Quince Therapeutics to Host Investor Webinar Today Focused on Addressing the High Unmet Need in Ataxia-Telangiectasia

February 7, 2025

Phase 3 NEAT clinical trial nearing 50% enrollment; company reiterates expectation of enrollment completion in second quarter of 2025 and topline results in fourth quarter of 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 7, 2025-- Quince Therapeutics, Inc. (Nasdaq: QNCX), a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases, announced that it will host an investor webinar today, Friday, February 7, 2025, beginning at 10:00 a.m. Eastern Time, featuring key opinion leader (KOL) Dr. Mary Kay Koenig from UTHealth Houston with a discussion focused on addressing the high unmet need in Ataxia-Telangiectasia (A-T).

Quince also disclosed that the company has enrolled 46 participants to date in its pivotal Phase 3 NEAT (**N**eurologic **E**ffects of EryDex on Subjects with **A**-**T**; NCT06193200 / IEDAT-04-2022) clinical trial to evaluate the neurological effects of EryDex in patients with A-T.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "We continue to make significant progress with clinical site activations and enrollment of our pivotal Phase 3 NEAT clinical trial. With 61 participants screened to date, enrollment is nearing 50% and we expect screening and randomization to accelerate in the coming weeks due to several new geographic regions and sites scheduled for activation. We anticipate completing enrollment during the second quarter of 2025 and reporting topline results before the end of 2025."

Pivotal Phase 3 NEAT Clinical Trial

- Enrolled 46 participants to date in the company's Phase 3 NEAT clinical trial to evaluate the neurological effects of EryDex in patients with A-T, including 40 participants in the six to nine year-old primary analysis population. Quince plans to enroll approximately 86 patients with A-T ages six to nine years old (primary analysis population) and approximately 20 patients with A-T ages 10 years or older.
- Open label extension initiated with 17 participants rolling over to date in the U.S., U.K., and European Union. Participants who complete the full treatment period, complete study assessments, and provide informed consent are eligible to transition to an open label extension study.
- Pivotal Phase 3 NEAT clinical trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).
- Expect to report Phase 3 NEAT topline results in the fourth quarter of 2025 with a New Drug Application (NDA) submission to the FDA and a Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) in 2026, assuming positive study results.
- NEAT is an international, multi-center, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of the company's lead asset, EryDex (dexamethasone sodium phosphate [DSP] encapsulated in autologous red blood cells), in patients with A-T.
- Participants will be randomized (1:1) between EryDex or placebo and treatment will consist of six infusions scheduled once every 21 to 30 days. The primary efficacy endpoint will be measured by the change from baseline to last visit completion in a rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo as per the SPA agreement with the FDA.

Join Today's A-T KOL Investor Webinar

Quince will host an investor webinar today focused on addressing the high unmet need in the company's lead rare pediatric neurodegenerative disease indication, Ataxia-Telangiectasia (A-T), today, Friday, February 7, 2025, beginning at 10:00 a.m. Eastern Time.

The webinar will feature leading A-T KOL Mary Kay Koenig, M.D., who will: 1) provide an A-T natural history overview, 2) detail current symptomatic treatment approaches for patients with A-T, 3) discuss the competitive therapeutic A-T landscape, and 4) provide an overview of Quince's Phase 3 clinical trial of EryDex for the treatment of A-T. Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, will join the discussion to provide a corporate and scientific overview, as well as an enrollment update on the company's ongoing Phase 3 NEAT clinical trial.

Mary Kay Koenig, M.D., is a board certified child neurologist specializing in neurodegenerative disorders, including A-T, mitochondrial disease, and tuberous sclerosis complex. She currently serves as a Professor and Associate Vice-Chair for Clinical Research in the Department of Pediatrics, Division of Child and Adolescent Neurology at the McGovern Medical School at the University of Texas, Houston. Dr. Koenig is also an Endowed Chair of Mitochondrial Medicine at the McGovern Medical School at the University of Texas, Houston, in addition to serving as a Director at the Center for the Treatment of Pediatric Neurodegenerative Disease and a Co-Director of the Tuberous Sclerosis Center within the UTHealth Houston system – one of the nation's most comprehensive academic health science centers. She strives to provide excellent clinical care and advance research for children afflicted with genetic neurodegenerative disease. Dr. Koenig also works to mentor and educate junior faculty, fellows, residents, and medical students

in the art of medicine and clinical research. She received her M.D. from St. George's University School of Medicine and completed her pediatrics residency at the University of Texas Medical Branch in Galveston, Texas, in addition to a fellowship in child and adolescent neurology at the University of Texas Medical School in Houston, Texas.

To register for this webinar, please click here. A live webcast of the presentation will be accessible on Quince's Events page under the News & Events heading of the company's Investor Relations website at ir.quincetx.com. An archive of the webcast will be available shortly following the end of the live event.

About Quince Therapeutics

Quince Therapeutics, Inc. (Nasdaq: QNCX) is a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases. For more information on the company and its latest news, visit www.quincetx.com and follow Quince on social media platforms LinkedIn, Facebook, X, and YouTube.

Forward-looking Statements

Statements in this news release contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. All statements, other than statements of historical facts, may be forward-looking statements. Forward-looking statements contained in this news release may be identified by the use of words such as "believe," "may," "should," "expect," "anticipate," "plan," "believe," "estimated," "potential," "intend," "will," "can," "seek," or other similar words. Examples of forward-looking statements include, among others, statements relating to the timing, success, and reporting of results of the clinical trials and related data, including plans and the ability to enroll, conduct, and/or complete current and additional studies; current and future clinical development of EryDex, including for the potential treatment of Ataxia-Telangiectasia (A-T) and other potential indications; the strategic development path for EryDex; planned regulatory agency submissions and clinical trials and timeline, prospects, and milestone expectations; and the potential benefits of EryDex and the company's market opportunity. Forward-looking statements are based on Quince's current expectations and are subject to inherent uncertainties, risks, and assumptions that are difficult to predict and could cause actual results to differ materially from what the company expects. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, but are not limited to, the risks and uncertainties described in the section titled "Risk Factors" in the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 13, 2024, and other reports as filed with the SEC. Forward-looking statements contained in this news release are made as of this date, and Quince undertakes no duty to update such information except as required under applicable law.

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