Quoin Pharmaceuticals Provides Clinical and Regulatory Update from Constructive Type C Meeting with U.S. FDA for QRX003 in Netherton Syndrome

March 25, 2026

FDA indicated that a single Phase 3 study may be sufficient to support marketing approval in the U.S.

FDA expressed openness to an alternative study design for Phase 3 that would likely not include a traditional upfront vehicle or placebo control

Quoin remains on track to initiate a Phase 3 study and complete Phase 3 patient recruitment in 2026 and potentially file for NDA approval in 2027

ASHBURN, Va., March 25, 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 provided a clinical and regulatory update from its recent constructive Type C meeting with the U.S. Food and Drug Administration (FDA) for its lead product candidate, QRX003, for the treatment of Netherton Syndrome (NS).

"We are very pleased to provide this update from our recent Type C meeting with FDA. Importantly, FDA acknowledged that a single Phase 3 study may be sufficient to support U.S. marketing approval of QRX003 for Netherton Syndrome, rather than the two Phase 3 studies the Company had originally contemplated. With our established network of U.S. and EU clinical trial sites, we are confident that we will be in a position to initiate our pivotal Phase 3 program and fully complete recruitment this year. FDA also expressed openness to an alternative, innovative clinical trial design, such as a randomized withdrawal or randomized delayed start study, which may be more appropriate Phase 3 design in the setting of Netherton Syndrome than a traditional upfront randomized, controlled study. Overall, this meeting represents an important milestone for Quoin and the Netherton Syndrome community at large. We are now in a position to move forward with clarity, and we remain on track to advance development of QRX003 with the goal of potentially delivering the first approved medication for the treatment of Netherton Syndrome. Finally, I would like to sincerely thank each of the KOLs who participated in the meeting: Professor Alan Irvine, Dr. Amy Paller, Dr. Keith Choate, Professor Jemima Mellerio, Professor Anna Martinez, Professor James Halpern and Professor Suzanne Pasmans. We are truly grateful for your continued support and expert input." said Dr. Michael Myers, CEO of Quoin Pharmaceuticals.

Key highlights from the meeting include:

- FDA indicated that a single Phase 3 study may be sufficient to support marketing approval for QRX003 for Netherton Syndrome, which is an alternative to the traditional expectation for two Phase 3 studies in NS patients originally proposed by the Company.
- FDA expressed openness to an alternative innovative clinical trial design such as a randomized withdrawal or a randomized delayed start for a pivotal Phase 3 study. Such trial design would likely not include a traditional upfront vehicle or placebo control.

Based on the feedback from the meeting, Quoin is implementing FDA recommendations consistent with the meeting outcomes, ensuring its readiness to advance toward registrational Phase 3 development. Quoin will submit clinical data from the ongoing Phase 2 and pediatric investigator studies and plans to request a meeting to discuss this data prior to initiating the Phase 3 pivotal program for QRX003 to gain alignment with FDA on the design of the program. Quoin remains on track to complete patient recruitment into its Phase 3 program by the end of 2026 and to potentially file for FDA approval for QRX003 as the first treatment for Netherton Syndrome in 2027

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, SAM 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: a single Phase 3 study being sufficient to support US marketing approval of QRX003 for Netherton Syndrome, rather than the two Phase 3 studies the Company had originally contemplated; remaining on track to initiate pivotal Phase 3 Study of QRX003 and complete Phase 3 patient recruitment in 2026; pursuing an alternative, innovative clinical trial design rather than a traditional upfront vehicle or placebo control study; potentially filing for FDA approval for QRX003 as the first treatment for Netherton Syndrome in 2027; being now in a position to move forward with clarity, advancing development of QRX003 with the goal of potentially delivering the first approved

medication for the treatment of Netherton Syndrome; implementing FDA recommendations consistent with the meeting outcomes; ensuring the Company's readiness to advance toward registrational Phase 3 development; submitting clinical data from the ongoing Phase 2 and pediatric investigator studies; plans to request a meeting with the FDA to discuss data prior to initiating the Phase 3 pivotal program for QRX003 to gain alignment on the design of the program; 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.

For further information, contact:

Quoin Pharmaceuticals Ltd.
Michael Myers, Ph.D., CEO
mmyers@quoinpharma.com

Investor Relations
PCG Advisory
Jeff Ramson
jramson@pcgadvisory.com
(646) 863-6341