September 25, 2024

Acasti Announces Completion of Patient Enrollment in Pivotal Phase 3 STRIVE-ON Safety Trial of GTX-104

Data Readout Expected Early Calendar 2025; NDA Submission on Track for 1H Calendar 2025

PRINCETON, N.J., Sept. 25, 2024 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (Nasdaq: ACST) (Acasti or the Company), a late-stage, biopharma company advancing GTX-104, its novel injectable formulation of nimodipine that addresses high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced that patient enrollment has been completed in the Company's Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405). The STRIVE-ON trial is a prospective, open-label, randomized (1:1 ratio), parallel group trial of GTX-104 compared with oral nimodipine, in 100 patients hospitalized for aSAH. Approximately 25 hospitals in the U.S. are participating.

"We are excited to announce the completion of enrollment in our STRIVE-ON trial, a significant milestone for the Company achieved ahead of our original expectations," said Prashant Kohli, CEO of Acasti. "I'm proud of our team's diligence in executing the clinical trial plan, and thankful to our investigators for their strong support. We believe that if approved, GTX-104 has the potential to address significant challenges with oral nimodipine administration and may transform the standard of care for patients with aSAH. We anticipate a data readout from the STRIVE-ON trial in early calendar 2025, and plan to submit a New Drug Application to the U.S. Food and Drug Administration in the first half of next year, consistent with our timeline."

The primary endpoint of the STRIVE-ON trial is safety, and will be measured as comparative adverse events, including hypotension, between the two patient groups.

About aneurysmal Subarachnoid Hemorrhage (aSAH)

aSAH is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is the rupture of an aneurysm. Approximately 70% of aSAH patients experience death or dependence, and more than 30% die within one month of hemorrhage. Approximately 50,000 patients in the United States are affected by aSAH per year, based on market research. Outside of the United States, annual cases of aSAH are estimated at approximately 60,000 in the European Union, and approximately 150,000 in China.

About the Acasti Asset Portfolio

GTX-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous (IV) infusion in aSAH patients to address significant unmet medical needs. The

unique nanoparticle technology of GTX-104 facilitates aqueous formulation of insoluble nimodipine for a standard peripheral IV infusion.

GTX-104 provides a convenient IV delivery of nimodipine in the Intensive Care Unit potentially eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. Intravenous delivery of GTX-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTX-104 has the potential to better manage hypotension in aSAH patients. GTX-104 has been administered in over 150 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine. The addressable market in the United States for GTX-104 is estimated to be about $300 million, based on market research.

GTX-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of Ataxia-Telangiectasia (A-T), for which there are currently no FDA-approved therapies. GTX-102 is a stable, concentrated oral spray formulation comprised of the gluco-corticosteroid betamethasone that, together with other excipients can be sprayed conveniently over the tongue of the A-T patient and is rapidly absorbed. The further development of GTX-102 has been deprioritized in favor of our focus on development of GTX-104. It is also possible that we may license or sell our GTX-102 drug candidate.

GTX-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with postherpetic neuralgia (PHN). GTX-101 is administered via a metered-dose of bupivacaine spray and forms a thin bio-adhesive topical film on the surface of the patient’s skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches, we believe that the biphasic delivery mechanism of GTX-101 has the potential for rapid onset of action and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 trial. The further development of GTX-101 has been deprioritized in favor of our focus on development of GTX-104. It is also possible that we may license or sell our GTX-101 drug candidate.

About Acasti

Acasti is a late-stage biopharma company with 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. Acasti's lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provides 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 asset, GTX-104, is an intravenous infusion targeting aneurysmal Subarachnoid Hemorrhage (aSAH), 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.

For more information, please visit: www.acasti.com.

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 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," "estimates", "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, including statements regarding the timing of a data readout from the Company's Phase 3 STRIVE-ON safety trial of GTX-104, the timing of the Company's planned NDA submission with the FDA in connection with the Company's Phase 3 STRIVE-ON safety trial, GTX-104's commercial prospects; the size of the addressable market for GTX-104, the Company's beliefs regarding the potential benefits of GTX-104, including GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated benefits and future development, license or sale of the Company's other drug candidates 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 Phase 3 STRIVE-ON safety trial for GTX-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed NDA application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations. 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 are 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.

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Source: Acasti Pharma, Inc.