Quince Therapeutics Completes Enrollment in Pivotal Phase 3 NEAT Clinical Trial in Ataxia-Telangiectasia

July 16, 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 16, 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, today announced that the company has completed enrollment in its pivotal Phase 3 NEAT (**N**eurological **E**ffects of eDSP on Subjects with **A**-**T**; NCT06193200/IEDAT-04-2022) clinical trial to evaluate its lead asset, eDSP, for the treatment of the rare neurodegenerative disease Ataxia-Telangiectasia (A-T).

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "The completion of enrollment in our pivotal Phase 3 NEAT clinical trial evaluating eDSP for the treatment of A-T is a major milestone for Quince that places us one step closer to advancing a first-to-market treatment for this devasting disease. We are confident that we have executed a well-designed study with a high degree of scientific integrity and vigilant operational oversight. Quince remains on track to deliver topline results in the first quarter of 2026 and positive results will lead to an NDA submission in the second half of 2026."

Key Phase 3 NEAT clinical trial enrollment highlights include:

- A total of 105 participants were enrolled, including 83 participants in the six to nine year-old primary analysis population and 22 participants aged 10 years or older.
- Quince expects to report topline results from its Phase 3 NEAT clinical trial in the first quarter of 2026.
- Concluding the NEAT study with 83 enrolled participants in the six to nine year-old primary analysis population reflects powering of approximately 90% to determine statistical significance of the primary endpoint.
- All NEAT participants to date have elected to transition to the NEAT open label extension (OLE) study (NCT06664853/IEDAT-04-2022). Participants who complete the full treatment period, complete study assessments, and provide informed consent are eligible to transition to the OLE study.
- Assuming positive study results, the company plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2026.
- The Phase 3 NEAT clinical trial is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.
- Quince was granted FDA Fast Track designation for the company's eDSP System for the treatment of patients with A-T based on the potential to address a high unmet medical need.
- NEAT is an international, multicenter, randomized, double-blind, placebo-controlled clinical trial to evaluate the neurological effects of Quince's lead asset, eDSP (dexamethasone sodium phosphate [DSP] encapsulated in autologous red blood cells; previously referred to as EryDex) in patients with A-T.
- Participants are randomized (1:1) between eDSP or placebo and treatment consists of six infusions scheduled once every 21 to 30 days. The primary efficacy endpoint will be measured by the change from baseline to last efficacy visit using the Rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo.

About Ataxia-Telangiectasia

A-T is an inherited autosomal recessive neurodegenerative and immunodeficiency disorder caused by mutations in the ATM gene, which is responsible for cell homeostatic and cell division functions including but not limited to double-stranded DNA repair. Typically, A-T is first diagnosed before the age of five as children begin to develop an altered gait and fall with greater frequency. Neurological symptoms worsen and patients with A-T frequently become wheelchair-bound by adolescence. Teenage years for patients with A-T are typically marked by repeated infections, pulmonary impairment, and malignancies. The median lifespan is approximately 25 to 30 years old with mortality due to infections and malignancy. Based on IQVIA Medical Claims (Dx), PharmetricsPlus (P+), and IQVIA Analytics information, there are approximately 4,600 diagnosed patients with A-T in the U.S. Quince estimates that there are approximately 5,000 patients with A-T in the U.K. and EU4 countries. There are currently no approved therapeutic treatments in any global market for A-T.

About eDSP for A-T

eDSP is comprised of dexamethasone sodium phosphate (DSP) encapsulated in a patient's own red blood cells (autologous erythrocytes). DSP is a corticosteroid well known for its anti-inflammatory properties as well as its dose-limiting toxicity due to adrenal suppression. The eDSP System is

designed to provide the efficacy of corticosteroids and to reduce or eliminate the significant adverse effects that accompany chronic use of corticosteroid treatment.

eDSP leverages Quince's proprietary Autologous Intracellular Drug Encapsulation, or AIDE, technology platform, which is a novel drug/device combination that uses an automated process designed to encapsulate a drug into the patient's own red blood cells. Red blood cells have several characteristics that make them a potentially effective vehicle for drug delivery, including potentially better tolerability, enhanced tissue distribution, reduced immunogenicity, and prolongation of circulating half-life. Quince's AIDE technology is designed to harness these benefits to allow for the chronic administration of drugs that have limitations due to toxicity, poor biodistribution, suboptimal pharmacokinetics, or immune response.

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 participants, impact of closing enrollment, conduct, and/or complete current and additional studies; current and future clinical development of eDSP, including for the potential treatment of Ataxia-Telangiectasia (A-T), Duchenne muscular dystrophy (DMD), and other potential indications; the strategic development path for eDSP; planned regulatory agency submissions, including NDAs, and clinical trials and timeline, prospects, and milestone expectations; and the potential benefits of eDSP 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 May 13, 2025, 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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Source: Quince Therapeutics, Inc.