



## **Quoin Pharmaceuticals Announces FDA Clearance to Initiate Second Pivotal Whole Body QRX003 Netherton Syndrome Clinical Study**

May 22, 2025

- *Study CL-QRX003-002 will test whole-body application of QRX003 in conjunction with off-label systemic therapy in approximately 12-15 subjects.*
- *Study CL-QRX003-002 complements first whole-body pivotal study, CL-QRX003-003, being led by Dr. Amy Paller at Northwestern University and supported by up to six international sites that are expected to open, where subjects are being tested with QRX003 as monotherapy.*
- *Combined data from Studies CL-QRX003-002 and CL-QRX003-003 is anticipated to provide QRX003 with the broadest possible label opportunity post-approval as both monotherapy and adjunct therapy in conjunction with off-label systemic treatments.*
- *Five U.S. clinical sites have been opened, and six international sites are being opened. All currently have available cohorts of subjects ready to be enrolled into the studies facilitating accelerated recruitment.*
- *Quoin anticipates completion of recruitment into both pivotal studies by end of Q1 2026 and filing an NDA for regulatory approval later in the year.*

ASHBURN, Va., May 22, 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 FDA clearance to initiate a second Netherton Syndrome (NS) pivotal clinical study CL-QRX003-002 for QRX003. Quoin's lead product, QRX003, is a topical lotion formulated with a broad-spectrum serine protease inhibitor that has been shown to significantly downregulate the hyperactivity of the kallikreins in the skin responsible for the excessive skin shedding associated with this disease. Clinical data from Quoin's ongoing studies has demonstrated clear evidence of rapid, prolonged and almost complete skin healing following twice-daily application of QRX003 to the treatment areas along with the almost complete elimination of key symptoms such as chronic, debilitating pruritus and has facilitated zero nightly sleep disturbances.

Study CL-QRX003-002 builds off of positive clinical data generated in Quoin's earlier stage open-label study where QRX003 was applied to the arms and lower legs or approximately 20% of each subject's body surface area (BSA). In this pivotal study, QRX003 will be applied to approximately 12-15 subjects twice daily to at least 80% of each of the subjects' BSA thereby generating substantially more safety and efficacy data per subject and will match how QRX003 is intended to be used if regulatory approval is obtained. All subjects recruited into this study are currently receiving off-label systemic therapy and will continue to remain on this treatment for the duration of the study. Study CL-QRX003-002 complements Quoin's other pivotal study, CL-QRX003-003, which is being conducted by Dr. Amy Paller, of Northwestern University, where QRX003 is being administered as monotherapy and subjects do not receive off-label systemic therapy. Quoin anticipates that combined both studies will recruit between 24-30 subjects in 6 U.S. sites and up to 6 international sites. Five of the U.S. sites are already open and the sixth is expected to be opened in June. All international sites are at an advanced stage of preparation for opening. Each of the U.S. and international sites has available cohorts of subjects that are ready to participate in both studies facilitating a rapid pace of recruitment which could enable Quoin to achieve its target of fully completing recruitment before the end of Q1 2026 and to file an NDA for regulatory approval later in the year.

Quoin CEO, Dr. Michael Myers, added, "I am very pleased to announce yet another important and significant milestone for Quoin. With FDA clearance to conduct this study, Quoin is the only company conducting two late-stage whole-body pivotal clinical studies in Netherton Syndrome patients. We believe that the combined data generated from Study CL-QRX003-003, where QRX003 is being administered as monotherapy and this study, CL-QRX003-002, where QRX003 is being tested in conjunction with off-label systemic therapy, has the potential to generate a highly comprehensive safety and efficacy data package that could support the regulatory approval of a treatment for this dreadful disease."

### **About Quoin Pharmaceuticals Ltd.**

Quoin Pharmaceuticals Ltd. is a late 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](http://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: study CL-QRX003-002 testing the whole-body application of QRX003 in conjunction with off-label systemic therapy in approximately 12-15 subjects, six international sites opening to support study CL-QRX003-003 testing subjects with QRX003 as monotherapy, combined data from Studies CL-QRX003-002 and CL-QRX003 providing QRX003 with the broadest possible

label opportunity post-approval as both monotherapy and adjunct therapy in conjunction with off-label systemic treatments, available cohorts of subjects being ready to be enrolled into the studies facilitating accelerated recruitment at the clinical sites, completing recruitment into both pivotal studies by end of Q1 2026, filing an NDA for regulatory approval later in the year, combined both studies recruiting between 24-30 subjects in 6 US sites and up to 6 international sites, opening a sixth US site in June, and 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 Company's ability to pursue its regulatory strategy; the Company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements; the Company's ability to complete clinical trials on time and achieve desired results and benefits as expected; and other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 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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