



Quoin Pharmaceuticals Announces European Medicines Agency (EMA) Grants Orphan Drug Designation for QRX003 for the Treatment of Netherton Syndrome

May 20, 2025

Company continues to advance QRX003 in late-stage clinical trials in Netherton Syndrome patients

Regulatory milestone provides 10 years of market exclusivity in Europe upon approval

ASHBURN, Va., May 20, 2025 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the "Company" or "Quoin"), a late clinical stage, specialty pharmaceutical company focused on rare and orphan diseases, today announces that it has been granted Orphan Drug Designation in Europe by the European Medicines Agency (EMA) for its lead product QRX003 in Netherton Syndrome.

Orphan Drug Designation in Europe affords the Company incentive benefits including scientific advice on study protocols, various fee reductions and access to EU grants. If approved, QRX003 will be granted 10 years of market exclusivity in Europe for the treatment of Netherton Syndrome.

Quoin CEO, Dr. Michael Myers, said, "We continue to make important clinical and regulatory progress for QRX003 as a potential treatment for Netherton Syndrome, and this milestone marks yet another significant step forward for Quoin. As we continue to generate positive clinical results from our ongoing studies we are very encouraged both by the efficacy signals we are seeing and the clean safety profile of the product to date. In particular, the extent of skin healing observed coupled with the almost complete elimination of severe chronic pruritus in our investigator pediatric study underscores QRX003's mechanism of action as a broad spectrum kallikrein inhibitor that has the potential to be a safe and effective treatment for this disease."

QRX003 is currently being evaluated in multiple late-stage clinical trials and is designed to be a topical, non-systemic treatment for Netherton Syndrome, a devastating, life-altering disease for which there are currently no approved therapies.

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, SAM Syndrome, Palmoplantar Keratoderma, Scleroderma, Epidermolysis Bullosa, 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 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.

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: advancing QRX003 in Quoin's late-stage Netherton Syndrome clinical studies, upon approval being granted 10 years of market exclusivity in Europe for the treatment of Netherton Syndrome, continuing to generate positive clinical results from ongoing studies of QRX003, QRX003's mechanism of action having the potential to be a safe and effective treatment for 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, SAM Syndrome, Palmoplantar Keratoderma, Scleroderma, Epidermolysis Bullosa, 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, 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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