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Grace Therapeutics Announces Alignment with the FDA Supporting the Planned NDA Submission for GTx-104

NDA Submission Anticipated Q2 Calendar 2025

PRINCETON, N.J., April 09, 2025 (GLOBE NEWSWIRE) -- Grace Therapeutics, Inc. (Nasdaq: GRCE) (Grace Therapeutics or the Company), a late-stage, biopharma company advancing GTx-104, a clinical-stage, novel, injectable formulation of nimodipine being developed for IV infusion to address significant unmet medical needs in aneurysmal subarachnoid hemorrhage (aSAH) patients, today announced details of the Company's Type C meeting with the U.S. Food and Drug Administration (FDA). The purpose of this meeting was to obtain FDA feedback on the completed Phase 3 STRIVE-ON safety trial of GTx-104 and its planned New Drug Application (NDA) submission including clinical, non-clinical, and chemistry, manufacturing, and control (CMC) requirements.

Based on feedback from the FDA, the Company believes that the data and regulatory packages as currently structured will be sufficient for submission of an NDA.

"Our recent interactions with the FDA have been positive and productive, and we are pleased to achieve alignment with the agency on the substance and structure of our NDA submission," said Prashant Kohli, Chief Executive Officer of Grace Therapeutics. "Due to a unique combination of nimodipine pharmacokinetic characteristics and debilitating aSAH pathophysiology, the enteral route of administration results in significant unmet medical needs in the treatment of aSAH, presenting a compelling clinical rationale for GTx-104 to be administered as an IV infusion of nimodipine. As evidenced from our STRIVE-ON trial data, GTx-104 had fewer patients with clinically significant hypotension, more patients with higher dose compliance and better functional recovery, and lower pharmacoeconomic burden. We are excited about the prospects of GTx-104 to help improve patient outcomes upon potential FDA approval, and to deliver the first innovation for the treatment of aSAH in almost four decades."

The Company anticipates filing its NDA for GTx-104 in the second quarter of 2025. Acceptance of the NDA will be subject to the FDA's review of the complete filing.

About the STRIVE-ON Trial

The STRIVE-ON trial ([NCT05995405](#)) was a prospective, randomized open-label trial of GTx-104 compared with oral nimodipine in patients hospitalized with aSAH. 50 patients were administered GTx-104 and 52 patients received oral nimodipine. The primary endpoint was the number of patients with at least one episode of clinically significant hypotension reasonably considered to be caused by the drug, and additional endpoints included safety, clinical, and pharmacoeconomic outcomes. The trial met its primary endpoint, with patients

receiving GTx-104 observed to have a 19% reduction in at least one incidence of clinically significant hypotension compared to oral nimodipine (28% versus 35%). Other measures also favored or were comparable to GTx-104, including: 54% patients had relative dose intensity (RDI) of 95% or higher compared to only 8% on oral nimodipine, and 29% more patients had favorable functional outcomes at 90 days. In addition, there were fewer intensive care unit (ICU) readmissions, ICU days, and ventilator days for patients receiving GTx-104 versus oral nimodipine. Adverse events were comparable between the two arms and no new safety issues were identified with patients receiving GTx-104. All deaths in both arms of the trial were due to severity of the patient's underlying disease. There were eight deaths on the GTx-104 arm compared to four deaths on the oral nimodipine arm. The survival status of one patient on the oral nimodipine arm was unknown. No deaths were determined to be related to GTx-104 or oral nimodipine.

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 in the brain. The result is a relatively uncommon type of stroke (aSAH) that accounts for about 5% of all strokes and an estimated 42,500 U.S. hospital treated patients.

About GTx-104

GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for 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 100 patients and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine.

About Grace Therapeutics

Grace Therapeutics, Inc. (Grace Therapeutics or the Company) is a late-stage biopharma company with drug candidates addressing rare and orphan diseases. Grace Therapeutics' 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. Grace Therapeutic'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. Grace Therapeutics' lead clinical asset, GTx-104, is an IV 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.gracetx.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 Grace Therapeutics 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 future prospects of the Company's GTx-104 drug candidate, the timing of the Company's anticipated NDA submission for GTx-104, GTx-104's potential to bring enhanced treatment options to patients suffering from aSAH, GTx-104's potential to be administered to improve the management of hypotension in patients with aSAH, the ability of GTx-104 to achieve a pharmacokinetic and safety profile similar to the oral form of nimodipine, GTx-104's potential to achieve pharmacoeconomic benefit, higher dose compliance and better functional recovery over the oral form of nimodipine, GTx-104's commercial prospects, and any future patent and other intellectual property filings made by the Company for new developments are based upon Grace Therapeutics' 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 regulatory pathways; and (iv) legislative, regulatory, political and economic developments. 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 the "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2024, Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024, the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024, the Quarterly Report on Form 10-Q for the quarterly period ended December 31, 2024, as amended by Amendment No. 1 on Form 10-Q/A, and other documents that have been and will be filed by Grace Therapeutics 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. Grace Therapeutics 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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