Quince Therapeutics Presents Data from Prior Phase 3 ATTeST Clinical Trial at 2024 International Congress for Ataxia Research

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 12, 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 presentation of two posters at the 2024 International Congress for Ataxia Research (ICAR) of data from its prior Phase 3 ATTeST (**A**taxia-**T**elangiectasia **T**rial with the **E**ryDex **S**ys**T**em; #IEDAT-02-2015/NCT02770807) clinical trial of the company's lead asset, EryDex (intra-erythrocyte dexamethasone sodium phosphate), for the treatment of Ataxia-Telangiectasia (A-T).

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "We continue to gain valuable insights from the robust dataset provided from our prior Phase ATTeST clinical trial, which is the largest study of patients with A-T completed to date. We are pleased to share new analyses of these data at the 2024 International Congress for Ataxia Research that showcase EryDex's strong safety profile and provide validation of the primary efficacy endpoint utilized in our study of EryDex for the treatment of A-T."

The objective of the poster titled *Growth and Bone Mineral Density (BMD) in Children with Ataxia-Telangiectasia (A-T) Treated with Intra-Erythrocyte Dexamethasone (EryDex) for 24 months* describes growth and bone mineral density in patients with A-T treated for 24 months with EryDex. Key findings reported in the poster presentation include:

- 24 months of EryDex treatment did not adversely affect growth and bone mineral density of patients with A-T.
- Results compare favorably to natural history of patients with A-T who experience height and weight faltering, in addition to abnormal bone mineral density.
- No weight gain, adverse growth, or bone health typically associated with the use of corticosteroids in children were observed.

The objective of the poster titled *Cross-sectional Analysis of International Cooperative Ataxia Rating Scale (ICARS) Subcomponent Scores in Children with Ataxia-Telangiectasia (A-T)* describes the baseline ICARS subcomponent scores by age in a cross-sectional analysis of treatment-naive patients from the ATTeST dataset and identifies ICARS subcomponents that best reflect progression of disease by age. Key findings reported in the poster presentation include:

- ICARS subcomponents in the mICARS (modified International Cooperative Ataxia Rating Scale) and RmICARS (Rescored modified International Cooperative Ataxia Rating Scale) analyses capture the fastest neurological symptom progression in patients with A-T between the ages of six to 10 year olds who were ambulatory at baseline.
- Posture and gait category of ICARS showed progression with age in untreated patients with A-T between the ages of six and 10 years old.
- Scales with reduced kinetic function domain may be more sensitive than full ICARS scores when assessing disease progression over shorter periods of time in younger children.
- mICARS and RmICARS measures focus on assessment of the participant's posture and gait as opposed to kinetic function and speech.
- mICARS and RmICARS subcomponents of ICARS best reflect progression of disease by age and capture the fastest neurological symptom progression in patients with A-T between the ages of six to 10 years.

Pivotal Phase 3 NEAT Clinical Trial

Quince is currently enrolling a pivotal Phase 3 NEAT (**N**eurologic **E**ffects of EryDex on Subjects with **A**-**T;** #IEDAT-04-2022/NCT06193200) clinical trial, which is an international, multi-center, randomized, double-blind, placebo-controlled clinical trial evaluating the neurological effects of EryDex in patients with A-T. The company 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 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

The EryDex System is a novel drug/device combination product comprised of dexamethasone sodium phosphate (DSP) which is encapsulated and administered using 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 (AIDE) technology platform that uses an automated process designed to encapsulate and administer a drug using a 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; 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 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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