August 14, 2019

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

Achieved 100% Patient Randomization in both TRILOGY trials

68% of randomized patients have completed the studies

On track to report topline results for TRILOGY 1 in December 2019 and TRILOGY 2 in January 2020

Fully funded beyond completion of Phase 3 studies

Approximately $8.1 million in additional proceeds from exercise of warrants since July 1, 2019

Acasti management to host conference call at1 PM ET today

LAVAL, Québec, Aug. 14, 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, today provided a business update and announced its operating and financial results for the first quarter of fiscal 2020 ended June 30, 2019. All amounts are in Canadian dollars.

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "Our TRILOGY Phase 3 trials in patients with severe hypertriglyceridemia (triglyceride blood levels from 500 mg/dL to 1500 mg/dL) continue to progress, and we remain on track to report topline TRILOGY 1 results in December 2019, and topline TRILOGY 2 results in January 2020. Importantly, both of our TRILOGY studies have achieved 100% patient randomization, and 68% of the patients have now completed their 6-month plan. 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 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. The TRILOGY studies are designed to provide at least 90% statistical power to detect a difference of at least a 20% decrease from baseline in TGs between CaPre and placebo. We have shared the statistical analysis plan (SAP) for the analysis and reporting of the TRILOGY results with the FDA, and will finalize it prior to final database lock. Subject to any input from the FDA, Acasti is currently planning that the topline TRILOGY 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. Physician investigators determined 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 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. 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 our preliminary topline data, we will seek to present the full data set, which will include results for our key secondary and exploratory endpoints of interest such as LDL-C, VLDL, HDL-C and HbA1c at key scientific meetings in the first half of 2020. The Company will communicate more information in the months ahead on how and when all of the TRILOGY results will be reported once the SAP is finalized.

Jan D'Alvise continued, "Given the positive results we saw from our Phase 2 trials in a total of 675 patients, we eagerly await the completion of the results from our two TRILOGY clinical studies. These trials showed not only a significant reduction of triglycerides, but also indicated that CaPre may have a positive effect on other major lipid markers such as VLDL, LDL-C, and HDL-C, as well as HbA1c in patients with diabetes. As previously disclosed, we believe our Phase 3 trial is well designed to meet our primary endpoint due to the fact the patients enrolled have higher baseline triglyceride levels (above 500 mg/dl) versus our Phase 2 studies, where most had baseline triglycerides significantly below 500 mg/dl. Additionally, the patients randomized to CaPre in TRILOGY all received 4 grams per day and will remain on drug for 6 months, while our Phase 2 studies included patients receiving a range of doses from 1 gram, 2 grams and 4 grams per day for only 8 to 12 weeks, which is important given the favorable dose response we saw in our Phase 2 studies. Assuming our TRILOGY trials replicate our Phase 2 data, we believe CaPre has the potential to provide an attractive alternative to current therapies, and thus improve the lives of the millions of patients with cardiometabolic disease. Finally, we continue to expand our patent estate in more key jurisdictions, and believe we have built a highly defensible IP portfolio covering all of the important markets."

At June 30, 2019, Acasti had $25.4 million of cash, cash equivalents and marketable securities, which funds the Company beyond completion of our Phase 3 trials, including funding to initiate work on the NDA, assuming the TRILOGY Phase 3 program is successful, as well as expanded business and US commercial launch activities. In addition, the Company reported that approximately $8.1 million in proceeds had been received from the recent exercise of warrants since July 1, 2019, which further extends the runway through June of 2020.

Recent Developments:

- **On April 1, 2019**, the Company announced the publication of a CaPre® bioavailability study, entitled “A Single-dose, Comparative Bioavailability Study of a Formulation Containing OM3 as Phospholipid (PL) and Free Fatty Acid (FFA) to an Ethyl Ester (EE) Formulation in the Fasting and Fed States,” which was published in the March 2019 issue of Journal of Clinical Therapeutics (Clinical Therapeutics 41 (2019) pp. 426-444), a leading peer-reviewed journal in the field of clinical pharmacology and therapeutics. The study found that among subjects within the fasting state, CaPre® demonstrated greater bioavailability of EPA and DHA as compared to "esterified" pharmaceutical omega-3s derived from fish oils. CaPre’s superior absorption profile could represent a significant clinical advantage, since taking it with a low-fat meal represents a healthier and more realistic regimen for patients with HTG who must follow a restricted low-fat diet.

