Quince Therapeutics to Acquire EryDel SpA and its Phase 3 Asset Targeting Ataxia-Telangiectasia with No Currently Approved Treatments and Estimated $1+ Billion Peak Sales Opportunity

July 24, 2023

Well-capitalized into 2026 with ability to fully fund lead asset EryDex expected through Phase 3 trial under special protocol assessment (SPA) and to NDA submission

EryDex utilizes autologous intracellular drug encapsulation (AIDE) technology designed for slow release of steroids over several weeks without long-term toxicity typically associated with chronic administration

Potential for rapid expansion of EryDex to other rare and debilitating disease indications where chronic steroid treatment is or could become the standard of care

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 24, 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 company has entered into an agreement to acquire EryDel SpA, a privately-held, late-stage biotech company, in a stock-for-stock upfront exchange and potential downstream milestone cash payments. EryDel has developed an autologous intracellular drug encapsulation (AIDE) technology and a Phase 3 lead asset, EryDex, targeting a rare fatal pediatric neurological disease, Ataxia-Telangiectasia (A-T), which currently has no approved treatments. Upon completion of the transaction, EryDel stockholders will own approximately 16.7% of the combined company (subject to downward adjustment) and will be entitled to up to $485 million upon the achievement of development, regulatory, and commercial milestone payments, with no royalties. The transaction, which has been unanimously approved by the Boards of Directors of both companies, is subject to certain regulatory approvals and other closing conditions and is expected to close in the third quarter of 2023.

Dirk Thye, M.D., Quince's Chief Executive Officer, said, "We are highly enthusiastic and optimistic about our acquisition of this unique drug/device combination technology platform and promising late-stage clinical asset to drive Quince's next stage of growth. EryDel's proprietary AIDE technology enables the autologous intracellular encapsulation and delivery of dexamethasone in a controlled, slow-release manner that has the potential to allow chronic administration of steroids over many months or years with a favorable safety profile. This represents a tremendous opportunity to target not only A-T, but also the potential to expand into several debilitating rare diseases where chronic steroid treatment is the standard of care – or could be in the absence of long-term steroid toxicity. Upon the close of the acquisition, we will quickly focus our considerable development expertise and financial resources toward advancing the lead asset EryDex for A-T through a single global Phase 3 clinical trial under a SPA already in place with the FDA to an anticipated NDA submission, assuming positive study results."

Luca Benatti, EryDel's Chief Executive Officer, said, "EryDel's acquisition by Quince offers the opportunity to advance our innovative, point-of-care autologous intracellular encapsulation technology through development to commercialization and to fulfill our mission to provide the first treatment for patients living with the devastating disease of A-T. Quince's effort will be supported by the encouraging Phase 3 data generated from EryDel's prior international study of EryDex, which demonstrated a significant delay in disease progression in A-T patients and further supported more than 10 years of safety data. Quince is well-positioned to advance EryDel's differentiated AIDE technology and development of our lead asset EryDex to deliver innovative treatments to patients in need."

Transformative Acquisition with Value-Creating Clinical Milestones

Key highlights of the EryDel acquisition include:

Well-capitalized into 2026 with ability to fully fund lead asset EryDex expected through Phase 3 clinical trial under SPA and to NDA submission

- Strong balance sheet with approximately $87.6 million in cash, cash equivalents, and short term investments (unaudited) as of June 30, 2023, to provide funding for operating requirements into 2026.
- Capital efficient development plan allows for funding of EryDex through global Phase 3 clinical trial under SPA and, assuming positive study results, to NDA submission, in addition to pursuing European regulatory activities related to potential MAA submission.
- Potential to out-license ex-U.S. regional territories to provide runway through regulatory approval of EryDex.

Plan to enroll first patient in global Phase 3 trial of EryDex in second quarter of 2024 with NDA submission targeted by end of 2025

- SPA in place with FDA for a single global Phase 3 clinical trial of EryDex expected to be sufficient for NDA submission, assuming positive study results.
- EryDex designated as orphan drug for treatment of A-T from both the FDA and EMA.
- Phase 3 NEAT (**N**eurologic Effects of **E**ryDex on Subjects with **A-T**) clinical trial is a planned double blind, randomized, placebo controlled, global efficacy 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 included for potential broader label support.
- Primary endpoint, as agreed upon with the FDA, to measure neurological function based on rescored modified International

Cooperative Ataxia Rating Scale (RmICARS) from baseline to month six of treatment.
- Secondary endpoints to measure Clinical Global Impression scores for severity (CGI-S) and change (CGI-C), as well as EuroQol quality of life scoring.
- Plan to enroll first patient in Phase 3 NEAT clinical trial in the second quarter of 2024.
- Commercial version of EryKit treatment consumables approved in Europe and currently under partial clinical hold pending response to FDA query.
- Target EryDex NDA submission with the FDA by the end of 2025, assuming positive Phase 3 NEAT study results.

EryDex efficacy and safety profile demonstrated in prior Phase 3 clinical trial of A-T patients

- Pursuing European regulatory activities related to potential MAA submission of EryDex based on prior Phase 3 clinical trial.
- Completed largest global interventional study of A-T patients (N=175) in Phase 3 ATTeST (**A**taxia **T**elangiectasia **T**rial with the **E**ryDex **S**ys**T**em) clinical trial and open label extension (OLE) (N=104).
- Primary endpoint measured modified International Cooperative Ataxia Rating Scale (mICARS) score from baseline to month six of treatment.
- Secondary endpoints measured CGI-C, Quality of Life (QOL), and Vineland Adaptive Behavior Scales (VABS) scores.
- EryDex high dose treatment arm demonstrated slowed neurological deterioration in A-T disease progression as measured by mICARS in intent to treat population (ITT) with statistically significant effect in six to nine year-old subgroup across multiple endpoints.
- 12-month safety analysis demonstrated EryDex well-tolerated with no major adverse events typically associated with chronic steroid administration.
- Sustained therapeutic effect and favorable safety profile maintained for more than three additional years in high dose treatment arm in OLE study, in addition to no steroid related toxicity observed in patients receiving more than 10 years of treatment.
- Conformité Européene (CE) mark already obtained in Europe for drug/device combination and commercial version of EryKit treatment consumables.

