Quoin Pharmaceuticals Reports Positive Interim Data from Ongoing Phase 2/3 Study of QRX003 in Netherton Syndrome

August 28, 2026

- *Interim Analysis of the First Six Patients to Complete 12 Weeks of Treatment Met Pre-Specified Alpha Adjusted Target for Primary Endpoint with Statistical Significance*
- *Four of Six (66.7%) Participants Achieved the Target 1-Grade or Greater Improvement in Investigator Global Assessment at Week 12 (p=0.0087) With Statistical Significance versus the Pre-Specified Alpha of 0.0215*
- *Key Secondary Endpoint of Global Impression of Change Also Achieved Statistical Significance at Week 12 (p=0.0070) Versus the Pre-Specified Alpha of 0.0215*
- *All Three Participants with Moderate-Severe Pruritus (Itch) at Baseline Achieved a Clinically Meaningful Outcome of at Least a 3-Grade Improvement After 12 Weeks of Treatment with QRX003*
- *No Treatment Related Serious Adverse Events were Recorded*

ASHBURN, Va., Aug. 28, 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 positive interim results from CL-QRX003-004, its ongoing Phase 2/3 study of QRX003 4% lotion in patients with Netherton Syndrome.

Summary of CL-QRX003-004 Interim Results in Netherton Syndrome

- The primary endpoint of 1-grade improvement or greater for IGA on all of the treatment area met the pre-specified alpha-adjustment for interim analysis with statistical significance (p= 0.0087 vs. α=0.0215.) Four of six (66.7%) participants achieved the target 1-grade or greater improvement across all of the treatment area in Investigator Global Assessment (IGA) from baseline at Week 12, or 66.67% (95% CI: 22.28%, 95.67%), p=0.0087 against a pre-specified alpha of 0.0215.
- Two of those four (50%) participants achieved a 2-grade or greater IGA improvement across all of the treatment area.
- Key secondary endpoint, a Global Statistical Test of Global Impression of Change, achieved statistical significance at week 12 with a mean change of -1.5 (SD 0.82), (p-value=0.007 vs α=0.0215.) All three participants with moderate to severe pruritus at baseline achieved a clinically meaningful greater than 3-grade improvement in Worst Itch Numeric Rating Scale (WI-NRS, scale 0-10) at Week 12. One participant had a greater than 6-grade improvement.
- For the Ichthyosis Area and Severity Index (IASI), improvements ranging from 31-87% reduction in severity from baseline were recorded after 12 weeks of treatment with QRX003. These results mirrored those for the IGA with the same 4 participants recording clinically meaningful improvements for both endpoints.
- No treatment-related serious adverse events were reported. No clinically significant ECG, laboratory, or vital sign abnormalities were identified.
- Quoin expects to complete recruitment of all 20 participants in CL-QRX003-004 by the end of 2026 and report topline data in the second quarter of 2027.
- If approved, QRX003 could become the first FDA-approved treatment for Netherton Syndrome.

Study Design

CL-QRX003-004 is a Phase 2/3, multicenter, baseline-controlled, open-label study evaluating the safety, tolerability, and efficacy of QRX003 4% lotion applied twice daily to all of the body excluding the scalp in patients with Netherton Syndrome. The study will enroll approximately 20 evaluable participants aged four years and older across multiple clinical sites in both the US and the UK.

Treatment duration is 12 weeks, followed by a four-week post-treatment End of Study visit. Subjects must discontinue all standard of care therapy, including topical and systemic prescriptions, for the duration of the study.

Interim Results

This interim analysis covers the first six participants to complete the 12-week treatment period. The cohort comprised three male and three female

participants ranging in age from 11 to 52 years.

Primary Endpoint: IGA 1-Grade or Greater Improvement from Baseline

The primary endpoint is the proportion of participants achieving a 1-grade or greater reduction in IGA from baseline at Week 12. Four of six participants met that threshold, a rate of 66.67% (95% CI: 22.28%, 95.67%). The result achieved a p-value of 0.0087 against a pre-specified null hypothesis of one responder, easily clearing the pre-specified alpha adjustment for interim evaluation of 0.0215.

