September 30, 2019

Acasti Pharma Announces Additional Phase 3 Milestones Reached, and Remains on Track to Report Topline Results for TRILOGY 1 in December 2019 and TRILOGY 2 in January 2020

Nearly 80% of randomized patients have completed the studies

Data clean-up for TRILOGY 1 is 90% completed

Plan to present full data set including results for key secondary and exploratory endpoints of interest such as non-HDL-C, LDL-C, VLDL, HDL-C and HbA1c at key scientific meetings in 2020

LAVAL, Quebec, Sept. 30, 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, today reported additional milestones reached and provided a business update on its clinical trials.

Pierre Lemieux, Ph.D., COO and CSO of Acasti, commented, "Our TRILOGY Phase 3 trials in patients with severe hypertriglyceridemia (triglyceride blood levels from 500 mg/dL to 1500 mg/dL) continue to progress, and we remain on track to report topline TRILOGY 1 results in December 2019, and topline TRILOGY 2 results in January 2020. Importantly, both of our TRILOGY studies have achieved 100% patient randomization, and nearly 80% of the patients in both studies combined have now completed their 6-month plan. It is important to note that data clean up is approximately 90% complete in TRILOGY 1, bringing us closer to database lock. We have also progressed TRILOGY 2 and anticipate database lock as planned in January 2020."

Jan D'Alvise, president and CEO of Acasti, further noted, "Given the positive results we saw from our Phase 2 trials in a total of 675 patients, we eagerly await the completion of the results from our two TRILOGY clinical studies. It is also important to note:

- patients enrolled in the Phase 3 TRILOGY trials have higher baseline triglyceride levels (above 500 mg/dl) versus our Phase 2 studies, where most had baseline triglycerides significantly below 500 mg/dl;
- patients randomized to CaPre in the Phase 3 TRILOGY trials all received 4 grams per day and will remain on drug for 6 months, while our Phase 2 studies included patients receiving a range of doses from 1 gram, 2 grams and 4 grams per day for only 8 to 12 weeks with a favorable dose response;
- the Phase 2 trials also indicated that CaPre may have a positive effect on other major

lipid markers such as VLDL, LDL-C, and HDL-C, as well as HbA1c in patients with diabetes."

As previously disclosed, 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. The placebo used in the TRILOGY trials is cornstarch, which is inert, and consequently is expected to have a neutral effect on key biomarkers of patients in the placebo group. The TRILOGY studies are designed to provide at least 90% statistical power to detect a difference of at least a 20% decrease from baseline in TGs between CaPre and placebo.

The Company has shared the statistical analysis plan (SAP) for the analysis and reporting of the TRILOGY results with the FDA, and expects to finalize the SAP prior to final database lock. Subject to any input from the FDA, Acasti is currently planning that the topline TRILOGY results will include the primary endpoint of TG reduction at Week 12 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 follow shortly after the release of the topline results of TRILOGY 2, currently anticipated in late January, 2020. According to the SAP, the primary endpoint must first be positive with statistical significance prior to analyzing the secondary and exploratory endpoints. These endpoints will then be analyzed in the following order: 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 ≤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. Physician investigators determined if patients with high LDL-C and/or high HbA1c levels at screening needed to be put on standard therapy, and if so, they were stabilized prior to being randomized into TRILOGY. Results for both LDL-C and HbA1c will then require subgroup analyses, which are done by combining diabetic patients and separately patients with high LDL-C from both studies at baseline to reach adequate statistical power to detect a difference if one exists, and therefore potentially show any incremental benefit of CaPre above and beyond the standard of care. Acasti expects that the remaining secondary and exploratory endpoints along with various additional subgroup analyses should be completed before the end of March 2020.

In addition to the preliminary topline data, the Company will seek to present the full data set, which will include results for key secondary and exploratory endpoints of interest such as Non-HDL-C, LDL-C, VLDL, HDL-C and HbA1c at key scientific meetings in 2020. The Company will communicate more information in the months ahead on how and when all of the TRILOGY results will be reported once the SAP is finalized.

Jan D'Alvise concluded, "We are well capitalized beyond completion of our Phase 3 trials with over $25 million of cash as of June 30th, plus $8.1 million in additional proceeds from 5.9 million warrants exercised during the period from July 1 to August 12, 2019, which includes funding to progress preparation of the NDA, assuming the TRILOGY Phase 3

program is successful, as well as expanded business and US commercial launch activities. Assuming our TRILOGY trials replicate our Phase 2 data, we believe CaPre has the potential to provide an attractive alternative to current therapies, and thus improve the lives of the millions of patients with cardiometabolic disease."

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® (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.

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, on EDGAR at www.sec.gov/edgar/shtml, and on the investor section of Acasti'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 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.

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.

Acasti Contact:
Jan D'Alvise
Chief Executive Officer
Tel: 450-686-4555
Email: info@acastipharma.com
www.acastipharma.com

Investor Contact:
Crescendo Communications, LLC
Tel: 212-671-1020

Email: ACST@crescendo-ir.com

Source: Acasti Pharma, Inc.