February 14, 2022

Acasti Pharma Provides Business Update for the Third Quarter of Fiscal 2022

Provides updates on key milestones: GTX-104 PK study remains on track for results to be reported in the first half of calendar 2022; GTX-102 and GTX-101 progressing on schedule

Conference call to be held on Monday, February 14th at 1:00 p.m. ET

LAVAL, Québec, Feb. 14, 2022 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST and TSX-V: ACST) today provided a business update and announced its operating and financial results for the third quarter of its fiscal 2022 ended December 31, 2021.

"We made significant progress during the third quarter, advancing all three of our lead programs," commented Jan D'Alvise, Chief Executive Officer of Acasti. "Immediately following the completion of the merger with Grace Therapeutics, Inc. (now Acasti Pharma U.S., Inc., a wholly owned subsidiary of Acasti), we initiated our pivotal PK bridging study for GTX-104, and in December we reported positive interim PK results for this novel aqueous formulation of water insoluble nimodipine being developed for the treatment of Subarachnoid Hemorrhage (SAH). In the interim analysis of the first 20 of about 50 normal healthy subjects enrolled, we were pleased to report that GTX-104 met both primary endpoints for maximum concentration (Cmax) on Day 1 and area under the concentration-time curve (AUC 0-24 hours) on Day 3, allowing us to continue the study under the current infusion protocol. We believe that the tight correlation of the primary endpoint data for the first 20 patients is a strong indication that GTX-104 could achieve comparable bioavailability with oral nimodipine in the full study cohort of about 50 subjects. Furthermore, the inter- and intra-subject variability in the interim analysis was much lower for GTX-104 as compared with oral nimodipine. This is very important, as reduced variability of blood levels should correlate with better control of hypotension, which could result in better outcomes for patients with SAH, as well as improved economics for the healthcare system. There were no serious adverse events observed in the first 20 subjects, and only mild adverse events were reported in both groups such as headaches, which were resolved with common medications.

"We remain on track to report the final study results during the first half of calendar 2022, and assuming the results are consistent with the interim data reported, we believe we can quickly proceed with finalizing the Phase 3 safety study design and protocol for GTX-104 with the U.S. Food and Drug Administration (FDA) and move forward with the initiation of the Phase 3 trial in the second half of calendar 2022, as planned. Assuming the full results of the pivotal PK bridging study for GTX-104 are consistent with the interim results, and given the safety profile seen to date, we believe that the Phase 3 safety study should be relatively low risk and can be conducted quickly and cost-effectively due to its small trial size. The safety study would be the final development step required to seek FDA approval, and if these Phase 3 safety study results meet the primary end points, we expect to move swiftly to submit the data in a Section 505(b)(2) New Drug Application (NDA) filing with the goal to

obtain FDA approval.

“Moving forward, we expect to reach significant additional key milestones in 2022, including PK bridging study results for GTX-102, our novel, easy-to-use oral mucosal spray formulation of betamethasone, intended to improve neurological symptoms of Ataxia-Telangiectasia (A-T), as well as single ascending dose (SAD) and multiple ascending dose (MAD) study results and the initiation of a Phase 2 trial for GTX-101, our novel bio-adhesive film forming topical spray formulation of bupivacaine being developed for the treatment of Postherpetic Neuralgia (PHN). We believe these near-term milestones have the potential to drive shareholder value while addressing rare and orphan diseases that are poorly served by available therapies or have no approved therapies,” concluded Ms. D’Alvise.