- **On April 15, 2019**, the Company announced that its two on-going Phase 3 TRILOGY trials (TRILOGY 1 and TRILOGY 2) have exceeded a combined 89% patient randomization, and more than 40% of the patients in both trials have completed their 6-month treatment plan. This means that the “last patient in” to the TRILOGY 1 trial, will complete the trial by November. With the expected approximate 1 month of data clean-up following the “last patient out”, topline results for TRILOGY 1 are expected in December.

- **On May 15, 2019**, the Company announced that it has received Notices of Allowance for both composition of matter and method of use patents by the Mexican, Chilean and the Israeli Patent Offices. The granted patents are valid until 2030 and relate to a concentrated phospholipid composition and method of using the same for modulating blood lipids.

- **On June 4, 2019**, the Company announced that its TRILOGY 2 trial studying CaPre in patients with severe hypertriglyceridemia achieved 100% patient randomization. Additionally, the Company announced that its two on-going Phase 3 TRILOGY trials (TRILOGY 1 and TRILOGY 2) exceeded the target of a combined 500 randomized patients, and more than 60% of the patients in both trials had already completed their 6-month treatment plan.

- **On June 24, 2019**, the Company announced that it has received a Notice of Allowance for its second patent to be awarded in the People’s Republic of China. This new patent expands the Company’s existing claims and is valid until 2030. This patent also covers methods for the treatment and prevention of cardiovascular diseases, metabolic syndrome, inflammation, neurodevelopmental and neurodegenerative diseases.

First Quarter Fiscal 2020 Financial Results:

- **Loss from operating activities** for the first quarter ended June 30, 2019 was $10.6 million, compared to a loss from operating activities of $9.9 million for the quarter ended June 30, 2018. The approximately $0.7 million increase was related to an increased level of spending to support US market development and commercial prelaunch activities, and increase in insurance expense offset by the planned

deceleration of clinical Phase 3 program.

- **Net loss** for the first quarter ended June 30, 2019 was $11.8 million or $0.15 per share, compared to a net loss of $7.4 million or $0.23 per share for the quarter ended June 30, 2018. The higher net loss of $4.3 million was primarily due to a $1.1 million financial loss during the quarter ended June 30, 2019, as compared to a financial gain of $2.5 million for the quarter ended June 30, 2018. Financial loss was due mostly to the change in fair value of the warrant derivative liability, which was a non-cash item, partially offset by a decrease in financing fees. Also contributing to the net loss was the formation of the commercial leadership team during the second quarter of fiscal year 2019 to support expanded business and market development activities, additional administrative fees incurred in connection with the implementation of a new ERP system, increased insurance costs and accounting and legal fees.
- **R&D expenses** before depreciation, amortization and stock-based compensation expense were $7.4 million for the quarter ended June 30, 2019, down from $8.1 million in the quarter ended June 30, 2018. The $0.7 million decrease was primarily attributable to a $0.6 million decrease in clinical research contracts and $0.2 million decrease in legal fees for contracting and due diligence, partially offset by an increase in salaries and benefits of $0.1 million due to higher headcount. The lower research contract expense is primarily attributed to the advancement of the Phase 3 clinical trial program, as it nears completion.
- **General and Administrative expenses** before stock-based compensation expense were $1.3 million for the quarter ended June 30, 2019, compared to $0.9 million for the quarter ended June 30, 2018. The net increase was mainly due to a $0.2 million rise in expenses associated with increased insurance expense, which also increased our insurance expense, as well increased legal fees and salaries and benefits due to higher headcount.
- **Sales and Marketing expenses** before stock-based compensation expense were $0.9 million for the three months ended June 30, 2019 compared to nil for the three months ended June 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 $25.4 million as of June 30, 2019, which decreased by $9.0 million compared to March 31, 2019. The decrease was primarily due to the Company's cash used in operating activities of $9.2 million. 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, August 14, 2019 at 1:00 PM Eastern Time to discuss the Company's financial results for the first quarter ended June 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 November 14, 2019. A telephone replay of the call will be available approximately one hour following the call, through August 28, 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: 52892.

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.

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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