Quoin Pharmaceuticals Announces FDA Grants Rare Pediatric Disease Designation for QRX003 in Netherton Syndrome

June 24, 2025

ASHBURN, Va., June 24, 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 Rare Pediatric Disease (RPD) Designation for the Company's lead asset, QRX003, for the treatment of Netherton Syndrome.

The designation reinforces the potential of QRX003 as a therapeutic candidate for a profoundly underserved pediatric population. It follows earlier regulatory recognition by the European Medicines Agency (EMA), which granted Orphan Drug Designation to QRX003 in May 2025.

"We are very pleased to announce the receipt of Rare Pediatric Disease Designation for QRX003 for Netherton Syndrome, a severe and underserved genetic disease," said Dr. Michael Myers, Chief Executive Officer of Quoin Pharmaceuticals. "The Quoin team is fully focused on completing our pivotal clinical studies and advancing QRX003 towards a New Drug Application as the first potential treatment for this terrible disease. We are highly encouraged by the promising efficacy data and clean safety profile seen to date."

The FDA's Rare Pediatric Disease Designation program is intended to encourage the development of new therapies for serious and life-threatening diseases that primarily affect individuals under 18 years of age. If a New Drug Application (NDA) for QRX003 is approved, upon reauthorization of the program Quoin may be eligible to receive a Priority Review Voucher (PRV), which can be redeemed to receive priority review for another marketing application or may be sold or transferred.

About Netherton Syndrome in Children
Netherton Syndrome is a rare genetic disorder affecting approximately 1 in 200,000 newborns worldwide. Symptoms typically present at birth or in early infancy and persist throughout life. Affected infants often require prolonged hospitalization due to severe skin inflammation, dehydration, and increased risk of infection. The condition can be challenging to diagnose early, as it may resemble other dermatological or immunological disorders. Mortality in infancy is estimated at 10 to 20 percent, underscoring the serious clinical burden associated with the 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 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: potential of QRX003 as a therapeutic candidate for a profoundly underserved pediatric population, completing the Company's pivotal clinical studies, advancing QRX003 towards a New Drug Application as the first potential treatment for Netherton Syndrome, if a New Drug Application for QRX003 is approved, upon reauthorization of the program, Quoin may be eligible to receive a Priority Review Voucher, 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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