Quoin Pharmaceuticals Announces FDA Clearance to Recruit Teen Subjects into Both Ongoing Netherton Syndrome Clinical Studies

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Clearance to include teen patients in both the company's open label and placebo controlled studies expected to significantly expand the number of eligible subjects, potentially expedite recruitment and lead to a more robust data set

This important development represents the first ever inclusion of non-adult subjects in Netherton Syndrome clinical studies conducted under an open Investigational New Drug Application

ASHBURN, Va., March 04, 2024 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the "Company" or "Quoin"), a specialty pharmaceutical company focused on rare and orphan diseases, today announced clearance from the U.S. Food and Drug Administration (FDA) to recruit teen subjects aged 14 years and older into its two ongoing clinical trials for QRX003, which is being developed as a potential treatment for Netherton Syndrome (NS). Both trials are being conducted under Quoin's open Investigational New Drug Application (IND) for QRX003.

Dr. Michael Myers, Chief Executive Officer of Quoin, said, "We are very pleased to announce this exciting development, not just for Quoin's clinical program, but for the Netherton community as a whole. We are frequently petitioned by parents and caregivers that teen subjects be allowed to participate in our clinical studies, given the severity of the disease and the absolute dearth of viable treatment options. Today, it is our privilege to announce that we have FDA clearance to do just that.

"This FDA clearance represents the very first time that non-adult Netherton subjects will be tested in clinical studies conducted under an open-IND and, as such, represents a very significant and important step forward for members of this community. Significantly, teens who are currently receiving off-label systemic therapy will be eligible to participate in our open-label study, while those who are not receiving such therapy may be recruited into the placebo controlled blinded study. This important feature not only widens the pool of eligible subjects but also eliminates the need for parents or caregivers to make difficult decisions about treatments these patients and loved ones are receiving. The inclusion of this patient population in our studies will be, we believe, a critical component of the development of a robust data set that could result in regulatory approval with a broad label as QRX003 is being tested both as monotherapy and in conjunction with off-label treatments.

"Quoin remains fully committed to the Netherton community, their families and treating physicians, and we are proud to be the only company actively dosing Netherton subjects in clinical studies conducted under an open IND. We look forward to continuing our mission to deliver what we hope will be the first safe and effective treatment for this debilitating disease," concluded Dr. Myers

For more information about Quoin's clinical trials in Netherton Syndrome, please visit: https://www.nethertonsyndromeclinicaltrials.com/

About Netherton Syndrome

Netherton Syndrome, a form of Ichthyosis, is a rare, hereditary skin disorder caused by a mutation in the SPINK5 gene (serine protease inhibitor, Kazal Type 5) that leads to severe skin barrier defects and recurring infections, as well as a pronounced predisposition to allergies, asthma, and eczema. Patients also often suffer from severe dehydration, chronic skin inflammation and stunted growth.

Currently, there is no cure for Netherton Syndrome, nor are there any approved therapeutic treatments.

About QRX003

QRX003 is a topical lotion, formulated with a proprietary delivery technology, and contains a broad- spectrum serine protease inhibitor, whose mechanism of action is intended to perform the function of a specific protein, called LEKTI. The absence of LEKTI in Netherton patients leads to excessive skin shedding resulting in a highly porous and compromised skin barrier. QRX003 is designed to lead to a more normalized skin shedding process and the formation of a stronger and more effective skin barrier.

About Quoin Pharmaceuticals Ltd.

Quoin Pharmaceuticals Ltd. is an emerging 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 three 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, Epidermolysis Bullosa and others. For more information, go to: www.quoinpharma.com.

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," and "will," among others. These forward-looking statements are based upon current estimates and assumptions and include statements regarding the clearance to treat teens expected to significantly expand the number of eligible subjects, potentially expedite recruitment and lead to a more robust data set; inclusion of the teen patient population in the Company's studies being a critical component of the development of a robust data set that could result in regulatory approval with a broad label and

the hope that QRX003 will be the first safe and effective treatment for this debilitating disease. 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 may not be able to recruit teen subjects into its two ongoing clinical studies, the clinical studies may not be successful and the Company may not be able to obtain regulatory approval for QRX003. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" included in the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2023, 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. 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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