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Acasti Pharma Reports Topline Triglyceride Results from Phase 3 TRILOGY 2 Study of CaPre in Patients with Severe Hypertriglyceridemia

CaPre achieved a 30.4% median reduction in triglycerides at 12 weeks and 38.4% at 26 weeks, but did not achieve statistical significance for the primary endpoint

LAVAL, Québec, Aug. 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 top-line results for the Primary Endpoint (triglyceride reduction at 12 and 26 weeks) from its 278 patient Phase 3 TRILOGY 2 study evaluating the efficacy, safety and tolerability of CaPre in patients with severe hypertriglyceridemia.

The Company reported a 30.4% median reduction in triglyceride levels among all patients receiving CaPre, as compared to 30.5% in TRILOGY 1, and a 17.9% median reduction in triglyceride levels among patients receiving placebo at 12 weeks (the Primary Endpoint), as compared to 27.5% in TRILOGY 1. The unadjusted, placebo corrected triglyceride reduction of 12.4% achieved a "p" value of 0.19, which was not statistically significant, and therefore the TRILOGY 2 study did not meet its primary endpoint. As a result, the company will not file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for patients with severe hypertriglyceridemia, and does not plan to conduct additional clinical trials for CaPre.

CaPre was well tolerated in TRILOGY 2, with a safety profile similar to placebo, and consistent with the Company's previously conducted Phase 2 and 3 studies.

"Compared to their baseline levels, the observed triglyceride reductions among patients taking CaPre were similar or larger than seen with prior omega-3 therapies," said Dr. Dariush Mozaffarian, Professor at Tufts University and academic PI of the trial. "However, an unusual reduction in triglyceride levels in the placebo group meant that statistical significance was not achieved. We plan to now pool together the results from the two studies to see if we can better understand this phenomenon in post-hoc explorations. We want to thank all of the investigators for their participation, and Acasti for sponsoring the Trilogy program."

Jan D'Alvise, Chief Executive Officer of Acasti, stated, "We are very disappointed in the outcome of the Trilogy 2 study. Based on what we have seen in the preliminary topline data,

we believe TRILOGY 2 was likely not affected by the same “Pre-Randomization Triglyceride Normalization” effect that we saw in TRILOGY 1. While the triglyceride reduction observed in the control arm was less than what was observed in the Trilogy 1 Study, it still remains one of the highest seen amongst the previously conducted triglyceride reduction studies, and may be explained by the excellent background standard of care that is being provided to these patients today.”

D’Alvise continued, “We extend our sincere gratitude to all of the patients and their families, as well as the investigators who participated in this important trial, and to our employees who have worked tirelessly to develop and evaluate CaPre as a therapeutic for this indication. We especially want to thank Dr. Dariush Mozaffarian, our Principal Investigator, for his expert counsel and support throughout this program. The Acasti team and our clinical advisors will review the full dataset once it is available, and will complete the full data analyses as contemplated in the Statistical Analysis Plan, including the secondary and exploratory endpoints and the pooling of the data from TRILOGY 1 and 2. Taking into consideration all of the analyses from TRILOGY once completed, we will seek to maximize the value of the CaPre® asset by continuing to explore a range of options available to us.”

The Company has decided not to host a conference call today as previously disclosed, as there is no additional material information at this time that can be shared beyond what is contained in this press release. The Company and its board of directors has been and will continue to evaluate all strategic options and will provide updates on this process as warranted.

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, its review of strategic options, potential value for CaPre®, prospects and the plans of management.

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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