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Acasti Pharma Provides Business Update for the First Quarter of Fiscal 2021

On track to report TRILOGY 2 topline data on or about August 31, 2020

LAVAL, Québec, Aug. 13, 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 provided a business update and announced its operating and financial results for the first quarter of fiscal 2021 ended June 30, 2020.

Corporate Highlights:

- Finalized and submitted TRILOGY 2 Statistical Analyses Plan ("SAP") to the FDA on July 31, 2020
- Provided business update, on June 29, 2020, in which the Company identified "Triglyceride Normalization" phenomenon prior to patient randomization and treatment as likely contributor to unusually high placebo effect in TRILOGY 1; post-hoc analyses 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); meaningful efficacy trend for CaPre was observed after correcting for the unexpectedly large placebo response in the original analysis
- Received a Notice of Allowance for second composition of matter patent to be awarded by the Canadian Intellectual Property Office, expanding the Company's existing claims to include any composition containing EPA and DHA, where at least 50% of the composition consists of phospholipids.
- Received a notice of issuance of a composition of matter patent to be awarded by the Intellectual Property Office in Hong Kong granting claims for any composition containing EPA and DHA, where at least 50% of the composition consists of phospholipids
- TRILOGY 2 topline results expected on or about August 31, 2020
- Update on the timing for reporting the key secondary and exploratory endpoints from both TRILOGY 1 and TRILOGY 2 trials, and pooled results from both studies, will be provided after TRILOGY 2 results are reported

As previously reported, 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. These analyses 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 U.S. Food and Drug Administration (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 the Company's Type C Meeting request and briefing package, and confirmed that pivotal efficacy analyses for TRILOGY 2 will 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.

After reviewing feedback from the FDA and from key experts including Dr. Mozaffarian, Acasti finalized the SAP for TRILOGY 2, and submitted it to the FDA on July 31, 2020. The Company remains blinded to the TRILOGY 2 data, and remains on track to report topline TG data on or about August 31, 2020. An update on the timing for reporting the key secondary and exploratory endpoints from both the TRILOGY 1 and TRILOGY 2 trials, as well as pooled results from both studies, will be provided after TRILOGY 2 results are reported.

Jan D'Alvise, President and CEO of Acasti, commented, "With the TRILOGY 2 SAP finalized and now submitted to the FDA, we continue to advance the process towards unblinding of our TRILOGY 2 clinical data. We believe if TRILOGY 2 can achieve statistical significance, and if the pooled efficacy results with TRILOGY 1 using the Intent to Treat population also reaches significance, we can proceed with our Pre-NDA meeting where we intend to discuss with the FDA the use of this data to support an NDA filing. We look forward to the unblinding of TRILOGY 2 data and reporting our findings, concurrent with a conference call update on or about August 31, 2020."

As of June 30, 2020, Acasti had cash and cash equivalents totaling $12.1 million, compared to $16.0 million as of June 30, 2019. The Company believes it is sufficiently funded through the first calendar quarter of 2021, based on management's current projections.

First Quarter of Fiscal 2021 Financial Results (US dollars):

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

- **Loss from operations** for the three months ended June 30, 2020 was $4.1 million, compared to a loss from operations of $8.0 million for the three months ended June 30, 2019. The decrease was due mainly to a reduction in research contract expenses as the Phase 3 clinical program for CaPre was nearing completion.
- **Net loss** for the three months ended June 30, 2020 was $4.7 million or $0.05 per share, compared to a net loss of $8.8 million or $0.11 per share for the three months ended June 30, 2019. The decreased net loss is primarily due to the reduction of research and development expenses as the Phase 3 clinical program for CaPre was nearing completion, lower net financial expenses, and the change in fair value of the warrants derivative liabilities.

- **R&D expenses** before depreciation, amortization and stock-based compensation expenses were $1.1 million for the three months ended June 30, 2020, compared to $5.5 million for the three months ended June 30, 2019. The net decrease was mainly attributable to a reduction in research contract expense due to the advancement of the Phase 3 clinical trial program, as it moved closer to completion.
- **General and Administrative expenses** before stock-based compensation expenses were $1.3 million for the three months ended June 30, 2020, an increase of $0.33 million from $0.97 million for the three months ended June 30, 2019. This increase was mainly attributable to consulting, accounting, and legal fees in connection with the conversion from IFRS to U.S. GAAP.
- **Sales and Marketing expenses** before stock-based compensation expenses were $0.57 million for the three months ended June 30, 2020, compared to $0.68 million for the three months ended June 30, 2019. The decrease was mostly due to a reduction in professional fees as a result of a slowdown in pre-launch marketing activities pending the results of the TRILOGY Phase 3 clinical studies are obtained. The decrease was partially offset by an increase in salaries and benefits as a result of increased headcount in the commercial team to support expanded business and market development activities.
- **Cash and cash equivalents** totaled $12.1 million as of June 30, 2020, compared to $16.0 million at June 30, 2019. As stated above, Acasti believes that current cash will fully fund the Company's operations through the first calendar quarter of 2021. Acasti projects that additional funds will be needed in the future for activities necessary to prepare for the commercial launch of CaPre if regulatory approval is received, including the scale-up of its manufacturing operations, the completion of the potential regulatory NDA submission package (assuming positive Phase 3 clinical results), and the expansion of business development and U.S. commercial launch activities. The Company is working towards development of strategic partner relationships, as well as actively seeking additional non-dilutive funds in the near future, but there can be no assurance as to when or whether Acasti will complete any strategic collaborations or non-dilutive financings. If the Company does not raise additional funds or find one or more strategic partners, it may not be able to realize its assets and discharge its liabilities in the normal course of business. As a result, there exists substantial doubt about the Company's ability to continue as a going concern, and therefore, realize its assets and discharge its liabilities in the normal course of business.

Conference Call

Acasti 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. Details for the call will be provided as we get closer to announcing TRILOGY 2 results.

ATM Update

On June 29, 2020, Acasti entered into an amended and restated ATM sales agreement (the "Sales Agreement") with B. Riley FBR Inc., Oppenheimer & Co. Inc. and H.C. Wainwright & Co., LLC (collectively, the "Agents"), to implement an "at-the-market" equity offering program under which Acasti may issue and sell from time to time our common shares having an aggregate offering price of up to $75 million through the Agents (the "ATM Program").

Pursuant to the ATM Program, as required pursuant to the policies of the TSX Venture Exchange ("TSXV"), since the last distributions reported on June 29, 2020, Acasti issued an aggregate of 4,404,152 common shares (the "ATM Shares") over the NASDAQ Stock Market for aggregate gross proceeds to the Company of $3.5 million. The ATM Shares were sold at prevailing market prices averaging $0.80 per share. No securities were sold through the facilities of the TSXV or, to the knowledge of the Company, in Canada. The ATM Shares were sold pursuant to a U.S. registration statement on Form S-3 (No. 333-239538) as made effective on July 7, 2020, as well as the Sales Agreement. Pursuant to the Sales Agreement, a cash commission of 3.0% on the aggregate gross proceeds raised was paid to the Agents in connection with their services.

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; the impact of the "Pre-Randomization Triglyceride Normalization" phenomenon on 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 and quarterly report on Form 10-Q, which are 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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