Quince Therapeutics Announces The Lancet Neurology Publication of Phase 3 ATTeST Clinical Trial Data Evaluating EryDex for the Treatment of Ataxia-Telangiectasia (A-T)

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Findings from largest completed study in A-T demonstrated favorable safety profile

Study showed positive effect of EryDex treatment in a subset of patients with A-T ages six to nine – the age range that typically experiences rapid clinical decline

Quince recently initiated pivotal Phase 3 NEAT study, which is currently enrolling and being conducted under U.S. FDA Special Protocol Assessment agreement

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 15, 2024-- 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 the online publication of data in *The Lancet Neurology* from its Phase 3 ATTeST (**A**taxia-**T**elangiectasia **T**rial with the **E**ryDex **S**ys**T**em; #IEDAT-02-2015/NCT02770807) clinical trial evaluating the safety and efficacy of its lead asset, EryDex (dexamethasone sodium phosphate encapsulated in autologous erythrocytes), for the treatment of A-T.

"The results of this study demonstrate the encouraging efficacy and safety profile of our lead asset, EryDex, for the treatment of patients with A-T, a rare pediatric disease with vast unmet need and no approved treatments," said Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer. "These findings provide us with additional confidence in our pivotal Phase 3 study of EryDex now underway with a primary analysis population comprised of patients with A-T experiencing the most rapid clinical decline – children ages six to nine – in addition to including participants who are ten years of age or older."

***The Lancet Neurology* Publication Highlights**

The Lancet Neurology publication entitled ***Safety and efficacy of intra-erythrocyte dexamethasone sodium phosphate in children with ataxia-telangiectasia (ATTeST): a multicenter, randomized, double-blind, placebo-controlled phase 3 trial*** describes safety and efficacy results from the Phase 3 ATTeST clinical trial.

Highlights include:

- ATTeST was the largest completed study in A-T, with 175 participants conducted at 22 academic institutions and medical centers on five continents in 12 different countries.
- ATTeST was a randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate the safety and efficacy of two dose levels of EryDex compared to placebo on neurological symptoms of patients with A-T.
- In the ATTeST study, following six-months of EryDex treatment, none of the serious safety concerns typically associated with chronic corticosteroid administration were observed. There were no reports of hyperglycemia, hypertension, hirsutism, or cushingoid appearance in any of the treatment groups.
- The primary efficacy endpoint was measured by the change in modified International Cooperative Ataxia Rating Scale (mICARS), from baseline to month six, comparing results from the active and placebo control groups. mICARS included assessment of the participant's posture and gait, kinetic functions, and speech. The higher score denotes higher burden of neurological symptoms.
- In the ATTeST study, patients receiving high-dose EryDex had reduced neurological symptoms with a -1.40 change in mICARS observed in the treated group compared to placebo. This result was not statistically significant (a nominal p-value =0.077). However, patients in the per-protocol population who received high-dose EryDex demonstrated statistical significance with a -2.2 change in mICARS and a nominal p-value of 0.019.
- In a pre-specified subgroup analysis by age, a statistically significant reduction in neurological symptoms observed in patients ages six to nine years old receiving high-dose EryDex, notably, a -2.8 and -4.4 change in mICARS was observed in the modified intent-to-treat (mITT) and per-protocol populations compared to placebo, with nominal p-values of 0.019 and 0.002, respectively.
- Inability to confirm the effect of treatment in the overall population might be related to delays and omissions in treatments, as indicated by positive efficacy results in the per-protocol population, which excluded participants with delayed and missed

treatments, and potential differences in treatment effect in patients ages six to nine, compared with patients 10 years or older.

- Contributors to delayed treatments included difficulties with travel to treatment centers and disruptions caused by the COVID-19 pandemic. Pandemic control guidelines, including travel restrictions, which varied among countries and institutions, resulted in missed and delayed treatments. In some instances, treatment was delayed because investigators delayed visits to hospital to protect immunocompromised participants in the peak of the pandemic. Because of delays in treatment and missed doses, 35% of the mITT population did not receive treatment as planned.

"The publication of the ATTeST trial results in *The Lancet Neurology* highlights promising clinical data that demonstrate progress being made toward a potential treatment option for patients with A-T, a rare pediatric disorder characterized by progressive neurological decline, impaired motor control, speech difficulties, and a life expectancy typically in the twenties or thirties," said Dr. William Whitehouse, Honorary Clinical Associate Professor of the School of Medicine at the University of Nottingham, and Consultant Paediatric Neurologist at Nottingham Children's Hospital, Nottingham University Hospitals NHS Trust. "Natural history studies have shown that children between age six and 10 with classic A-T experience rapid clinical decline, after neurological symptoms worsen and patients with A-T frequently become wheelchair-bound by adolescence. The differential response in mICARS score by age seen in subgroup analyses from the ATTeST study emphasizes the need to stratify future A-T clinical trials by age."

Quince is currently enrolling the pivotal Phase 3 NEAT study (#IEDAT-04-2022/NCT06193200), which is an international, multi-center, randomized, double-blind, placebo-controlled clinical trial evaluating the neurological effects of EryDex in patients with A-T. 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. Seven patients with A-T have enrolled in the Phase 3 NEAT study to date.

The Phase 3 NEAT trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA), and the company expects to report topline results in the fourth quarter of 2025 with a potential 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. Additionally, Quince was granted Fast Track designation by the FDA for the company's EryDex System for the treatment of patients with A-T based on the potential for EryDex to address a high unmet medical need in A-T.

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 EryDex for A-T

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

EryDex 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 (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 Therapeutics 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 current and future clinical development of EryDex, including for the potential treatment of Ataxia-Telangiectasia (A-T) and other potential indications, related development and commercial-stage inflection point for EryDex, the company's proprietary Autologous Intracellular Drug Encapsulation (AIDE) technology for treatment of other rare diseases; the strategic development path for EryDex; planned regulatory agency submissions and clinical trials and timeline, prospects, and milestone expectations; the timing and success of the clinical trials and related data, including plans and the ability to initiate, fund, enroll, conduct, and/or complete current and additional studies; research and development costs; the company's future development plans and related timing; cash position and projected cash runway; the company's focus, objectives, plans, and strategies; and the potential benefits of EryDex, AIDE technology 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 August 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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