Quince Therapeutics Receives U.S. FDA Fast Track Designation for EryDex System

June 3, 2024

Fast Track designation underscores the high unmet medical need, with currently no approved therapeutic treatments for the rare pediatric disease Ataxia-Telangiectasia

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 3, 2024-- Quince Therapeutics, Inc. (Nasdaq: QNCX), a late-stage biotechnology company developing an innovative drug delivery technology designed to leverage a patient's own biology to deliver rare disease therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its EryDex System for the treatment of patients with Ataxia-Telangiectasia (A-T). EryDex is comprised of dexamethasone sodium phosphate (DSP) encapsulated in a patient's own red blood cells utilizing Quince's proprietary Autologous Intracellular Drug Encapsulation (AIDE) technology platform. 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 corticosteroid treatment.

Fast Track designation has been granted based on the potential for EryDex to address a high unmet medical need for patients with A-T, a serious and life-threatening condition, and represents a significant regulatory milestone for Quince. There are currently no approved therapeutic treatments in any global market for this rare pediatric disease.

A-T is an inherited autosomal recessive neurodegenerative and immunodeficiency disorder with an estimated prevalence of approximately 10,000 patients with A-T in the U.S., U.K., and EU4 countries. Data from a prior Phase 3 study of EryDex (#IEDAT-02-2015/NCT02770807) showed encouraging efficacy results and a favorable safety profile. Quince is actively enrolling participants for its global Phase 3 NEAT clinical trial (#IEDAT-04-2022/NCT06193200) to evaluate the neurological effects of EryDex in patients with A-T, with plans to enroll approximately 86 patients with A-T ages six to nine years old (primary analysis population) and approximately 20 patients ages 10 years or older. This pivotal Phase 3 clinical trial is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "The granting of Fast Track status for EryDex System marks another important milestone in our endeavor to identify a beneficial therapeutic solution for patients with A-T. We have initiated our pivotal Phase 3 NEAT clinical trial, which is being conducted in the U.S., U.K., and the European Union."

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), IQVIA Analytics information, there are approximately 3,400 diagnosed patients with A-T in the U.S., which aligns with an estimated U.S. prevalence of approximately 5,000 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. 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 potential of a patient's own biology to deliver innovative and life-changing therapeutics to those living with 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, and Twitter/X.

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 May 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240603425785/en/

Media & Investor Contact:
Stacy Roughan
Quince Therapeutics, Inc.
Vice President, Corporate Communications & Investor Relations
ir@quincetx.com

Source: Quince Therapeutics, Inc.