Quince Therapeutics Provides Business Update and Reports First Quarter 2024 Financial Results

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 13, 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 first quarter ended March 31, 2024.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "Our primary corporate objective is the advancement of our lead asset, EryDex, for the treatment of patients with ataxia-telangiectasia. We remain on track to begin enrollment of our pivotal Phase 3 study in the second quarter of 2024 and will diligently pursue enrollment at U.S. and European study sites to provide an opportunity for patients living with this rare, devastating disease to participate in research to identify a beneficial therapeutic solution.

"We are pleased to report the selection of Duchenne muscular dystrophy (DMD) as Quince's second development program for EryDex. We consider DMD a promising indication for EryDex as corticosteroids are the standard of care for this rare disease, but its utility is limited by significant chronic toxicity due to adrenal suppression. We believe EryDex has the potential to provide the therapeutic benefit of corticosteroids without this chronic toxicity. Physicians caring for patients with DMD, along with DMD advocacy groups, also have encouraged the development of EryDex for DMD as a potentially safer alternative to conventional corticosteroids for their patients," concluded Dr. Thye.

Pivotal Phase 3 NEAT Clinical Trial

- Secured regulatory approvals in the U.S. and European Union related to the company's pivotal Phase 3 NEAT (**N**eurologic **E**ffects of EryDex on Subjects with **A**-**T**; IEDAT-04-2022/NCT06193200) clinical trial.
- Commenced NEAT study site initiation and activation activities throughout the U.S., U.K., and European Union as NEAT enrollment remains on track to begin in the second quarter of 2024.
- 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.
- 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.
- Pivotal Phase 3 NEAT clinical trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food & Drug Administration (FDA).
- 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) compared to placebo.
- 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.

Pipeline and Corporate Updates

- Completed initial patient sizing project with third-party analysis from IQVIA Medical Claims (Dx), IQVIA Analytics confirming 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. 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.
- Advanced evaluation of other potential indications for EryDex with the selection of Duchenne muscular dystrophy (DMD) as the company's second development program. DMD is an ideal indication for EryDex as corticosteroids are the standard of care for this rare disease, but its utility is limited by significant chronic toxicity due to adrenal suppression. Corticosteroid treatment in patients with DMD is commonly interrupted during adolescence due to interference with sexual maturation and

delayed puberty.

- Targeting EryDex for the potential treatment of patients with DMD would leverage the company's AIDE technology designed to encapsulate the corticosteroid DSP in a patient's own red blood cells, which have several characteristics that make them an ideal vehicle for drug delivery. EryDex is designed to alter the biodistribution, pharmacokinetics, and pharmacodynamics of the DSP, allowing for potentially safe and effective treatment for patients with DMD.
- Focused on generating proof-of-concept clinical trial study designs to evaluate EryDex for the potential treatment of patients with DMD, including corticosteroid intolerant populations, in addition to evaluating optimal capital efficient study approaches such as investigator initiated trials and Phase 2/3 options.
- Investigating 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.
- Evaluate potential strategic partnerships to out-license ex-U.S. rights to extend operational runway to support potential NDA approval of EryDex in the U.S., as well as further advance other potential indications and programs using the AIDE platform.
- Participation at The Citizens JMP Life Sciences Conference on Monday, May 13, 2024 beginning at 1:30 p.m. Eastern Time. A live webcast and archive of the presentation will be accessible here.

First Quarter 2024 Financial Results

- Reported cash, cash equivalents, and short-term investments of $67.8 million for the first quarter ended March 31, 2024. 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 clinical trial and approximately $15 million in direct trial costs for the open label extension study.
- Reported research and development (R&D) expenses of $3.7 million for the quarter ended March 31, 2024. R&D expenses for the quarter primarily reflected costs related to the advancement of lead asset EryDex, the startup of related Phase 3 NEAT clinical trial activities, and stock-based compensation expense.
- Reported general and administrative (G&A) expenses of $5.0 million for the quarter ended March 31, 2024. G&A expenses for the quarter primarily included personnel-related expenses, insurance, professional and legal fees, and stock-based compensation.
- Reported a net loss of $11.1 million, or a loss of $0.26 per basic and diluted share, for the quarter ended March 31, 2024. Weighted average shares outstanding for the quarter were 43.0 million.
- Reported net cash used in operating activities of $8.4 million for the quarter ended March 31, 2024, which included adjustments for $3.6 million of non-cash items: a $2.5 million change in the fair value of contingent consideration liabilities due to passage of time, $1.3 million in stock-based compensation, and $0.4 million change in the fair value of long-term debt due to passage of time, offset by a $0.6 million amortization of discount on the company's investments.

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), 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 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; 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 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-K filed with the Securities and Exchange Commission (SEC) on April 1, 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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