February 14, 2020

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

Acasti management to host conference call at 1 PM ET today

LAVAL, Québec, Feb. 14, 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 (HTG) (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 third quarter of fiscal 2020 ended December 31, 2019. All amounts are in Canadian dollars.

Corporate highlights:

- Reported topline results in January for the TRILOGY 1 Phase 3 Trial of CaPre:
  - 30.5% and 36.7% reduction in triglyceride levels, compared with baseline, among patients receiving CaPre at 12 and 26 weeks respectively, as well as 42.2% reduction in triglyceride levels among patients receiving CaPre while on background statin therapy at 12 weeks
  - Despite meaningful triglyceride lowering in the CaPre arm, the study did not reach statistical significance due to unusually large placebo effect
  - No treatment-related serious adverse events were reported in the trial
  - Audits and additional post-hoc data analyses are underway into the unexpected and inconsistent findings that may have negatively impacted the results reported in TRILOGY 1
  - Acasti now 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
- Released preliminary new data in a diet-induced obesity animal model with preliminary, statistically significant findings showing that CaPre may promote insulin secretion, and showing a significant increase in plasma levels of 17S-HDHA and PDX as compared to metformin and icosapent ethyl
- Approximately $25.7 million of cash and cash equivalents as at December 31, 2019; fully funded through December 2020 based on current projections.

Jan D’Alvise, president and CEO of Acasti Pharma, commented, “We are making steady progress with the audit of TRILOGY 1 data and additional post-hoc analyses. This data has been very informative, and provided we have the FDA’s support, any learnings we can take from this investigation that may allow us to adjust the Statistical Analysis Plan (SAP) for TRILOGY 2, gives us a better chance of accurately reflecting the clinical value that we see in CaPre. As previously noted, 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 now to complete this

work and secure a meeting with the FDA. Until we have that important meeting, we intend to keep TRILOGY 2 blinded. Consequently, we now anticipate the unblinding of the topline results for TRILOGY 2 sometime in calendar Q3 of 2020, to allow time for the FDA meeting. Accordingly, key secondary and exploratory endpoints from both TRILOGY 1 and TRILOGY 2 studies, would now be expected after the unblinding of TRILOGY 2 results. We are moving as quickly as possible and will provide material updates when available."

On January 13, 2020 the Company announced preliminary topline results for the primary endpoint (triglyceride reduction at 12 and 26 weeks) from our Phase 3 TRILOGY 1 trial for CaPre. Acasti reported a 30.5% median reduction in triglyceride (TG) levels among all patients receiving CaPre, compared to a 27.5% median reduction in triglyceride levels among patients receiving placebo at 12 weeks. The Company also reported a 42.2% median reduction in TGs among patients receiving CaPre while on background statin therapy at 12 weeks, compared to a 31.5% median reduction in TG levels among patients receiving placebo and on background statin therapy. In addition, the Company reported a 36.7% median reduction in TG levels among patients receiving CaPre at 26 weeks (end of the study), compared to a 28.0% median reduction in TG levels among patients receiving placebo. Both the placebo and CaPre study groups experienced significant reductions in TGs within the first four weeks from baseline, and even though the difference at 12 and 26 weeks was in favor of CaPre, due to the unexpectedly large placebo response, TRILOGY 1 did not reach statistical significance. The safety profile of CaPre in TRILOGY 1 was similar to placebo, as there was no significant difference in treatment-related serious adverse events in the trial.

The observed reductions in TG levels in the placebo group were far greater than that seen in any previous triglyceride lowering trial with a prescription omega-3. The placebo used in the TRILOGY trials is simple cornstarch, which is a complex carbohydrate with a low glycemic index, and consequently would be expected to have a neutral effect on key biomarkers of patients in the placebo group. In similar previously conducted triglyceride lowering trials involving prescription omega-3 preparations, the placebo responses (using corn oil, olive oil, or vegetable oil) ranged from a change of +16% to -17% across 18 interventions arms, with 14 of 18 arms ranging between +10% to -10%. The Company noted that 5 sites out of the total 54 enrolling sites disproportionately contributed to this unusually high 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 with a total of 278 patients enrolled. The 5 sites that are a focus of the TRILOGY 1 investigation also participated in TRILOGY 2, however these sites accounted for only about 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 respond and schedule a meeting.

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 TRILOGY 1 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.

At December 31, 2019, Acasti had $25.7 million of cash, cash equivalents and marketable securities. This capital is expected to also fund the ongoing study investigations, as well as continued work on the NDA. With the Government funding, capital raised through the established at-the-market program (ATM) during Q3, recent exercise of warrants and cash on hand, the Company is sufficiently funded through December 2020, based on management's current projections.

Recent Developments:

- **On September 9, 2019,** Acasti announced that the Corporation was awarded up to $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 eligible research and development disbursements of the Corporation's unique commercial production platform for CaPre.

- **On September 30, 2019**, Acasti announced that 100% of the required total patients for its 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, 2019,** Acasti made the determination that the Corporation will migrate from reporting in IFRS to US GAAP effective beginning with Q4, FY'20 (March 31, 2020 year-end) reports.

- **On November 4, 2019,** Acasti announced that it had partnered with Aker BioMarine to deliver raw krill oil (RKO) to Acasti, under a two-year, fixed price supply agreement.

- **On November 7**, **2019**, 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.

- **On November 18, 2019**, Acasti released preliminary new animal study data which provides additional insights into CaPre’s potential mechanism of action in diabetes. The preliminary findings obtained for the diabetes mouse study showed that CaPre may promote insulin secretion as seen by statistically significant results produced in a standard glucose challenge test, thus suggesting a mechanism of action different and unique when compared to metformin, which does not promote insulin secretion.

