Quoin Pharmaceuticals Announces FDA Clearance to Initiate New QRX003 Netherton Syndrome Clinical Study

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- *Groundbreaking 'Whole Body' Study will be conducted by Dr. Amy Paller at Northwestern University*
- *Up to eight subjects will have QRX003 applied twice daily to greater than 80% of their body surface area over a 12-week period*
- *Study intended to generate data based on product use resembling potential real-world use*
- *Third Netherton Syndrome clinical study to be conducted under Quoin's open Investigational New Drug application*

ASHBURN, Va., Dec. 19, 2024 (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 FDA clearance to initiate a new additional Netherton Syndrome (NS) clinical study for QRX003. QRX003 is a topical lotion that contains a broad-spectrum serine protease inhibitor designed to target the kallikreins in the skin responsible for the excessive skin shedding associated with this disease.

The study will be conducted by Dr. Amy Paller, of Northwestern University. It is planned that up to eight subjects will be enrolled into the study and will have QRX003 applied twice daily to greater than 80% of their entire body surface area (BSA) over a 12-week period. By comparison, in Quoin's ongoing open-label and double-blinded clinical studies, QRX003 is applied to approximately 20% of the subject's BSA, typically the arms and lower leg. This new study, designed to mimic how NS patients will use QRX003 if approved, represents the most extensive use of QRX003 in a clinical setting to date. It is anticipated that the data generated from this study will be used to supplement the data package to support the potential regulatory approval of QRX003 as a treatment for NS.

Dr. Amy Paller said, "The best kind of treatment, short of curative gene therapy, focuses on reversing the mechanism by which skin disease occurs. Targeting kallikreins, which are thought to lead to the clinical manifestations of Netherton Syndrome, could be an ideal approach."

Quoin CEO, Dr. Michael Myers, added, "Following our recent announcement of positive interim clinical data from two of our ongoing Netherton Syndrome clinical studies, we are very excited to announce FDA clearance to initiate this groundbreaking additional study for QRX003, where the product will be applied to greater than 80% of each subject's body surface area. We are extremely pleased to be working with Dr. Paller on this new study and look forward to generating data in a real-world setting, which will be a key component of our future filing. This will be Quoin's third clinical study in NS subjects to be conducted under our open Investigational New Drug application and reflects our absolute commitment to generating the most robust and diverse data set possible to support our mission of delivering the first-ever approved treatment for this horrendous disease."

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," "look forward to," 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, statements relating to: plans to initiate whole body study, the data generated from this study to be used to supplement the data package to support the potential regulatory approval of QRX003 as a treatment for NS, Quoin's belief that its products in development 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. 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 timing of the clinical studies may be delayed, the clinical studies may not generate the results anticipated, the Company needing to raise additional funds sooner than planned, or the clinical studies not generating data which is sufficiently robust and comprehensive to support an NDA filing and the Company's ability to obtain regulatory approvals. More detailed information about the risks and uncertainties affecting the Company is summarized 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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