Quoin Pharmaceuticals Announces FDA Fast Track Designation for QRX003 for the Treatment of Peeling Skin Syndrome

September 22, 2026

– First-Ever Fast Track Designation Granted for a Peeling Skin Syndrome Therapy

– Second Fast Track Designation Granted to QRX003, in Addition to Netherton Syndrome

– Fast Track Designation Facilitates Development and Expedites Regulatory Review of Therapies Addressing Serious Conditions with Significant Unmet Medical Need

– Follows July 2026 FDA Clearance of the First-Ever IND Submitted for Peeling Skin Syndrome

– Phase 2/3 Study Expected to Initiate in 2H 2026, Enrolling up to 12 Pediatric and Adult Patients in the U.S. and Europe

– Peeling Skin Syndrome Currently Has No Approved Treatment

ASHBURN, Va., Sept. 22, 2026 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) ("Quoin" or the "Company"), 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 granted Fast Track Designation to QRX003 for the treatment of Peeling Skin Syndrome (PSS). QRX003 is an investigational topical serine protease inhibitor lotion. Peeling Skin Syndrome is a rare genetic skin disease for which there is currently no approved treatment.

Key Facts

- Fast Track Designation applies to QRX003 for the treatment of Peeling Skin Syndrome.
- This is the first ever Fast Track Designation granted for a Peeling Skin Syndrome therapy.
- Peeling Skin Syndrome is the second indication for which QRX003 has received Fast Track Designation. The FDA granted Fast Track Designation to QRX003 lotion (4%) for the treatment of Netherton Syndrome on March 11, 2026.
- The designation follows FDA clearance in July 2026 of Quoin’s Investigational New Drug (IND) application for QRX003 in Peeling Skin Syndrome. Quoin submitted that IND on June 2, 2026, and it was the first IND ever submitted to the FDA for the disease.
- Quoin expects to initiate a Phase 2/3 clinical study of QRX003 in Peeling Skin Syndrome in the second half of 2026.
- The IND submission was supported by clinical observations from an ongoing investigator-led pediatric study in a single subject. Significant improvements in skin appearance along with positive changes in pruritus and a number of quality-of-life measures have been recorded. Treatment is ongoing and has continued for more than 15 months, with no adverse events reported.
- There is currently no approved treatment for Peeling Skin Syndrome.

"This is an important regulatory milestone for QRX003 and for a community that today has no approved treatment," said Dr. Michael Myers, CEO and Co-Founder of Quoin Pharmaceuticals. "Quoin submitted the first IND ever filed with the FDA for Peeling Skin Syndrome, that IND was cleared in July, and QRX003 has now been granted Fast Track Designation for the disease. We expect to initiate our Phase 2/3 study in the second half of 2026, and we believe Fast Track status will allow us to work closely with the agency as we advance the first company-sponsored clinical study in this disease."

Peeling Skin Syndrome Development Program

The planned Phase 2/3 study is expected to enroll up to 12 pediatric and adult patients with Peeling Skin Syndrome in the United States and Europe. In the study, QRX003 will be applied twice-daily to greater than 80% of patients’ body surface area (BSA) over a 48-week period, with an interim data review at 24 weeks. Quoin is targeting approval of QRX003 as a potential treatment for Peeling Skin Syndrome in 2028.

The IND submission was supported by clinical observations from an ongoing investigator-led pediatric study. The subject has achieved improvements across key objective severity endpoints, including the Modified Ichthyosis Area Severity Index (M-IASI), Investigator’s Global Assessment (IGA) as well as pruritus 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.

About Fast Track Designation

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. A therapy granted Fast Track Designation may benefit from more frequent interactions with the FDA, eligibility for rolling review of regulatory submissions, and potential qualification for Accelerated Approval and Priority Review, if relevant criteria are met.

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 has also been granted Rare Pediatric Disease and Fast Track Designation by the FDA for Peeling Skin Syndrome. QRX003 lotion (4%) is currently being evaluated in Phase 2/3 whole-body clinical trials in patients with Netherton Syndrome. Quoin expects to initiate a Phase 2/3 clinical study of QRX003 in Peeling Skin Syndrome in the second half of 2026.

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: Fast Track Designation facilitating development and expediting regulatory review of therapies addressing serious conditions with significant unmet medical need; plans to initiate a Phase 2/3 clinical study of QRX003 in Peeling Skin Syndrome in the second half of 2026; Fast Track status allowing Quoin to work closely with the FDA to advance the first company-sponsored clinical study in Peeling Skin Syndrome; the study expecting to enroll up to 12 pediatric and adult patients with Peeling Skin Syndrome in the United States and Europe; QRX003 expected to be applied twice-daily to greater than 80% of a patients' body surface area over a 48-week period, with an interim data review at 24 weeks; targeting approval of QRX003 as a potential treatment for Peeling Skin Syndrome in 2028; therapies granted Fast Track Designation benefiting from more frequent interactions with the FDA, eligibility for rolling review of regulatory submissions, and potential qualification for Accelerated Approval and Priority Review, if relevant criteria are met; 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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