Quoin Pharmaceuticals to Initiate Clinical Study for Peeling Skin Syndrome

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Peeling Skin Syndrome is a rare autosomal disease with no approved treatment or cure

Initial clinical site and pediatric patient identified in New Zealand

Company actively evaluating opening additional clinical sites in other countries

ASHBURN, Va., Aug. 06, 2024 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the “Company” or “Quoin”) a clinical stage, specialty pharmaceutical company focused on developing and commercializing novel treatments for rare and orphan diseases, today announced the planned initiation of an investigator-led clinical study in New Zealand to evaluate the safety and efficacy of QRX003 in a pediatric patient with Peeling Skin Syndrome (PSS). QRX003 is Quoin’s most advanced pipeline product and is currently being evaluated in two late stage clinical trials in the United States as a potential treatment for Netherton Syndrome (NS). Both studies are being conducted under an open Investigational New Drug (IND) application with the Food and Drug Administration (FDA).

“We are excited to expand QRX003’s development into this second indication, peeling skin syndrome, where it is believed the mechanism of action of our product could also provide a benefit for this devastating disease. Given the overlapping nature of how PSS presents, patients with the disease are known to have been previously misdiagnosed as having NS. Currently there are no clinical studies listed for peeling skin syndrome on clinicaltrials.gov as actively recruiting and dosing subjects and there is no approved treatment or cure, presenting a further opportunity for Quoin to achieve the first regulatory approval for another rare genetic disease,” stated Michael Myers, CEO, Quoin Pharmaceuticals. “The planned initiation of this study represents the execution of a key pillar of Quoin’s strategy to expand the clinical testing of QRX003 into other rare and orphan disease indications and we are actively assessing additional opportunities beyond this one.”

QRX003 is a unique “whole body, whole life” topical lotion that targets the vicious circle of skin inflammation and barrier disruption.

Quoin is conducting two ongoing clinical trials evaluating QRX003 for the treatment of Netherton Syndrome. For more information about the trials, please visit: https://www.nethertonsyndromeclinicaltrials.com/.

About Peeling Skin Syndrome (PSS)

Generalized inflammatory peeling skin syndrome (PSS) is a rare autosomal recessive genodermatosis caused by loss-of-function disease-causing variants of the corneodesmosin gene (CDSN), resulting in excessive shedding of the superficial layers of the epidermis. Patients generally suffer from a variety of conditions including severe pain and chronic pruritis (itch). There is currently no approved treatment for PSS, and patients manage symptoms using over-the-counter emollients.

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. 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 the Company’s expected cash runway, the belief that the data set from both clinical studies could potentially be sufficiently robust and comprehensive to support an NDA filing, without the need for any additional clinical studies in Netherton subjects, and the belief that certain protocol changes has enhanced the potential for a successful outcome and Quoin’s 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 may need to raise additional funds sooner than planned, the clinical studies may not generate data which is sufficiently robust and comprehensive to support an NDA filing and the Company's ability to obtain regulatory approvals. More detailed information about the risks and uncertainties affecting the Company is summarized in the Company's Annual Report on Form 10-K for the year ended December 31, 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. 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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