$1+ billion estimated peak global sales opportunity for A-T indication alone with rapid expansion potential for EryDex to other rare and debilitating diseases

- A-T population estimated to be approximately 10,000 patients in the U.S., U.K., and EU4 countries with no currently approved therapies and $1+ billion estimated peak sales opportunity globally.
- EryDex for A-T indication holds potential to be first-to-market with attractive pricing comparables and no known late-stage competition.
- EryDex designated as orphan drug for A-T treatment from the FDA and EMA.
- Potential for rapid expansion of EryDex to other rare and debilitating disease indications where chronic steroid administration is the standard of care – or could be in the absence of long-term steroid toxicity.
- AIDE platform capable of expansion to other drugs or biologics, including enzyme replacement therapy.
- Multi-faceted technology protections create high barriers to entry with intellectual property exclusivity until at least 2034 globally and at least 2035 in the U.S.

Transaction Details

Under the terms of the acquisition transaction, EryDel will operate as a wholly owned subsidiary of Quince Therapeutics with plans to retain EryDel's corporate and manufacturing presence in Italy. The integrated company will be led by Dirk Thye, M.D., Quince's Chief Executive Officer and member of the Quince Board of Directors. In addition, David Lamond remains Chairperson of Quince's Board of Directors, which will be expanded by one member with the addition of EryDel representative Luca Benatti following the close of the transaction.

Upon completion of the stock-for-stock upfront exchange, EryDel stockholders will own a maximum of approximately 16.7%, or 7,250,352 shares, of the combined company (subject to downward adjustment). The transaction agreement includes up to $485 million in potential total downstream cash payments, including up to $5 million in development milestones, $25 million at NDA acceptance, $60 million in approval milestones, and $395 million in market and sales milestones, with no royalties paid to EryDel stockholders. The transaction will include the assumption of EryDel's $13 million (€10 million in principal) European Investment Bank (EIB) loan with scheduled payments beginning in the second half of 2026.

The transaction, which has been unanimously approved by the Boards of Directors of both companies, is subject to certain regulatory approvals and other closing conditions and is expected to close in the third quarter of 2023.

Financial Statements

Quince has not completed preparation of its financial statements for the second quarter of 2023. The cash, cash equivalents, and short term investments presented as of June 30, 2023, are preliminary and unaudited and are, thus, inherently uncertain and subject to change. The company is in the process of completing its customary close and review procedures for the second quarter of 2023, and there can be no assurance that final results for this period will not differ from these preliminary, unaudited amounts. The company's independent registered public accounting firm has not audited, reviewed, compiled, or performed any procedures with respect to such preliminary data for the second quarter ended June 30, 2023.

Advisors

MTS Health Partners, L.P. is serving as financial advisor and Cooley LLP is serving as legal counsel to Quince. Perella Weinberg Partners is serving as financial advisor and Goodwin Procter LLP and Clifford Chance LLP are serving as legal counsel to EryDel.

Investor Presentation Available

To learn more about the transaction, investors are encouraged to access an investor presentation provided by Quince management detailing the EryDel acquisition, which is currently available for viewing on the company's Investor Relations website. Please visit the Events page under the News & Events heading of Quince's Investor Relations website at ir.quincetx.com to access the presentation.

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.

About EryDel SpA

EryDel SpA is a global late-stage biotech company aimed at developing and commercializing therapies for the treatment of rare diseases delivered by its proprietary red blood cell technology. Its most advanced product, EryDex, is under late-stage development for the treatment of Ataxia Telangiectasia (A-T), a rare autosomal recessive neurological disorder for which no established therapy is currently available. EryDex is an automated outpatient bedside technology to ex-vivo encapsulate dexamethasone sodium phosphate (DSP; a pro-drug) into patient's red blood cells, which are then re-infused, allowing for the circulation of controlled, slow release, low doses of dexamethasone (active drug) over the subsequent several weeks following treatment. EryDex has received orphan drug designation for the treatment of A-T both from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). An international multicenter, Phase 3 clinical trial, ATTeST, and its open label extension have been successfully completed. In addition to EryDex, EryDel's technology platform is capable of expansion to other drugs or biologics, including enzyme replacement therapy, and has the potential to support a wide range of therapeutic opportunities.

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 Quince's acquisition of EryDel; the timing of the closing of the transaction; the expected benefits of the transaction, including the continued current and future clinical development and potential expansion of EryDel assets, related platform, and related timing and costs; the strategic development path for EryDex; planned FDA and EMA 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; 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; the integration of EryDel's business, operations, and employees into Quince; Quince's future development plans and related timing; its cash position and projected cash runway; the company's focus, objectives, plans, and strategies; and the ability to execute on any strategic transactions. 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 15, 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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Quince Therapeutics:
Stacy Roughan
Quince Therapeutics, Inc.
Vice President, Corporate Communications & Investor Relations
ir@quincetx.com

Media:
Dan Gagnier & Riyaz Lalani
Gagnier Communications
quinceGFC@gagnierfc.com

Source: Quince Therapeutics, Inc.