



Quince Therapeutics Announces Frontiers in Neurology Publication of Long-Term Safety of EryDex in Pediatric Patients with Ataxia-Telangiectasia

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 27, 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 the online publication of safety data from patients with Ataxia-Telangiectasia (A-T) treated with EryDex for a minimum of 24 months in *Frontiers in Neurology*.

"A-T is a rare pediatric disease with unmet medical need and no approved therapeutic treatment. This post-hoc analysis of patients with A-T treated for a minimum of 24 months in a Phase 3 clinical trial (ATTeST) and an open label extension study, provides data supporting the potential to deliver dexamethasone sodium phosphate encapsulated in a patient's own red blood cells using our EryDex System without the chronic debilitating toxicities observed with standard corticosteroid treatment," said Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer. "Adverse events typically observed with prolonged corticosteroid use such as Cushingoid features, weight gain, hypertension, hirsutism, diabetes, or stunted growth were rarely reported in these studies. With more than 6,000 monthly doses administered to nearly 400 patients over the last 10-plus years, we are building a strong safety database as our pivotal Phase 3 clinical trial (NEAT) and its open label extension study continue."

Frontiers in Neurology Publication Highlights

The *Frontiers in Neurology* publication entitled [Long-term safety of dexamethasone sodium phosphate encapsulated in autologous erythrocytes in pediatric patients with Ataxia-Telangiectasia](#) describes the safety of long-term use of EryDex in treatment of pediatric patients with A-T.

Highlights include:

- EryDex is dexamethasone sodium phosphate (DSP) encapsulated in autologous erythrocytes that has been developed in an effort to address chronic steroid toxicity while maintaining efficacy.
- Results include analyses of data from patients with A-T treated with EryDex for a minimum of 24 months.
- Analyses included treatment-emergent and treatment-related adverse events, serious adverse events, and adverse events of special interest.
- The most common treatment-related adverse event was transient infusion-related pruritus, which is the most common steroid related side effect, and low serum iron levels, which are not associated with negative clinical outcomes.
- Adverse events typically observed with prolonged glucocorticoid use such as Cushingoid features, weight gain, hypertension, hirsutism, diabetes, or stunted growth were infrequently reported over 24 to 61 months of dosing.
- There was a decline in bone mineral density (BMD) of 0.4 z scores over the two-year period – which could not be distinguished from the natural course of disease in patients with A-T.
- There were no reported adverse effects on height, weight and body mass index as supported by stable z-scores throughout the two years of treatment.
- Values for glucose, HbA1c, cortisol, and CD4+ lymphocyte counts did not show clinically significant changes during prolonged treatment with EryDex.

Quince is currently enrolling the pivotal Phase 3 NEAT clinical trial ([#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.

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 treatment of patients with A-T based on the potential 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. The EryDex 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.

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, 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 current and future clinical development of EryDex, including for the potential treatment of Ataxia-Telangiectasia (A-T), Duchenne muscular dystrophy (DMD), and other potential indications, related development and commercial-stage inflection point for EryDex, and expansion of 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, success, and reporting of results of the clinical trials and related data, including plans and the ability to initiate, fund, enroll, conduct, and/or complete current and additional studies; the company's future development plans and related timing; 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 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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