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Acasti Pharma Provides Business Update for the First Quarter of Fiscal 2019

TRILOGY studies surpass 50% enrollment and continue on track to complete enrollment in 2018

Awarded composition-of-matter patent by the U.S. Patent and Trademark Office

Acasti nears completion of clinical supply manufacturing and scale-up for commercial production

LAVAL, QUÉBEC, Aug. 14, 2018 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (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 ending June 30, 2018. All amounts are in Canadian dollars.

Jan D’Alvise, president and CEO of Acasti Pharma, commented, “Our two TRILOGY Phase 3 studies remain on track to complete enrollment this year. Importantly, as of August 10, 2018 we have reached almost 60% enrollment, with 770 patients enrolled, and 110 patients randomized at 126 clinical sites across the U.S., Canada, and Mexico. We continue to project that we will complete these studies on schedule in mid-2019, and expect to report topline results before the end of 2019.”

“We have nearly completed the manufacturing of all of the clinical trial materials needed for TRILOGY, and have further diversified our supply of raw krill oil by having completed the validation of a new supplier. Our commercial scale cGMP manufacturing is also in place, and we believe we have sufficient capacity to meet market demand in anticipation of the potential commercial launch of CaPre. In Q1, we successfully completed the Factory Acceptance Test of a proprietary, new high-throughput encapsulation machine designed by Acasti specifically for the commercial production of CaPre.

“We are also very pleased to report that during the first quarter of 2019, we were issued an important composition-of-matter patent by the U.S. Patent and Trademark Office. This patent covers a wide range of concentrated omega-3 and phospholipid compositions including Acasti’s lead product, CaPre. We believe the compositions covered by the issued claims are key to the unique therapeutic properties and mechanism of action of CaPre. As a result, we believe this patent strengthens Acasti’s already solid intellectual property position, and provides additional competitive and commercial advantage.”

“We have witnessed a significant interest in CaPre in Asia and around the world, and continue to actively advance partnership discussions. This is due in large part to the progress of our TRILOGY Phase 3 clinical program and the positive data we reported in our

four clinical trials to date in 773 patients. Specifically, the data showed a significant reduction of triglycerides (TG) and non-high density lipoprotein cholesterol (non-HDL-C) levels in the blood of patients with mild to severe HTG, as well as the potential to reduce LDL-C (“bad cholesterol”) and increase high-density lipoprotein cholesterol (HDL-C), or “good” cholesterol, at the therapeutic dose of 4 grams/day. These studies also confirmed good bioavailability (absorption by the body), even under fasting conditions and no significant food effect when taken with either low-fat or high-fat meals. Assuming we can replicate our earlier clinical results in the TRILOGY Phase 3 trials, these important clinical benefits could position CaPre as a best-in-class in the marketplace. We also believe the potential exists to expand CaPre’s initial indication to the roughly 36 million patients with high TGs (blood levels between 200 – 499 mg/dL) (The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease, 2011), although at least one additional clinical trial would likely be required to support FDA approval of a supplemental New Drug Application to expand CaPre’s indications to this segment.”

Recent Developments:

- **As of August 10, 2018, 126 clinical sites have been activated, 770 patients have been enrolled and 110 patients have been randomized for the two CaPre TRILOGY Phase 3 studies:** This is a double-blind, placebo-controlled, 26-week, two-study Phase 3 clinical program that is being conducted in a total of about 500 patients, and is designed to evaluate the safety and efficacy of CaPre in patients with severe hypertriglyceridemia. Additional cGMP production lots of active pharmaceutical ingredient (API) and CaPre were manufactured during the first quarter, enabling Acasti to continue to accumulate the CaPre inventory required to complete the TRILOGY trials.
- **Patents:** On July 24, 2018, Acasti announced it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) on its composition-of-matter patent application for “Concentrated Therapeutic Phospholipid Compositions.” The patent provides comprehensive coverage over a broad range of concentrated phospholipid compositions.
- **On June 6, 2018, Acasti provided an update on the progress of its phase 3 TRILOGY clinical trials at the XVIIIth International Symposium on Atherosclerosis (ISA2018),** the premier conference for international atherosclerosis research.

First Quarter 2019 Financial Results:

- **Net loss** for the first quarter ended June 30, 2018 was \$7.4 million or \$0.23 per share, compared to a net loss of \$2.8 million or \$0.19 per share for the quarter ended June 30, 2017. The higher net loss was primarily due to the planned increase in research and development expenses (“R&D”) for the TRILOGY Phase 3 program.
- **R&D expenses** were \$8.9 million for the quarter ended June 30, 2018, up from \$2.0 million in the quarter ended June 30, 2017. The \$6.9 million increase was primarily attributable to a \$6.7 million increase in clinical research contracts. The increased contract research expense primarily resulted from the planned increased patient enrollment and randomization activities combined with the contract manufacturing production activities to support the Phase 3 clinical program.
- **General and Administrative (“G&A”) expenses** were \$1.0 million for the quarter

ended June 30, 2018, compared to \$0.8 million for the quarter ended June 30, 2017. The net increase was mainly attributable to a \$0.2 million increase in stock compensation expenses for the G&A team.

- **Cash flows** – Cash and cash equivalents totaled \$12.9 million as of June 30, 2018, and increased with \$11.5 million in gross proceeds from the May 2018 underwritten public offering in Canada with the full exercise of the overallotment option. As previously disclosed, there exists a material uncertainty about the company’s ability to continue as a going concern and to realize its assets and discharge its liabilities in the normal course of business. Management has a reasonable expectation that the company should be able to raise additional funds later in 2018 to continue to finance the TRILOGY Phase 3 program for CaPre.

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 that 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. Acasti’s CaPre 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 outcomes studies (REDUCE-IT and STRENGTH). 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” 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, 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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