July 31, 2020

Acasti Pharma Submits Statistical Analysis Plan to FDA and Remains On Track to Report TRILOGY 2 Topline Data On or About August 31, 2020

LAVAL, Québec, July 31, 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 (sHTG) (triglyceride blood levels from 500 mg/dL to 1500 mg/dL), today announced it has completed its revisions to the pre-specified Statistical Analysis Plan (SAP) for the TRILOGY 2 Phase 3 trial of CaPre, and has filed it with the Food and Drug Administration (FDA).

As previously disclosed, the Company, along with the academic Principal Investigator (PI) of the study, Dariush Mozaffarian M.D., Dr.P.H., and external clinical and statistical experts, conducted rigorous post-hoc analysis of TRILOGY 1 data. Analysis of the TRILOGY 1 data revealed a rapid, significant and sustained reduction in TG levels between screening (during qualification) and the time of patient randomization (prior to patients starting on either drug or placebo), which Acasti refers to as "Pre-randomization Triglyceride (TG) Normalization." This artefactual phenomenon affected both treatment groups, but was much greater in the placebo group, resulting in the large placebo effect and significant underestimation of the post-randomization treatment effect of the active drug, CaPre. The post-hoc analyses of the primary endpoint using a revised, single point baseline value from Week 0 (Visit 4) corrected for a significant amount of the pre-randomization TG reduction in subjects that were most affected by the normalization phenomenon, and a meaningful efficacy trend for CaPre was observed.

The Company provided all of the TRILOGY 1 background information and accompanying data to the FDA in a Type C briefing package, which was filed on April 29, 2020. As previously disclosed, the FDA provided Acasti with a written response to its Type C Meeting request and briefing package, and confirmed that it will require pivotal efficacy analyses for TRILOGY 2 to be performed on the full Intent to Treat (ITT) population, as contemplated in the original Statistical Analysis Plan (SAP), and they supported the conduct of post-hoc analyses in TRILOGY 1 for exploratory purposes. Based on the FDA's feedback and input from key experts including Dr. Mozaffarian, Acasti finalized the Statistical Analysis Plan (SAP) for TRILOGY 2 and has now submitted it to the FDA. The Company remains blinded to the TRILOGY 2 data, and remains on track to report topline TG data on or about August 31, 2020. The key secondary and exploratory endpoints from both TRILOGY 1 and TRILOGY 2 trials, and pooled results from both studies, are still expected within several weeks following the unblinding of TRILOGY 2 results.

Acasti also announced it plans to host a conference call on or about August 31, 2020 to discuss the TRILOGY 2 topline results, as well as to provide an update on the timing for the reporting of the secondary and exploratory endpoints, and the pooled results from both TRILOGY studies. For this reason, the Company does not plan to host its usual quarterly conference call to discuss the financial results for the first fiscal quarter ended June 30, 2020, but expects to report and file its first fiscal quarter 2021 financial results on August 13, 2020.

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, as noted above.

About Acasti

Acasti 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 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; CaPre's potential to become the "best-in-class" cardiovascular drug for treating severe Hypertriglyceridemia; the timing and outcome of the unblinding of TRILOGY 2; and Acasti's ability to file an NDA based on the results of its TRILOGY Phase 3 program.

The forward-looking statements contained in this press release are expressly qualified in their entirety by this cautionary statement, the "Special Note Regarding Forward-Looking Statements" section contained in Acasti's latest annual report on Form 10-K, which will be available on EDGAR at www.sec.gov/edgar/shtml, on SEDAR at www.sedar.com 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 10-K under the caption "Risk Factors".

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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