- **On November 26, 2019**, Acasti announced that the last patient completed their final visit in the Corporation's TRILOGY 1 Phase 3 trial of CaPre.

- **On December 23, 2019**, Acasti provided an update on the expected delay of topline results into January 2020 for the Corporation's TRILOGY 1 Phase 3 trial of CaPre. The delay was caused by gaps in the data when the dataset was transferred from the Central laboratory to the CRO data management group. When this problem was identified by the CRO data management group, it triggered an immediate hold on the data transfer to the CRO statistical group, and initiated a full quality review by the CRO of the processes and procedures involved at the central testing laboratory. This review was completed in early January 2020, and topline results for TRILOGY 1 were subsequently released on January 13, 2020. A more comprehensive audit of the central laboratory is currently ongoing.

- **On December 18, 2019**, Acasti incorporated a new wholly owned subsidiary named Acasti Innovation AG (“AIAG”) under the laws of Switzerland for the purpose of future development of the Corporation’s intellectual property and global distribution of its products. AIAG currently does not have any operations.

- **On January 9, 2020**, Acasti announced that the last patient completed their final visit in Acasti's TRILOGY 2 Phase 3 trial of CaPre.

- **On January 13, 2020**, Acasti reported topline results for TRILOGY 1, which, despite showing a meaningful reduction of TGs in the CaPre arm, did not reach statistical significance due to an unusually large placebo effect.

- **On February 10, 2020**, Acasti provided an update on its TRILOGY 1 and TRILOGY 2 Phase 3 Trials of CaPre. This announcement disclosed that a full investigation was being conducted, including specific site audits, and a full audit of the central testing laboratory involved its TRILOGY 1 Phase 3 trial for CaPre. It also announced that once the full analysis of TRILOGY 1 is completed, that the Company would request a meeting with the FDA to discuss the data and seek guidance on how to modify the statistical analysis plan (SAP) for TRILOGY 2 before unblinding the results. This important decision will push out the reporting of TRILOGY 2 results until calendar Q3 of 2020.

Third Quarter Fiscal 2020 Financial Results:

- **Loss from operating activities** for the third quarter ended December 31, 2019 was $7.9 million, compared to a loss from operating activities of $10.7 million for the quarter ended December 31, 2018. The decrease was due mainly to a reduction in research contract expenses as the Phase 3 clinical program is getting closer to completion.

- **Net loss** for the quarter ended was $15.7 million or ($0.18) per share, compared to a net loss of $4.6 million or ($0.07) per share for the quarter ended December 31, 2018. The higher net loss was primarily due to the non-cash financial loss of $7.9 million for the three months ended December 31, 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 $4.2 million for the quarter ended December 31, 2019, compared to $8.8 million for the three months ended December 31, 2018. The $4.6 million decrease was mainly attributable to a $5.6 million decrease in research contracts. The lower research contract expense is primarily attributed to the Phase 3 clinical trial program getting closer to completion.

- **General and Administrative expenses** before stock-based compensation expenses were $1.6 million for the three months ended December 31, 2019, an increase of $.8 million from $.76 million for the three months ended December 31, 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 $.5 million in corporate, accounting and legal fees.

- **Sales and Marketing expenses** before stock-based compensation expenses were $.74 million for the three months ended December 31, 2019, compared to $.13 million for the three months ended December 31, 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 $25.7 million as of December 31, 2019, compared to $28.9 million for the quarter ended December 31, 2018. The decrease was mainly generated by the operating loss partially offset by the net proceeds from the sale of shares through the established ATM program and the recent exercise of warrants. As stated above, Acasti believes that existing cash will fully fund the Company's operations through at least December of 2020. Acasti projects that additional funds will be needed in the future, for activities necessary to prepare for commercial launch, including the scale up of our manufacturing operations, the completion of the potential regulatory (NDA) submission package (assuming positive Phase 3 clinical results), and the expansion of business development 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.

ATM Update

Acasti also provided an update on recent distributions under its previously adopted ATM program, as required pursuant to the policies of the TSX Venture Exchange. Since the last distributions under the ATM program reported on December 23, 2019, Acasti issued an aggregate of 1,355,798 common shares of the Company (the "ATM Shares") over the NASDAQ Stock Market for aggregate gross proceeds to the Company of US$1.4 million. The ATM Shares were sold at prevailing market prices which ranged from US$2.02 per share to US$0.85 per share. No securities were sold through the facilities of the TSX Venture Exchange or, to the knowledge of the Company, in Canada. The ATM Shares were sold pursuant to a U.S. registration statement on Form F-3 (No. 333-223464) as made effective on March 16, 2018, as well as an at-the-market issuance sales agreement dated February 14, 2019 among Acasti and B. Riley FBR, Inc.

Conference Call

Acasti will host a conference call today, Friday, February 14, 2020 at 1:00 PM Eastern Time to discuss the Company's financial results for the third quarter ended December 31, 2019, as well as an update on the TRILOGY 1 and TRILOGY 2 Phase 3 trials of CaPre.

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 May 14, 2020. A telephone replay of the call will be available approximately one hour following the call, through February 21, 2020, 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: 33138.

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 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.

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.

Acasti Contact:

Jan D'Alvise
Chief Executive Officer
Tel: 450-686-4555
Email: info@acastipharma.com
www.acastipharma.com

Investor Contact:
Crescendo Communications, LLC
Tel: 212-671-1020
Email: ACST@crescendo-ir.com

Source: Acasti Pharma, Inc.