Primary Endpoint: IGA 1-Grade or Greater Improvement from Baseline			
Visit	**Responders (N)**	**Percent (95% CI)**	**P-Value**
Week 12 End of Treatment	4 (6)	66.67% (22.28%, 95.67%)	0.0087

- Pre-specified alpha adjustment for interim evaluation (p=0.0087 vs. α=0.0215)
- Null hypothesis was 1 patient responder

Global Statistical Test- Global Impression of Change (GIC)

On the key secondary endpoint, Global Statistical Test of Global Impression of Change, participants recorded a mean change of -1.5 (SD 0.82) at Week 12, with a 95% confidence interval of -2.3 to -0.6 and a statistically significant p-value of 0.007 vs pre-specified alpha adjustment for interim evaluation α=0.0215.

Global Statistical Test- Global Impression of Change (GIC)		
Visit	**Statistics**	**Observed Value**
Week 12	N	6
	Mean (SD)	-1.5 (0.82)
	95% Confidence Interval	(-2.3, -0.6)
	One Sample T-Test P-value	0.0070

WI-NRS: 2-Grade or Greater Improvement from Baseline

On the WI-NRS responder analysis, three of six participants achieved a 3-grade or greater improvement from baseline, a rate of 50% (95% CI: 11.81%, 88.19%), p=0.0623. Notably, this result was achieved by all three participants with moderate to severe pruritus at baseline. One participant had a greater than 6-grade improvement.

WI-NRS: 2-Grade or Greater Improvement from Baseline			
Visit	**Responders (N)**	**Percent (95% CI)**	**p-Value**
Week 12	3 (6)	50.00% (11.81%, 88.19%)	0.0623

Secondary Endpoint: IASI Individual Scores

Four of the six participants achieved a greater than 25% reduction in IASI severity with clinically meaningful scores ranging from 31%- 87% improvement from baseline achieved. The same four responders who met the primary IGA endpoint also achieved improvement in IASI scoring, demonstrating a high degree of consistency between both physician assessed skin endpoints, which further underscores the robustness of these clinical outcomes.

Safety

QRX003 4% lotion applied twice daily was well tolerated. No deaths and no treatment-related serious adverse events were reported. No clinically significant ECG, clinical laboratory, or vital sign abnormalities were identified. The safety profile observed to date supports continued clinical development.

Management Commentary

“These interim results provide further objective evidence that QRX003 has the potential to change the course of Netherton Syndrome. Four of the first six participants achieved a statistically significant improvement in the primary endpoint and in a key secondary endpoint after 12 weeks of treatment with QRX003 vs pre-specified alpha adjustment. Importantly, this was accomplished after participants had stopped every other topical and systemic therapy they were using. The same four participants who met the primary endpoint achieved clinically significant improved IASI scores underscoring

the robustness and consistency of the results across two objective clinician assessments. In addition, for the three participants who had the highest and most severe pruritus or itch at baseline, a highly clinically meaningful 3-grade or greater improvement was achieved after treatment with QRX003, including a greater than 6 grade improvement for one participant. Finally, these results match those previously reported from our ongoing pediatric compassionate use program as we continue to assemble a broad body of clinical evidence regarding the potential efficacy of QRX003 as treatment for this disease. We look forward to completing recruitment into this study by the end of the year and reporting the full data set in 2Q next year," said Dr. Michael Myers, Chief Executive Officer and Co-Founder of Quoin Pharmaceuticals.

About Netherton Syndrome

Netherton Syndrome is a rare, serious genetic skin disease caused by mutations in the SPINK5 gene. The condition is characterized by impaired skin barrier function, persistent inflammation, and increased serine protease activity in the skin. There are currently no approved therapies in the United States indicated specifically for Netherton Syndrome.

About QRX003

QRX003 is an investigational topical serine protease inhibitor lotion in late-stage development for Netherton Syndrome and other orphan skin diseases. QRX003 has been granted Orphan Drug, Rare Pediatric Disease, and Fast Track designations by the U.S. Food and Drug Administration, and Orphan Drug Designation in the European Union and Japan. QRX003 lotion (4%) is currently being evaluated in whole-body clinical trials in patients with Netherton Syndrome, including the Phase 2/3 study CL-QRX003-004.

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 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.
This press release contains forward-looking statements. 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: completing recruitment in CL-QRX003-004 by the end of 2026; topline data from CL-QRX003-004 in the second quarter of 2027; a potential NDA filing in 2027; QRX003 potentially becoming the first approved treatment for Netherton Syndrome; QRX003 having the potential to change the course of Netherton Syndrome in patients treated with this product; the safety profile observed to date supporting continued clinical development; 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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