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Acasti Pharma Announces TRILOGY 2 Trial Has Achieved its 100% Patient Randomization Target in Patients with Severe Hypertriglyceridemia

More than 60% of patients have completed their 6-month treatment plan

Topline results remain on track for year-end

LAVAL, Quebec, June 04, 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® (omega-3 phospholipid) for the treatment of severe hypertriglyceridemia (HTG), today announced that the Company's TRILOGY 2 trial studying CaPre in patients with severe hypertriglyceridemia has achieved 100% patient randomization. This follows the Company's prior announcement in April 2019 that the Company's TRILOGY 1 trial had achieved 100% patient randomization.

The Company also announced that its two on-going Phase 3 TRILOGY trials (TRILOGY 1 and TRILOGY 2) have exceeded the target of a combined 500 randomized patients, and more than 60% of the patients in both trials have already completed their 6-month treatment plan.

The fact that both studies have now reached full randomization means that the "last patient, last visit" in the TRILOGY 1 trial is on track to take place in November, and the "last patient, last visit" in the TRILOGY 2 trial is on track to take place in December. It is then anticipated to take approximately 1 month for data clean-up prior to moving to database lock. Once the database is locked, the Company expects topline results for TRILOGY 1 to be released in December 2019 and TRILOGY 2 to be released in January 2020. Topline results will include readout of the primary endpoint, which will show CaPre's overall impact on lowering triglycerides after 12 weeks. In addition, the topline results will include CaPre's impact on several important secondary endpoints such as LDL, VLDL and HDL cholesterol and non-HDL cholesterol, as well as HbA1c, an exploratory endpoint which is an important biomarker of glucose control for diabetic patients. The full data set will include results on a number of additional lipid, metabolic and inflammatory markers including CRP, APOA1, APOB, APOA5, APOC3, Lp-PLA2, PCSK9, RLP-C and others. The Company plans to submit the full data set as a late breaker presentation at the American College of Cardiology at the end of March 2020.

Pierre Lemieux, Ph.D., COO and CSO of Acasti, commented, "Both of our TRILOGY Phase 3 trials remain on track and are proceeding according to plan. Consistent with our prior disclosures, there have been no severe adverse events associated with our product to date,

and we continue to experience a lower than expected drop-out rate, supporting the high safety profile and patient acceptability of CaPre. Importantly, we are encouraged by the growing excitement within the industry as we eagerly await the results of our TRILOGY program. We appreciate the on-going support of all of the investigators involved with these trials at more than 150 clinical sites across the U.S., Canada, and Mexico.”

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 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® (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. Acasti Pharma 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 Pharma 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 Pharma's strategy is to commercialize CaPre in the U.S. and Acasti Pharma is pursuing development and distribution partnerships to market CaPre in major countries around the world. For more information, visit 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 Pharma 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 Pharma’s strategy, future operations, prospects and the plans of management; Acasti Pharma’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, Acasti Pharma’s ability to commercially launch CaPre, and, Acasti Pharma’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 Pharma’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, on EDGAR at www.sec.gov/edgar/shtml, and on the investor section of Acasti Pharma’s website at www.acastipharma.com. All forward-looking statements in this press release are made as of the date of this press release. Acasti Pharma 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 Pharma’s public securities filings with the Securities and Exchange Commission and the Canadian securities commissions, including Acasti Pharma’s latest annual report on Form 20-F and most recent MD&A.

Neither NASDAQ, the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

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