

March 19, 2026



Grace Therapeutics to Present Data on the Unmet Medical Needs and Potential Benefits of GTx-104 in the Treatment of aSAH at Upcoming Medical Conferences

PRINCETON, N.J., March 19, 2026 (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 intravenous infusion to address significant unmet medical needs in aneurysmal subarachnoid hemorrhage (aSAH) patients, today announced that abstracts discussing the unmet medical needs and the potential benefits of GTx-104 have been accepted for presentation at two major medical conferences taking place in March 2026.

The Company is participating in an industry education workshop during the [Society of Critical Care Medicine's Critical Care Congress](#), to be held March 22-24, 2026 in Chicago, IL. In a session titled *Unmet Needs in aSAH: Limitations of Current Treatments*, speakers will discuss the role of orally administered nimodipine as the standard of care for patients with aSAH, including factors that can limit full dosing, such as hypotension and gastrointestinal intolerance. The session will also introduce data from the Company's Phase 3 STRIVE-ON Trial evaluating GTx-104's potential to address the shortcomings of oral nimodipine.

At the [American Association of Neuroscience Nurses](#) annual meeting, to be held March 21-24, in Dallas, TX, the Company will present a poster titled *Safety and Tolerability of GTx-104 (Nimodipine Injection for IV Infusion) Compared with Oral Nimodipine in Patients With Aneurysmal Subarachnoid Hemorrhage: a Prospective, Randomized Trial*. The poster will highlight data from the STRIVE-ON Trial and the potential of GTx-104 to improve upon the tolerability and dosing consistency of nimodipine therapy compared with oral administration.

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 secondary 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 GTx-104 or were comparable between GTx-104 and oral nimodipine, including: 54% patients on GTx-104 had relative dose intensity (RDI) of 95% or higher compared to only 8% on oral nimodipine, and 29% more patients on GTx-104 than

on oral nimodipine 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 200 patients and healthy volunteers 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 if certain conditions are met at NDA approval, 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.

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, 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, gastrointestinal intolerance and dosing consistency compared with oral administration, the ability of GTx-104 to achieve a pharmacokinetic and safety profile similar to the oral form of nimodipine, and GTx-104’s potential to achieve medical and pharmacoeconomic benefit, 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 of regulatory submissions of the Phase 3 STRIVE-ON safety trial for GTx-104; (ii) regulatory requirements or developments and the outcome of the Company’s NDA submission for GTx-104; (iii) changes to regulatory pathways; (iv) our ability to protect our intellectual property for our drug candidates; and (v) 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, 2025, the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025, the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025 and the Company’s Quarterly Report on Form 10-Q for the quarterly period ended December 31, 2025, filed with the Securities and Exchange Commission (“SEC”) and other documents that have been and will be filed by Grace Therapeutics from time to time with the SEC 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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Source: Grace Therapeutics, Inc.