# Quoin Pharmaceuticals Announces FDA Grants Fast Track Designation for QRX003 for the Treatment of Netherton Syndrome

March 11, 2026

*— Fast Track Designation facilitates development and expedites regulatory review of therapies addressing serious conditions with significant unmet medical need —*

*— QRX003 lotion (4%) currently being evaluated in two late-stage whole-body clinical trials for treatment of Netherton Syndrome —*

*— Fast Track Designation follows Pediatric Rare Disease and Orphan Drug Designation previously granted by the FDA and Orphan Drug Designation granted by the European Medicines Agency for QRX003 in Netherton Syndrome —*

ASHBURN, Va., March 11, 2026 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) ("Quoin" or the "Company"), a late clinical-stage specialty pharmaceutical company focused on developing and commercializing therapeutic products that treat rare and orphan diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to QRX003 lotion (4%) for the treatment of Netherton Syndrome, a rare and severe genetic skin disorder for which there are currently no approved treatments.

"We believe that the FDA's decision to grant Fast Track Designation to QRX003 reflects the urgent unmet need faced by patients and families living with Netherton Syndrome," said Dr. Michael Myers, CEO and Co-Founder of Quoin Pharmaceuticals. "Fast Track status enables more frequent communication with the FDA and the potential for accelerated regulatory review pathways, which may help bring the first approved treatment for Netherton Syndrome to patients as quickly as possible."

**QRX003 Development Program**

QRX003 lotion (4%) is currently being evaluated in two late-stage whole-body clinical trials designed to assess safety and efficacy in patients with Netherton Syndrome.

QRX003 previously received Orphan Drug Designation from both the U.S. FDA and the European Medicines Agency (EMA) for the treatment of Netherton Syndrome, providing potential benefits including market exclusivity upon approval, tax credits for clinical testing, and certain regulatory fee reductions. QRX003 has also been granted Pediatric Rare Disease Designation by the FDA.

**About Netherton Syndrome**

Netherton Syndrome is a rare, inherited skin disorder caused by mutations in the SPINK5 gene, leading to severe skin barrier dysfunction, chronic inflammation, and a heightened risk of infections and allergic complications. Patients often experience widespread skin redness, scaling, persistent itching, and significant impairment in quality of life. There are currently no FDA-approved therapies for the treatment of Netherton Syndrome, and treatment options are limited to supportive care and off-label therapies.

**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 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 several 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, Microcystic Lymphatic Malformations, Venous Malformations, Angiofibroma 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: the potential for an accelerated regulatory review pathway for QRX003, bringing the first approved treatment for Netherton Syndrome to patients as quickly as possible, timing of clinical studies, 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, 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 the 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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