Quoin Pharmaceuticals Receives FDA IND Clearance to Initiate Phase 2 Study of QRX003 in Peeling Skin Syndrome

July 9, 2026

- *Quoin Expects to Initiate Phase 2 Study in 2H 2026, Study Plans to Enroll 6-8 Pediatric and Adult Patients in the U.S. and Europe*
- *FDA Expressed No Safety Concerns Over Study Design and Duration of Dosing*
- *First-Ever Formal Clinical Study for a Potential Peeling Skin Syndrome Therapy*
- *Second Cleared IND Indication for QRX003, in Addition to Netherton Syndrome*
- *Peeling Skin Syndrome Currently Has No Approved Treatment*
- *Quoin Anticipates Also Testing QRX003 in Additional Ichthyosis Indications for Which There Are No Approved Treatments*

ASHBURN, Va., July 09, 2026 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX), a late clinical-stage specialty pharmaceutical company focused on rare and orphan diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for QRX003 for the treatment of Peeling Skin Syndrome (PSS), enabling initiation of its planned Phase 2 clinical study. Quoin expects to initiate the study in the second half of 2026. Potential clinical sites, clinical investigators and study participants have already been identified.

Key Facts

- Clearance enables Quoin to initiate a Phase 2 clinical study of QRX003 in Peeling Skin Syndrome in the second half of 2026.
- The study is expected to enroll 6-8 pediatric and adult patients in the United States and Europe.
- The IND is the first ever submitted to the FDA for Peeling Skin Syndrome, and its clearance now enables the first company-sponsored formal clinical study for the disease to be conducted.
- PSS is the second IND cleared indication for QRX003, in addition to Netherton Syndrome.
- In an ongoing investigator-led pediatric study, subject achieved clinically meaningful improvements by 12 weeks across key objective severity endpoints Modified Ichthyosis Area Severity Index (M-IASI), Investigator’s Global Assessment (IGA) and a pediatric dermatology-specific quality-of-life measure (CDLQI). Treatment is ongoing and after continued dosing with QRX003 for over 15 months, no adverse events have been reported.
- FDA expressed no safety concerns regarding study design and duration of dosing.
- Quoin submitted the IND on June 2, 2026, and received FDA clearance in July 2026.

Phase 2 Study Design

The Phase 2 study is expected to recruit 6-8 pediatric and adult patients with PSS in both the United States and Europe. In the Phase 2 study, QRX003 will be applied twice-daily to greater than 80% of the patients’ body surface area (BSA) over a 52-week period. The Company is targeting the approval of QRX003 as a potential treatment for PSS in 2028.

"For families living with Peeling Skin Syndrome, there is still no approved treatment and no other active clinical development of a potential treatment for the disease. This is what makes FDA clearance to initiate our Phase 2 study so meaningful for this community," said Dr. Michael Myers, CEO of Quoin Pharmaceuticals. "We are excited to start this Phase 2 study of QRX003 and take yet another step toward developing a treatment for another disease that has long been overlooked. This is now the second rare dermatologic indication for QRX003, and it fully reflects Quoin’s mission to provide hope to patient communities and families where none has previously existed. We are particularly encouraged by the FDA expressing no safety concerns in terms of study design and dosing duration which we believe is a very positive indicator as we seek to reach alignment with the agency for our upcoming Phase 3 study in Netherton Syndrome."

About Peeling Skin Syndrome (PSS)

Generalized inflammatory peeling skin syndrome (PSS) is a rare autosomal recessive genodermatosis caused by loss-of-function disease-causing variants of the corneodesmosin gene (CDSN), resulting in excessive shedding of the superficial layers of the epidermis. Patients generally suffer from a variety of conditions including severe pain and chronic pruritus (itch). There is currently no approved treatment for PSS.

About QRX003

QRX003 is an investigational topical serine protease inhibitor lotion in late-stage development for Netherton Syndrome and other orphan skin diseases. QRX003 has been granted Orphan Drug, Rare Pediatric Disease, and Fast Track designations by the U.S. Food and Drug Administration, and Orphan Drug Designation in the European Union and Japan for Netherton Syndrome. QRX003 lotion (4%) is currently being evaluated in Phase 2 whole-body clinical trials in patients with Netherton Syndrome. Quoin's pivotal Phase 3 study is expected to initiate in the second half of 2026, with a potential NDA filing in 2027. QRX003 is also being evaluated for the treatment of Peeling Skin Syndrome.

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 is focused on two key platform products, QRX003 and QRX009, that collectively have the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Pachyonychia Congenita, Gorlin Syndrome and Tuberous Sclerosis Complex, Microcystic Lymphatic Malformations, Venous Malformations, Angiofibromas and others. For more information, visit: www.quoinpharma.com or LinkedIn for updates.

Forward-Looking Statements

The Company cautions that statements in this press release that are not descriptions 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,” “hope,” “plan,” “potential,” “anticipate,” “look forward,” “believe,” “may,” and “will,” among others. This press release contains forward-looking statements. 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 a Phase 2 clinical study of QRX003 in Peeling Skin Syndrome in the second half of 2026; the study expecting to enroll 6-8 pediatric and adult patients in the United States and Europe; conducting the first company-sponsored formal clinical study for Peeling Skin Syndrome; developing a treatment for another disease that has long been overlooked; Quoin’s mission to provide hope to patient communities and families where none has previously existed; reaching alignment with the FDA for Quoin’s upcoming Phase 3 study in Netherton Syndrome; 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, Pachyonychia Congenita, Gorlin Syndrome, Tuberous Sclerosis Complex, Microcystic Lymphatic Malformations, Venous Malformations, Angiofibroma 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, 2025 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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