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Acasti Announces Court Dismissal of Stockholder Litigation

LAVAL, Québec, Sept. 30, 2022 (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, announced today that a U.S. court has dismissed the remaining stockholder litigation filed in connection with the Company's acquisition of Grace Therapeutics, Inc. ("**Grace**") via merger in August 2021 (the "**Merger**"). As previously disclosed, four stockholder lawsuits were filed against Acasti and certain of its directors and officers in connection with the Merger, claiming that the Company's public disclosures relating to the Merger misstated or omitted material information and violated Section 14(a) of the U.S. Securities Exchange Act of 1934. Two of the four cases were voluntarily dismissed. The remaining two cases were consolidated before Judge Katherine Polk Failla in the United States District Court for the Southern District of New York. Acasti and the individual defendants filed a motion to dismiss on February 25, 2022. In a 45-page opinion released earlier today, Judge Failla granted the motion to dismiss in its entirety, finding that the consolidated complaint failed to allege any facts showing that Acasti made a materially misleading statement or material omission in its Merger-related disclosures. Accordingly, subject to any appeal that may be taken in response to today's ruling, all four stockholder suits filed in connection with the Merger have now been dismissed.

About Acasti

Acasti is a late-stage, specialty pharma company advancing three clinical stage 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 provides the assets with seven years of marketing exclusivity post-launch in the United States and have 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,” “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 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 and Acasti’s other pre-clinical and clinical trials for GTX-102 and GTX-101; (ii) regulatory requirements or developments and the outcome of meetings with the FDA; (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 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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