May 8, 2023

Acasti Successfully Submits Pivotal GTX-104 Phase 3 Safety Study Protocol with FDA and Implements Strategic Realignment Plan That Extends Projected Cash Runway Through Calendar Q2 2025

Company successfully submits GTX-104 Pivotal Phase 3 protocol IND amendment to the FDA with expectation for first patient dosed in calendar Q4 2023

Strategic realignment prioritizes GTX-104 and expects to extend cash runway through a potential New Drug Application (NDA) filing for GTX-104

LAVAL, Québec, May 8, 2023 /PRNewswire/ -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST), 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 the successful submission to the FDA of GTX-104's full protocol of its pivotal Phase 3 Safety Study and implementation of a strategic realignment plan to maximize shareholder value.

Prashant Kohli, CEO of Acasti, commented, "We are extremely pleased to execute on this important submission milestone as we advance GTX-104, a critically important drug candidate to the thousands of patients that suffer from subarachnoid hemorrhage without effective treatment options. We expect this pivotal Phase 3 Safety Study will be the final clinical step required to seek FDA approval under the 505(b)(2) regulatory pathway."

The realignment follows a comprehensive strategic review of the company by Prashant Kohli, its recently appointed CEO, and its Board of Directors.

"As a result of the positive progress made with GTX-104, and following a strategic review, we felt it was critical to move swiftly and boldly to implement a plan that we believe will benefit Acasti's shareholders by prioritizing resources to this high-value asset," Kohli continued.

Key strategies being implemented are:

1. Prioritizing resources to Acasti's biggest value driver – GTX-104. Acasti has submitted the full pivotal Phase 3 Safety Study protocol with all supporting documentation. Pending final feedback and approval from the FDA, the first patient, first dose for the pivotal Phase 3 Safety Study is expected in calendar Q4 2023.
2. Strategic transformation of Acasti's operating model to an agile biopharma reflecting its complete focus on GTX-104. In alignment with the operating model, Acasti has brought on a highly experienced new management team with deep subject matter knowledge and direct, hands-on clinical trial experience in aSAH.
3. Significant extension of the Company's cash runway expected to be sufficient to fund the Company through calendar Q2 2025, facilitating achievement of critical value inflection milestones, including a potential New Drug Application (NDA) filing for GTX-104.
4. Evaluation of strategic alternatives to maximize value of de-prioritized pipeline assets (GTX-102 and GTX-101) including out-licensing or sale.

Vimal Kavuru, Acasti's Board Chair, added, "In today's current turbulent markets, we determined it is imperative to narrow our focus to accelerate development of GTX-104, our lead value creation driver. We believe this strategic realignment will allow us to achieve key inflection milestones without the near-term need for a significant dilutive capital raise."

In connection with the transformation of the operating model, the Company has moved to appoint the following industry experts to its senior management team:

- Dr. R. Loch Macdonald, MD, PhD, as Chief Medical Officer. A world-renowned practicing neurosurgeon-scientist and respected authority in SAH, Dr. Macdonald is the former founder of a clinical-stage biotechnology company focused on subarachnoid hemorrhage.
- Carrie D'Andrea, as VP Clinical Operations. Ms. D'Andrea is a highly experienced professional who has built and led the planning, implementation, management, and execution of global Phase 2 and Phase 3 trials for a drug candidate for subarachnoid hemorrhage.
- Amresh Kumar, PhD, as VP Program Management. Mr. Kumar is an experienced drug development, CMC, and program management expert. Amresh is the former product leader of GTX-104 while at Grace Therapeutics (which was acquired by Acasti).

"A key requirement of the strategic realignment was to build a high-performing, nimble team of professionals with specific experience in our target disease state and product knowledge. The new Acasti is a highly motivated and energized organization that is flatter, agile, and strategically closer to our addressable market opportunity in the U.S. Importantly, the new team will leverage invaluable insights in aSAH from their prior experience with a focus on executional excellence to drive value for patients and Acasti's shareholders," Kohli concluded.

As a result of this strategic realignment, Acasti is over time discontinuing its operations in Canada, and has proceeded to lay off substantially all its workforce, allowing Acasti's new management team to rebuild a leaner organization in the United States.

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 rupture of an aneurysm. Approximately 70% of aSAH patients experience death or dependence, and a third die within one month after the hemorrhage (Becske, 2018). Approximately 50,000 patients are affected by aSAH per year, based on market research conducted by Fletcher Spaght.

About GTX-104
GTX-104 is a clinical stage, novel aqueous formulation of nimodipine being developed for IV infusion in aSAH patients to address significant unmet medical needs. GTX-104 provides a more convenient IV delivery of nimodipine in the ICU eliminating the need for nasogastric tube administration of the drug in unconscious or dysphagic patients. Due to IV delivery, 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 dosed in over 150 healthy subjects and was well tolerated with significantly lower inter and intra subject PK variability compared to the oral drug. The addressable market in the United States for GTX-104 is estimated to be about $300 million, based on market research conducted by Fletcher Spaght.

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.

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 on the Company's anticipated cash runway, 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 study for GTX-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed IND application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations; and (vi) the projected extension of the Company's cash runway to calendar Q2 2025. 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. The NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

Acasti Contact:

Prashant Kohli
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

View original content to download multimedia: https://www.prnewswire.com/news-releases/acasti-successfully-submits-pivotal-gtx-104-phase-3-safety-study-protocol-with-fda-and-implements-strategic-realignment-plan-that-extends-projected-cash-runway-through-calendar-q2-2025-301817840.html

SOURCE Acasti Pharma Inc.