Quoin Pharmaceuticals Announces U.S. FDA Grants Orphan Drug Designation for QRX003 in Netherton Syndrome

October 21, 2025

Upon Approval of NDA Quoin Will Receive Seven Years Marketing Exclusivity for QRX003 in the US

Orphan Drug Designation previously granted by the European Medicines Agency in May 2025

ASHBURN, Va., Oct. 21, 2025 (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 Orphan Drug Designation (ODD) to its lead product candidate, QRX003, for the treatment of Netherton Syndrome. The designation follows previously granted Orphan Drug Designation by the European Medicines Agency (EMA) in May 2025.

The FDA's Orphan Drug Designation program provides orphan status to therapies intended for the treatment, diagnosis, or prevention of rare diseases that affect fewer than 200,000 people in the United States. This designation provides certain benefits, including tax credits for qualified clinical testing, waiver or partial payment of FDA application fees and seven years of market exclusivity, if approved. QRX003 is on track to potentially become the first approved treatment for Netherton Syndrome.

"Receiving Orphan Drug Designation from the FDA is yet another important milestone in our mission to bring QRX003 to patients suffering with Netherton Syndrome," said Dr. Michael Myers, CEO of Quoin Pharmaceuticals. "Together with the EMA designation granted earlier in the year, this latest recognition by the FDA could potentially help facilitate the pathway of QRX003 to approval in the US whilst providing significant data protection to the product, if approved. Quoin remains steadfastly committed to completing the clinical development of QRX003 with a high degree of urgency on behalf of patients and families living with this devastating disease."

QRX003 lotion (4%) is being evaluated in two late-stage whole body pivotal clinical trials for Netherton Syndrome. Enrollment in both pivotal studies is expected to be completed in Q1 2026, top-line data is anticipated in the second half of 2026, and NDA submission is planned later in the year.

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: QRX003 being on track to potentially become the first approved treatment for Netherton Syndrome, FDA recognition of Orphan Drug Designation potentially helping to facilitate the pathway of QRX003 to approval in the US whilst providing significant data protection, completing the clinical development of QRX003, completing enrollment in two late-stage whole body pivotal clinical trials for Netherton Syndrome, evaluating QRX003 lotion (4%) in two late-stage whole body pivotal clinical trials for Netherton Syndrome, completing enrollment in both pivotal studies in Q1 2026, receiving top-line data in the second half of 2026 and submitting an NDA later in the year, 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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