January 5, 2023

Acasti to Host Conference Call on Tuesday, January 10, 2023 to Discuss Results from Recent Phase 1 PK Studies for GTX-101 and GTX-102 That Met All Outcome Measures

LAVAL, Québec, Jan. 05, 2023 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST), a late-stage, specialty pharma company advancing three clinical stage drug candidates addressing rare and orphan diseases, today announced that it will host a conference call on Tuesday, January 10, 2023 at 4:30 p.m. ET to review the recently reported preliminary topline results from two separate Phase 1 pharmacokinetic (PK) studies for GTX-101 and GTX-102. Both studies successfully met all target outcome measures.

The conference call will be available via telephone by dialing toll free 844-836-8745 for U.S. callers or +1 412-317-6797 for international callers. A webcast of the call may be accessed at https://app.webinar.net/ElY1p42obKW 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 January 10, 2024. A telephone replay of the call will be available approximately one hour following the call, through January 17, 2023, and can be accessed by dialing 877-344-7529 for U.S. callers or +1 412-317-0088 for international callers and entering replay access code: 1057983.

GTX-101 Summary

On December 22, 2022, Acasti announced that preliminary topline results for its single-dose, PK study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug in the U.S., bupivacaine subcutaneous injectable, met all primary outcome measures for the study. The final clinical study report is anticipated to be received by the Company in the first half of 2023. GTX-101 is a novel formulation of bupivacaine hydrochloride for topical administration via a bio-adhesive, film-forming polymer, for relief of pain associated with Postherpetic Neuralgia, 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. This PK study was the next step in the proposed 505(b)(2) regulatory pathway for GTX-101 and provides important information on the dose and dosing frequency in humans for future planned clinical studies. The full press release can be accessed at https://www.globenewswire.com/en/news-release/2022/12/22/2578577/0/en/Acasti-Pharma-Announces-Preliminary-Topline-Results-Met-All-Primary-Outcome-Measures-in-the-Single-Dose-Pharmacokinetic-Study-for-GTX-101-the-Company-s-Drug-Candidate-for-the-

Treat.html.

GTX-102 Summary

On December 28, 2022, Acasti announced that the preliminary topline results of the pharmacokinetic (PK) bridging study for GTX-102 met all primary outcome measures. The objectives of the study were to evaluate the bioavailability, pharmacokinetics, and safety of GTX-102, a novel, concentrated oral-mucosal metered spray of betamethasone in healthy volunteers and compare the PK profile to an intramuscular injection of betamethasone, the reference drug, which is approved in the US. This new and patented formulation of betamethasone is intended to improve the neurological symptoms of Ataxia Telangiectasia (A-T) in a pediatric population for which there are currently no FDA-approved therapies. The next step in the proposed 505(b)(2) regulatory pathway for GTX-102 is expected to be a Phase 3 safety and efficacy study in children with A-T, which could be initiated in the second half of calendar 2023, following a Type B meeting with the FDA. The full press release can be accessed at https://www.globenewswire.com/en/news-release/2022/12/28/2580187/0/en/Acasti-Announces-Preliminary-Topline-Results-Met-All-Outcome-Measures-in-the-Pharmacokinetic-Bridging-Study-for-GTX-102-the-Company-s-Drug-Candidate-for-the-Treatment-of-Ataxia-Tel.html

About Acasti

Acasti is a late-stage 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 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.acasti.com/en.

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 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 (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 each of the planned Type B meeting with the FDA and the anticipated Phase 3 safety and efficacy trial for GTX-102, (ii) the success and timing of regulatory submissions of the PK bridging study and Phase 3 safety study protocol for GTX-104, and Acasti's other pre-clinical and clinical trials; (iii) regulatory requirements or developments; (iv) changes to clinical trial designs and regulatory pathways; (v) legislative, regulatory, political and economic developments, and (vi) 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. 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.

Acasti Contact:

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

Investor Relations:
Robert Blum
Lytham Partners, LLC
602-889-9700
ACST@lythampartners.com

acasti

Source: Acasti Pharma, Inc.