February 10, 2020

Acasti Pharma Provides Update on TRILOGY 1 and TRILOGY 2 Phase 3 Trials of CaPre

Investigation underway into unexpected and inconsistent findings that may have negatively impacted results reported in TRILOGY 1

Announces plans to seek FDA guidance prior to unblinding TRILOGY 2 data, which is expected to delay reporting of TRILOGY 2 topline results until calendar Q3, 2020

LAVAL, Quebec, Feb. 10, 2020 (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, or HTG (triglyceride blood levels from 500 mg/dL to 1500 mg/dL), today announced that a detailed examination of the Phase 3 TRILOGY 1 results for CaPre is underway, including specific clinical site audits and an audit of the central testing laboratory.

As previously reported, the Company noted a highly unusual placebo response in its topline triglyceride reduction primary endpoint, far greater than seen in any prior omega-3 triglyceride lowering trials, with 5 sites out of the total 54 enrolling sites disproportionately contributing to this placebo response. These sites accounted for about 36% of the 242 patients enrolled in the TRILOGY 1 study. By comparison, TRILOGY 2 was conducted at 71 sites in Canada, Mexico and the United States that enrolled a total of 278 patients. The 5 sites also participated in TRILOGY 2, however these sites accounted for only 12% of the total patients, with the majority of these patients coming from only 3 sites.

Despite monitoring activities conducted throughout the TRILOGY 1 trial to ensure adherence to the protocol and identify protocol violations, the Company has subsequently identified some unexpected and inconsistent findings that it believes may have negatively contributed to the overall topline results. These findings are now being further explored via a comprehensive and rigorous review of data and patient medical records by an independent team of auditors. To support this effort, the Company, its independent Clinical Research Organization (CRO) that conducted the TRILOGY studies, its principal investigator Dr. Mozaffarian, and other clinical and regulatory advisors, are conducting a thorough review of all data and records from patients taking both CaPre and placebo. This assessment is well underway, and the Company has also determined that a thorough investigation of the data must be completed and reviewed with the FDA, before the Company can report the findings from TRILOGY 1 and the implications for TRILOGY 2.

Consequently, the Company intends to request a meeting with the FDA to discuss the TRILOGY 1 data, and will seek their guidance about how to conduct the analysis of the TRILOGY 2 data prior to unblinding TRILOGY 2. The Company continues to remain blinded

to the TRILOGY 2 data. Upon submission of the meeting request, which is expected to be sent to the FDA in calendar Q2, 2020, the FDA will have 75 days to review the findings and provide feedback and guidance.

Given the need to complete the audit and review of the TRILOGY 1 data, and obtain FDA feedback, the Company now anticipates the unblinding of the topline results for TRILOGY 2 sometime in calendar Q3 of 2020. Acasti will provide further guidance as to the timing of reporting TRILOGY 2 data based on progress of the audits and feedback from the FDA. Accordingly, key secondary and exploratory endpoints from both TRILOGY 1 and TRILOGY 2 studies, would now be expected as soon as possible after the unblinding of TRILOGY 2 results.

If the interpretation of the analyses produced as an outcome of the audits and post-hoc data review are supported by the FDA, and if TRILOGY 2 achieves statistical significance, Acasti believes it may still have a viable path forward to file an NDA for CaPre.

Jan D'Alvise, president and CEO of Acasti Pharma, stated, "Taking into account that the audit is still underway, that the data that we are evaluating is still preliminary, and that any findings will be subject to guidance from the FDA, we look forward to concluding the necessary work, which we hope will help us to better understand the unexpected TRILOGY 1 results. While we regret the additional delay in reporting TRILOGY 2 results, given our initial findings, we believe it is critical to conduct a thorough investigation and evaluation of the TRILOGY 1 results. Any learnings we can take from this investigation that may allow us to proactively adjust the SAP for TRILOGY 2, gives us a better chance of accurately reflecting the clinical value that we believe we still see in CaPre. Moreover, we have confirmed that there is established precedent for the FDA accepting post-hoc analyses of study results, assuming the analyses are transparent, well justified and well supported. We are moving as quickly as possible to gain a greater understanding of the TRILOGY 1 results, and will provide material updates as we learn more information. Furthermore, we project that our current cash position will now last through calendar 2020, giving us the necessary runway to complete our extended analysis of the TRILOGY program. We remain fully committed to our goal of gaining NDA approval for CaPre, and appreciate the tremendous support and patience of our shareholders."

About CaPre

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, as noted above.

About Acasti Pharma

Acasti Pharma is a biopharmaceutical innovator advancing a potentially best-in-class cardiovascular drug, CaPre, 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 potential exists to expand the treatable market in the United States to the approximately 50 million people with TGs above 150 mg/dl, given the recent FDA approval of expanded labeling for VASCEPA based on the recent positive REDUCE-IT outcome study results. 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 and to fund its continued operations, CaPre's potential to meet or exceed the target primary endpoint of reducing triglycerides by 20% compared to placebo, Acasti's ability to report topline results

for TRILOGY 2 within the contemplated timing as well as Acasti's ability to report key secondary and exploratory endpoints from both TRILOGY studies within the contemplated timing, and Acasti's ability to file an NDA based on the TRILOGY studies.

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.

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