Quoin Pharmaceuticals Announces Further Clinical Evidence of QRX003 Effectiveness in Netherton Syndrome

January 23, 2025

- *Four Weeks After Discontinuation of Treatment with QRX003 Complete Reversal of Positive Clinical Improvements Across all Measured Endpoints Observed*
- *Data Supports QRX003 Mechanism of Action as a Competitive Broad Spectrum Serine Protease Inhibitor*

ASHBURN, Va., Jan. 23, 2025 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the “Company” or “Quoin”), a clinical stage, specialty pharmaceutical company focused on rare and orphan diseases, today announces further clinical evidence of the potential efficacy of QRX003 in Netherton Syndrome.

In December 2024 and January 2025, Quoin announced positive data from the mid-point and at completion of 12 weeks of testing the first subject dosed twice-daily in Quoin’s ongoing open-label study which demonstrated evidence of clear improvement across all measured clinical endpoints. Today Quoin is sharing additional data on that subject at 4 weeks post-discontinuation of treatment with QRX003. As the table below illustrates all of the positive clinical benefits observed after 12 weeks of testing with QRX003 were completely reversed by 4 weeks after discontinuation of treatment resulting in the subject’s disease state reverting to the baseline status observed prior to QRX003 treatment. These results strongly indicate that ongoing, chronic treatment with QRX003 is necessary for a continued positive clinical outcome in Netherton Syndrome patients.

Table 1: First Patient Data from Open Label Study Part B- Dosed Twice Daily with QRX003

End Point	Baseline	6 weeks (Treatment period midpoint)	12 weeks (End of treatment period)	4 weeks post discontinuation of treatment
M-IASI*	18	4	3	18
WINRS**	7	4	2	8
IGA***	Moderate	Mild	Almost Clear	Moderate

**M-IASI*: Modified Ichthyosis Area of Severity Index, a score used to assess the severity and extent of skin symptoms associated with ichthyosis. Lower scores indicate improvement.*

***WINRS*: Worst Itch Numeric Rating Scale, which measures the severity of itch on an 11-point scale (0 = no itch, 10 = worst imaginable itch).*

****IGA*: Investigator’s Global Assessment, which uses descriptive categories (e.g., clear, mild, moderate, severe) to evaluate the overall severity of Netherton Syndrome symptoms.*

Quoin CEO, Dr. Michael Myers, said, “This data set provides the clearest clinical evidence to date that the active ingredient in QRX003 is a competitive broad spectrum serine protease inhibitor and that discontinuation of treatment with QRX003 results in a complete reversal of all clinical benefits derived from continued treatment with the product. The rapid reversal of all observed clinical benefits to baseline disease status after just 4 weeks of treatment discontinuation serves to further underscore that chronic, whole-body treatment with QRX003 is potentially required to maintain the positive clinical outcomes observed in our clinical study. These results increase our commitment to complete the clinical development of QRX003 as expeditiously as possible with a goal of making the product widely available to the Netherton community once approved.

With four clinical studies in Netherton subjects underway, three of which are being conducted under an open Investigational New Drug (IND) application with the FDA, we believe Quoin is assembling a broad and diverse clinical data package to support a New Drug Application (NDA) filing for QRX003 as potentially the first approved treatment for Netherton Syndrome.”

About Netherton Syndrome
Netherton Syndrome, a form of Ichthyosis, is a rare hereditary skin disorder caused by a mutation in the SPINK5 gene (serine protease inhibitor, Kazal Type 5) that leads to severe skin barrier defects and recurring infections, as well as a pronounced predisposition to allergies, asthma, and eczema. Patients often suffer from severe dehydration, chronic skin inflammation and stunted growth. Currently, there is no cure for Netherton Syndrome, nor are there any approved therapeutic treatments.

About QRX003
QRX003 is a topical lotion formulated with a proprietary delivery technology that contains a broad-spectrum serine protease inhibitor, whose mechanism of action is intended to perform the function of a specific protein called LEKTI. The absence of LEKTI in Netherton patients leads to excessive skin shedding, resulting in a highly porous and compromised skin barrier. QRX003 is designed to promote a more normalized skin-shedding process and the formation of a stronger and more effective skin barrier.
For more information about Quoin’s current clinical trials please visit: https://quoinpharma.com/pipeline/#trials

About Quoin Pharmaceuticals Ltd.
Quoin Pharmaceuticals Ltd. is a clinical-stage specialty pharmaceutical company focused on developing and commercializing therapeutic products that treat rare and orphan diseases. We are committed to addressing unmet medical needs for patients, their families, communities and care teams.

Quoin's innovative pipeline comprises four products in development that collectively have the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Scleroderma, Epidermolysis Bullosa and others. For more information, visit: www.quoinpharma.com or LinkedIn for updates.

Cautionary Note Regarding Forward Looking Statements

The Company cautions that statements in this press release that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as "expect," "intend," "plan," "anticipate," "believe," and "will," among others. All statements that reflect the Company's expectations, assumptions, projections, beliefs, or opinions about the future, other than statements of historical fact, are forward-looking statements, including, without limitation, the potential efficacy of QRX003 as a treatment for Netherton Syndrome, the goal of making the product widely available to the Netherton community once approved, we believe Quoin is assembling a broad and diverse clinical data package to support a New Drug Application (NDA) filing for QRX003 as potentially the first approved treatment for Netherton and Quoin's products in development collectively having the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Scleroderma, Epidermolysis Bullosa and others. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties including, but not limited to, the Company's ability to deliver a safe and effective treatment for Netherton Syndrome, its studies may not be successful or may not generate data which is sufficiently robust and comprehensive to an NDA filing for QRXOO3 as an approved treatment for Netherton Syndrome and other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and in other filings the Company has made and may make with the SEC in the future. One should not place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as may be required by law.

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