Quoin Pharmaceuticals Announces Japan's MHLW Grants Orphan Drug Designation for QRX003 in Netherton Syndrome

June 4, 2026

-Designation provides regulatory and development incentives in Japan, including up to 10 years of market exclusivity upon approval-

-Follows Orphan Drug Designation, Pediatric Rare Disease Designation, and Fast Track Designation previously granted by the U.S. FDA, and Orphan Drug Designation previously granted by the European Medicines Agency-

-Quoin is working closely with leading Japanese clinicians to refine clinical and regulatory pathway for approval-

ASHBURN, Va., June 04, 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 Japan's Ministry of Health, Labour and Welfare (MHLW) has granted Orphan Drug Designation to QRX003 for the treatment of Netherton Syndrome, a rare and severe genetic skin disorder for which there are currently no approved treatments.

The MHLW grants Orphan Drug Designation to medicines intended to treat rare diseases that affect fewer than 50,000 patients in Japan and for which there is high unmet medical need. The designation provides certain development incentives, including prioritized consultation, reduced consultation and application fees, tax incentives, priority review of applications, and up to 10 years of market exclusivity upon approval.

The MHLW designation adds to the global regulatory recognition QRX003 has received for Netherton Syndrome, which includes Orphan Drug Designation, Pediatric Rare Disease Designation, and Fast Track Designation from the U.S. Food and Drug Administration, and Orphan Drug Designation from the European Medicines Agency. Quoin has also filed an application for Breakthrough Medicine Designation with the Saudi Food and Drug Authority.

"Receiving Orphan Drug Designation from Japan's MHLW adds an additional important regulatory milestone for QRX003 and its potential as a safe and effective treatment for Netherton Syndrome," said Dr. Michael Myers, CEO of Quoin Pharmaceuticals. "Japan is a strategically important market for QRX003, and, along with the US and Western Europe, is one of three core territories in which we plan to self-commercialize QRX003 and our other pipeline products, once approved. This designation is another important step in that strategy and complements the regulatory recognition QRX003 has received in the United States and Europe."

QRX003 lotion (4%) is currently being evaluated in Phase 2 whole-body clinical trials in patients with Netherton Syndrome. Quoin's pivotal Phase 3 study is expected to initiate in the second half of 2026, with potential NDA filing in 2027. Quoin is working closely with leading Japanese clinicians to refine the clinical and regulatory pathway for approval of QRX003 for the treatment of Netherton Syndrome.

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 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.

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 ‘s potential as a safe and effective treatment for Netherton Syndrome; the strategic importance of Japan as a market for QRX003; plans to self-commercialize QRX003 and Quoin’s other pipeline products in Japan, the US and Western Europe, once approved; initiating Quoin's pivotal Phase 3 study in the second half of 2026, with potential NDA filing in 2027; working closely with leading Japanese clinicians to refine clinical and regulatory pathway for approval of QRX003 for the treatment of Netherton Syndrome;; 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, Pachyonychia Congenita, Gorlin Syndrome, Tuberous Sclerosis Complex, microcystic lymphatic malformations, venous malformations, angiofibromas 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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