U.S. FDA Partial Clinical Hold Lifted on IND for EryDel's Lead Phase 3 Asset EryDex for the Treatment of Ataxia-Telangiectasia

September 28, 2023

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 28, 2023-- Quince Therapeutics, Inc. (Nasdaq: QNCX), a biotechnology company focused on acquiring, developing, and commercializing innovative therapeutics that transform patients' lives, today announced that the U.S. Food and Drug Administration (FDA or the "Agency") has lifted the partial clinical hold on EryDel S.p.A's Investigational New Drug (IND) application for its lead Phase 3 asset, EryDex. Pending the closing of Quince's acquisition of EryDel, Quince intends to advance the global Phase 3 NEAT (Neurologic Effects of EryDex on Subjects with A-T) clinical trial evaluating the safety and efficacy of EryDex for the potential treatment of a rare, fatal pediatric neurological disease, Ataxia-Telangiectasia (A-T). Currently, there are no approved treatments for patients with A-T and the market represents a $1+ billion estimated peak sales opportunity.

Dirk Thye, M.D., Quince's Chief Executive Officer, said, "We are pleased with the FDA's decision to lift the partial clinical hold related to EryDel's lead asset, EryDex. We look forward to completing the clinical and regulatory activities necessary to advance EryDex into the Phase 3 NEAT study – with patient enrollment beginning as soon as the second quarter of 2024. Notably, this pivotal trial will be conducted under a Special Protocol Assessment (SPA) that has already been reviewed with the FDA, which should allow for the submission of a New Drug Application (NDA) following completion of this single study, assuming positive results."

The Agency had requested additional information on extractables and leachables related to a change in plastics utilized in the EryKit. The change in plastic bags and tubing in the EryKit were implemented in order to be compliant with recent European regulations regarding the type of plastics used in various products. The commercial version of the EryKit treatment consumables is already approved for clinical trial use in Europe.

Quince's acquisition of EryDel is subject to certain regulatory approvals, including the foreign direct investment screening clearance in Italy, and other closing conditions and is expected to close in the fourth quarter of 2023.

About EryDex and the Phase 3 NEAT Trial

EryDex utilizes a unique drug/device combination that enables a fully automated process at the point of patient care for the autologous intracellular drug encapsulation (AIDE) of dexamethasone sodium phosphate (DSP; a pro-drug) into a patient's red blood cells. Dexamethasone-loaded red blood cells are then re-infused into the patient, resulting in the circulation of controlled, slow release, low doses of dexamethasone, intended to provide efficacious dosing while avoiding the long-term toxicity typically associated with chronic steroid administration.

The Phase 3 NEAT clinical trial is a double blind, randomized, placebo-controlled, global study in approximately 86 A-T patients aged six to nine years-old – with up to an additional 20 patients aged 10 years or older to potentially expand the label. The study's primary endpoint will measure neurological function based on a rescored modified International Cooperative Ataxia Rating Scale (RmICARS) from baseline to month six of treatment. NDA submission is currently targeted for the end of 2025, assuming positive Phase 3 study results. EryDex has received orphan drug designation for the treatment of A-T from both the FDA and the European Medicines Agency (EMA).

About Quince Therapeutics

Quince Therapeutics is a biotechnology company focused on acquiring, developing, and commercializing innovative therapeutics that transform the lives of patients suffering from debilitating and rare diseases. For more information, visit www.quincetx.com and follow Quince Therapeutics on LinkedIn and @Quince_Tx on Twitter.

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 continued current and future clinical development of EryDel assets, related platform, and related timing; the strategic development path for EryDex; planned regulatory 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 conduct and/or complete the Phase 3 NEAT clinical trial; the potential therapeutic benefits, safety, and efficacy of EryDex; statements about its ability to obtain, and the timing relating to, further development of EryDex, regulatory submissions and interactions with regulators; therapeutic and commercial potential; Quince's future development plans and related timing; the company's focus, objectives, plans, and strategies; and the anticipated closing and related timing of Quince's acquisition of EryDel. 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 3, 2023, 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/20230928420547/en/

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

Source: Quince Therapeutics, Inc.