November 13, 2019

Acasti Pharma Provides Business Update for the Second Quarter of Fiscal 2020

Acasti management to host conference call at 1 PM ET today

LAVAL, Québec, Nov. 13, 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 (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 second quarter of fiscal 2020 ended September 30, 2019. All amounts are in Canadian dollars.

Corporate highlights:

- On track to report topline results for TRILOGY 1 in December 2019 and TRILOGY 2 in January 2020
- More than 90% of randomized patients have completed the studies
- Data clean-up for TRILOGY 1 is 95% 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 important scientific meetings beginning in the first quarter of 2020
- Approximately $25.8 million of cash and cash equivalents as at September 30, 2019; fully funded beyond completion of Phase 3 studies
- Awarded $750,000 in grants from the Government of Canada
- Partnered with Aker BioMarine to provide supply of raw krill oil to support product launch and commercialization

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "We continue on track to announce our Phase 3 TRILOGY 1 topline results in December 2019 and TRILOGY 2 topline results in January 2020. We eagerly await the completion of the results from our two TRILOGY clinical studies for a number of reasons, including: (a) the large patient population in our Phase 2 trials (675 patients) demonstrated both a significant reduction of triglycerides and also indicated that CaPre may have a positive effect on other major lipid markers such as VLDL, LDL-C, and HDL-C ("Trifecta Effect"), as well as HbA1c in patients with diabetes; (b) patients enrolled in our Phase 3 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; and (c) a favorable dose response was reported in the Phase 2 studies, in which patients received a range of doses (1 gram, 2 grams and 4 grams per day for only 8 to 12 weeks), which we believe bodes well for our Phase 3 trials, in which all patients randomized to CaPre received 4 grams per day and will remain on drug for 6 months."

"Assuming our TRILOGY trials replicate our Phase 2 data, we believe CaPre has the potential to become a best-in-class omega-3, due to both the Trifecta Effect and greater

bioavailability, especially in patients that follow the standard physician-recommended, restricted low-fat diet. We believe these benefits are due to our unique composition of phospholipids, EPA and DHA as compared to "esterified" pharmaceutical omega-3s derived from fish oils. Additionally, in all studies conducted to date, CaPre has shown no negative side effects or safety concerns."

"We are also ramping up our commercialization efforts. Most recently, we announced a supply agreement with Aker BioMarine to provide raw krill oil (RKO) to Acasti, under a two-year, fixed price supply agreement, which we believe will ensure an adequate raw material supply to meet our anticipated needs through at least mid-2021, including scale-up of production to build future inventory for anticipated commercial launch. At the same time, we are in active discussions with a number of pharma companies regarding potential commercialization partnerships in several countries around the world, and we look forward to providing further updates if and when developments unfold."

Both TRILOGY trials have achieved 100% patient randomization and more than 90% of the patients have now completed their 6-month plan. As a result, the "last patient, last visit" in the TRILOGY 1 study remains on track to take place in November with topline results expected in December 2019 and the "last patient, last visit" in the TRILOGY 2 study remains on track to take place in early January with topline results expected towards the end of January 2020. 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 TRILOGY studies are designed to provide at least 90% statistical power to detect a difference of at least a 20% reduction from baseline in TGs between CaPre and placebo. As previously disclosed, 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, and has been shown to not interfere with statin absorption and efficacy.

The Company has shared the statistical analysis plan (SAP) for the analysis and reporting of the TRILOGY results with the FDA and will finalize the SAP prior to final database lock of TRILOGY 1, which Acasti expects to occur shortly. Subject to any input from the FDA, Acasti currently intends to report topline TRILOGY results independently for each study as Acasti receives results and these topline 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. According to the protocol, physician

investigators were to determine if patients with high LDL-C and/or high HbA1c levels at screening should 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 at baseline from both studies 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 only. 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 Acasti's preliminary topline data, the Company will seek to present the full data set, which will include results for the Company's key secondary and exploratory endpoints of interest such as LDL-C, VLDL, HDL-C and HbA1c at important scientific meetings in the first half of 2020. The Company will communicate more information in the weeks ahead on how and when all of the TRILOGY results will be reported once the SAP is finalized.

Assuming TRILOGY results are positive, the Company intends to file an NDA by mid-2020 to obtain regulatory approval for CaPre in the United States, initially for the treatment of severe HTG. Acasti may pursue the opportunity to expand CaPre's indication to the treatment of patients with high TGs (200 – 500 mg/dl), but this would likely require the completion of at least one additional clinical study. Acasti continues to plan for the potential launch of CaPre in the U.S. by the second half of 2021. The Company also continues to strengthen its patent portfolio along with other intellectual property rights as a part of its commercialization strategy.

At September 30, 2019, Acasti had $25.8 million of cash, cash equivalents and marketable securities, including approximately $8.7 million in proceeds received from the recent exercise of warrants since July 1, 2019, which funds the Company beyond completion of the Phase 3 trials. This capital will fund continued work on the NDA, as well as expanded business and US commercial launch activities. Furthermore, the Company recently announced receiving an award for $750,000 in non-dilutive and non-repayable funding from the National Research Council of Canada Industrial Research Assistance Program (NRC IRAP). The Company intends to apply the funding towards the research and development of Acasti's exclusive commercial production platform for CaPre. With the Government funding, recent exercise of warrants and cash on hand, the Company is sufficiently funded until June 2020 based on management's current projections.

