Information” section contained in Acasti’s latest annual report on Form 20-F and most recent management’s discussion and analysis (MD&A), which are available on SEDAR at [www.sedar.com](http://www.sedar.com), on EDGAR at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml), and on the investor section of Acasti’s website at [www.acastipharma.com](http://www.acastipharma.com). 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 assumptions and 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, including Acasti’s latest annual report on Form 20-F and most recent MD&A.*

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