Third Quarter of Fiscal 2022 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 operating activities** for the three months ended December 31, 2021 was $4.5 million, compared to a loss of $2.0 million for the three months ended December 31, 2020. The increase was due to an increase in research and development expenses, and an increase in general and administrative expenses due to increased legal, tax, accounting, and other professional fees.
- **Net loss** for the three months ended December 31, 2021 was $3.8 million or $0.09 per share, compared to a net loss of $3.2 million or $0.26 per share for the three months ended December 31, 2020. The increase in net loss resulted primarily from an increase in research and development expenses related to the new clinical assets acquired in the merger with Grace Therapeutics, Inc.
- **Research and development expenses** before depreciation, amortization and stock-based compensation expenses for the three months ended December 31, 2021, totaled $2.0 million compared to $0.62 million for the three months ended December 31, 2020. The net increase was mainly attributable to increased research contract activities as the progression of work advances related to GTX-104, GTX-101, and GTX-102. In addition, salaries and benefits attributable to research and development increased due to the increased headcount following the merger.
- **General and administrative expenses** before stock-based compensation expenses for the three months ended December 31, 2021 were $1.5 million compared to $0.93 million for the three months ended December 31, 2020. This increase was a result of increased legal, tax, accounting, and other professional fees.
- **Sales and marketing expenses** before stock-based compensation expenses were $0.22 for the three months ended December 31, 2021, compared to $0.49 million for the three months ended December 31, 2020.
- **Cash, cash equivalents and short-term investments** totaled $46.3 million as of December 31, 2021, compared to $26.5 million in cash, cash equivalents and short term investments as of December 31, 2020. The Company believes these funding resources provide at least 21 months of operating runway, based on management’s current projections.

Conference Call

Acasti will host a conference call on Monday, February 14, 2022 at 1:00 PM Eastern Time to

discuss the Company's corporate progress and other developments, as well as financial results for its fiscal 2022 third quarter ended December 31, 2021.

The conference call will be available via telephone by dialing toll free 888-506-0062 for U.S. callers or +1 973-528-0011 for international callers and using entry code 316432. A webcast of the call may be accessed at https://www.webcaster4.com/Webcast/Page/2210/44486 or on the Company's Investor Relations section of the website: https://www.acastipharma.com/investors/.

A webcast replay will be available on the Company's Investors News/Events section of the website (https://www.acastipharma.com/investors/) through February 14, 2023. A telephone replay of the call will be available approximately one hour following the call, through February 21, 2022, 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: 44486.

About Acasti

Acasti is a specialty pharma company with drug delivery technologies and drug candidates addressing rare and orphan diseases. Acasti's novel drug delivery technologies have the potential to improve the performance of currently marketed drugs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery—all which could help to increase treatment compliance and improve patient outcomes.

Acasti's three lead clinical assets have each been granted Orphan Drug Designation by the U.S. FDA, which provide the assets with seven years of marketing exclusivity post-launch in the United States, and additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical assets target underserved orphan diseases: (i) GTX-104, an intravenous infusion targeting Subarachnoid Hemorrhage (SAH), a rare and life-threatening medical emergency in which bleeding occurs over the surface of the brain in the subarachnoid space between the brain and skull; (ii) GTX-102, an oral mucosal spray targeting Ataxia-telangiectasia (A-T), a progressive, neurodegenerative genetic disease that primarily affects children, causing severe disability, and for which no treatment currently exists; and (iii) GTX-101, a topical spray targeting Postherpetic Neuralgia (PHN), a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles), which may persist for months and even years. For more information, please visit: https://www.acastipharma.com/en.

Forward-Looking Statements

Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and "forward-looking information" within the meaning of Canadian 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 containing 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.

The forward-looking statements in this press release are based upon Acasti's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions of the PK bridging study for GTX-104 and Acasti's other pre-clinical and clinical trials; (ii) the final outcome of the PK bridging study for GTX-104, including the potential of GTX-104 to provide improved bioavailability and lower intra-subject variability compared to oral capsules; (iii) regulatory requirements or developments and the outcome of meetings with the FDA; (iv) changes to clinical trial designs and regulatory pathways; (v) legislative, regulatory, political and economic developments; (vi) costs associated with Acasti's clinical trials and (vii) the effects of COVID-19 on clinical programs and business operations. The foregoing list of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Acasti from time to time with the Securities and Exchange Commission and Canadian securities regulators. All forward-looking statements contained in this press release speak only as of the date on which they were made. Acasti undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by applicable securities laws.

Neither NASDAQ, the TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

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