Recent Developments:

- **On August 9, 2019**, Acasti announced that the Company participated on a lipid panel entitled "Lipids: Moving Beyond Statins: Omega 3s, Bempedoic, and More," moderated by Harold Bays MD, a key opinion leader within the space during the 2019 BTIG Biotechnology Conference.

- **On September 9, 2019,** Acasti announced that the Company was awarded $750,000 in non-dilutive and non-repayable funding, as well as technical and business advisory services, from the National Research Council of Canada Industrial Research Assistance Program (NRC IRAP) to apply towards research and development of the Company's unique commercial production platform for CaPre. With NRC IRAP support, Acasti aims to further expand and enhance its production capabilities for CaPre.

- **On September 30, 2019,** Acasti announced that 100% of the required total patients for the two Phase 3 studies had been randomized, and nearly 80% of the patients in both studies combined had completed their 6-month plans.

- **On September 30,** Acasti made the determination that the Company will migrate from reporting in IFRS to US GAAP effective beginning with Q4, FY 2020 (March 31, 2020 year-end) reports – see the Company's most recent management's discussion and analysis under the heading "Upcoming Changes in IFRS / Foreign Private Issuer Status".

- **On November 4, 2019,** Acasti announced that it had signed a two-year, fixed price supply agreement with Aker BioMarine for raw krill oil (RKO), the starting material for the production of CaPre.

- **On November 7,** Acasti announced the publication of a CaPre pharmacokinetics study entitled, "Evaluation of OM3-PL/FFA Pharmacokinetics After Single and Multiple Oral Doses in Healthy Volunteers" in a leading peer-reviewed journal, Clinical Therapeutics. The study showed that the bioavailability of CaPre did not appear to be meaningfully affected by the fat content of the meal consumed before dose administration.

Second Quarter Fiscal 2020 Financial Results:

- **Loss from operating activities** for the second quarter ended September 30, 2019 was $8.7 million, compared to a loss from operating activities of $10.4 million for the quarter ended September 30, 2018. The decrease was due in part to a reduction in research contract expenses as the Phase 3 clinical program is getting closer to completions.
- **Net loss** for the quarter ended was $28.3 million or ($0.34) per share, compared to a net loss of $22.7 million or ($0.62) per share for the quarter ended September 30, 2018. The higher net loss was primarily due to the non-cash financial loss of $19.7 million for the three months ended September 30, 2019, due mostly to the change in fair value of the warrant derivative liability partially offset by a decrease in the number of warrants.
- **R&D expense**s before depreciation, amortization and stock-based compensation expenses were $4.3 million for the quarter ended September 30, 2019, compared to $8.4 million for the three months ended September 30, 2018. The $4.1 million decrease was mainly attributable to a $4.6 million decrease in research contracts. The lower research contract expense is attributed primarily to the Phase 3 clinical trial program getting closer to completion.
- **General and Administrative expenses** before stock-based compensation expenses were $1.5 million for the three months ended September 30, 2019, an increase of $.6 million from $.89 million for the three months ended September 30, 2018. This increase was mainly attributable to a $.18 million increase associated with the Company's Directors and Officers insurance policy, as well as an increase of $.3 million in corporate, accounting and legal fees.
- **Sales and Marketing expenses** before stock-based compensation expenses were $.88 million for the three months ended September 30, 2019, compared to $.13 million for the three months ended September 30, 2018. This increase funded additional

headcount and marketing expenses for expanded business and market development activities.

- **Cash flows** – Cash and cash equivalents and marketable securities totaled $25.8 million as of September 30, 2019, compared to $5.99 million for the quarter ended September 30, 2018. The increase was mainly generated by the net proceeds from the Public Offerings and the recent exercise of warrants. As stated above, Acasti believes that existing cash plus the recent exercise of warrants will fully fund the Company's operations beyond the completion of our Phase 3 clinical trials through at least June of 2020. Acasti will need to raise additional capital in the future to complete the funding of the preparation and filing of our NDA, and US commercial launch activities. If Acasti does not raise additional funds, it may not be able to realize its assets and discharge its liabilities in the normal course of business. As a result, there exists a material uncertainty about the Acasti's ability to continue as a going concern and to realize its assets and discharge its liabilities in the normal course of business.

Conference Call

Acasti will host a conference call today, Wednesday, November 13, 2019 at 1:00 PM Eastern Time to discuss the Company's financial results for the second quarter ended September 30, 2019, as well as the Company's corporate progress and other developments.

The conference call will be available via telephone by dialing toll free 844-369-8770 for U.S. callers or +1 862-298-0840 for international callers, or on the Company's News and Investors section of the website: https://www.acastipharma.com/investors/.

A webcast replay will be available on the Company's News and Investors section of the website (https://www.acastipharma.com/investors/) through February 13, 2020. A telephone replay of the call will be available approximately one hour following the call, through November 27, 2019, and can be accessed by dialing 877-481-4010 for U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 56770.

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.

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Source: Acasti Pharma, Inc.