October 23, 2023

Acasti Announces Dosing of First Patient in GTX-104 STRIVE-ON Trial

- *With achievement of enrollment milestone, pivotal STRIVE-ON safety trial on track for potential NDA submission anticipated to occur in the first half of calendar 2025*
- *Recently announced $7.5 million private placement financing extends projected cash runway to the first calendar quarter of 2026*

PRINCETON, N.J., Oct. 23, 2023 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (Nasdaq: ACST) (Acasti or the Company), a late-stage, biopharma company advancing GTX-104, its novel formulation of nimodipine that addresses the high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced enrollment of the first patient in the Company's pivotal Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405). UTHealth Houston is the first site to enroll an aSAH patient in the STRIVE-ON trial.

"The dosing of our first patient in the STRIVE-ON trial is a significant milestone for Acasti, demonstrating our ability to execute our clinical development program for GTX-104," said Prashant Kohli, CEO of Acasti. "We're pleased to be working with a prestigious neurocritical care team such as UTHealth Houston, and look forward to welcoming additional centers. After the completion of our recently announced $7.5 million private placement offering, we have the balance sheet strength and are well positioned to continue GTX-104 development towards realizing its clinical and commercial prospects as a potential new treatment standard for aSAH."

The Company previously announced alignment with the U.S. Food and Drug Administration (FDA) on the protocol and dosing regimen for the STRIVE-ON trial, at which time the FDA provided guidance regarding a potential New Drug Application (NDA) submission for GTX-104, currently anticipated in the first half of calendar 2025. GTX-104 has already been administered in over 160 healthy subjects in prior Phase 1 trials and has a well-established safety profile. GTX-104 has the potential to disrupt the oral nimodipine dosage form and become the standard of care in aSAH patients addressing critical unmet medical needs.

Acasti also recently hosted a virtual key opinion leader event featuring W. Taylor Kimberly, MD, PhD (Massachusetts General Hospital) who discussed the high unmet medical need and current treatment landscape for patients suffering from aSAH.

A replay of the webinar is available here.

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.

About GTX-104

GTX-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous infusion (IV) 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.

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: 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 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 Company's anticipated cash runway, the anticipated timing of the completion of the Company's STRIVE-ON trial, the Company's anticipated NDA submission with the FDA, the anticipated use of proceeds raised in the Company's recent private placement offering, and GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH and become the new standard of care in aSAH treatment 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 planned Phase 3 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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