Quince Therapeutics Provides Business Update and Reports Fourth Quarter and Fiscal 2023 Financial Results

April 1, 2024

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 1, 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 provided an update on the company's development pipeline and reported financial results for the fourth quarter and fiscal year ended December 31, 2023.

"With the acquisition of EryDel S.p.A. in October last year, we have successfully shifted our strategic focus to become a Phase 3 biotechnology company dedicated to securing regulatory approval for our lead product, EryDex, for the treatment of patients with Ataxia-Telangiectasia (A-T)," said Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer. "With $75.1 million cash on hand, we expect to have sufficient funding to complete our Phase 3 clinical trial, in addition to supporting the expansion of EryDex into other indications and our Autologous Intracellular Drug Encapsulation (AIDE) technology platform into new products. By pioneering the delivery of drugs encapsulated in a patient's own red blood cells, we are working to redefine the standard of care, first for chronic corticosteroid therapy, and later for other drugs, that will meaningfully improve the quality of life for rare disease patients."

Pivotal Phase 3 NEAT Clinical Trial

- Completed the majority of study start up activities related to the company's pivotal Phase 3 NEAT (Neurologic Effects of EryDex on Subjects with A-T; IEDAT-04-2022/NCT06193200) clinical trial.
- NEAT is an international, multi-center, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of the company's lead asset, EryDex (dexamethasone sodium phosphate [DSP] encapsulated in autologous red blood cells), in patients with A-T.
- On track to meet expectations to begin enrollment in the NEAT study during the second quarter of 2024.
- Pivotal Phase 3 NEAT clinical trial will be conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food & Drug Administration (FDA).
- Plan 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.
- Participants will be randomized (1:1) between EryDex or placebo and treatment will consist of six infusions scheduled once every 21 to 30 days. The primary efficacy endpoint will be measured by the change from baseline to last visit completion in rescored modified International Cooperative Ataxia Rating Scale (RmICARS).
- Participants who complete the full treatment period, complete study assessments, and provide informed consent will be eligible to transition to an open label extension study.
- Expect to report Phase 3 NEAT topline results in the second half of 2025 with a potential NDA submission in 2026, assuming positive study results.
- Quince estimates there are an aggregate of approximately 10,000 patients with A-T in the U.S., U.K., and EU4 countries.
- There are currently no approved therapeutic treatments for A-T and the market represents a $1+ billion peak commercial opportunity globally based on the company's internal estimates and assumptions.

Scientific, Pipeline, and Corporate Updates

- Detailed EryDex's optimized delivery of DSP encapsulated in red blood cells with a comparison of company data relative to published corticosteroid pharmacokinetic and biodistribution information. Red blood cells have several characteristics that make them a potentially ideal vehicle for drug delivery, including potentially better tolerability, enhanced tissue distribution, reduced immunogenicity, and prolongation of circulating half-life. Learn more here.
- Intend to investigate other potential indications for EryDex where chronic corticosteroid treatment is – or has the potential to become – a standard of care if there were not corticosteroid-related safety concerns. This evaluation process is

expected to span across ataxias, neuromuscular indications, hematology, cancer, and autoimmune diseases, with a focus on rare diseases.

- Plan to evaluate additional potential applications of Quince's proprietary AIDE technology platform using drugs and biologics targeted at rare and debilitating diseases to further expand the company's drug development pipeline.
- Targeting participation at several A-T related global ataxia and neurology scientific congresses in 2024, in addition to ongoing engagement of global patient advocacy groups as enrollment of the Phase 3 NEAT study progresses.

Strong Cash Position Expected to Support Meaningful Clinical Milestone

- Reported $75.1 million in cash, cash equivalents, and short-term investments as of December 31, 2023. Quince expects its existing cash runway to be sufficient to fund the company's capital efficient development plan into 2026.
- Expect to fully fund lead asset, EryDex, through Phase 3 NEAT topline results and prepare for a potential NDA submission in 2026, assuming positive study results. This includes approximately $20 million for the NEAT study and approximately $15 million in direct trial costs for the open label extension.
- Evaluate potential strategic partnerships to out-license ex-U.S. regional territories to extend operational runway to support potential NDA approval of EryDex, as well as further advance other potential indications and programs discovered using the AIDE platform.

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 a pivotal trial for Ataxia-Telangiectasia, potential 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 and success of the clinical trials and related data, including plans and the ability to initiate, fund, 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 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 14, 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.

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