Quoin Pharmaceuticals Announces Plans to Initiate a Second Clinical Trial in Netherton Syndrome Patients

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A Multicenter Open Label Study of QRX003 Topical Lotion in Netherton Syndrome Patients Who Are Currently Receiving Systemic Biologic Therapy.

ASHBURN, Va., Oct. 18, 2022 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the “Company” or “Quoin”), a specialty pharmaceutical company focused on rare and orphan diseases, announces that it is initiating a second clinical trial in Netherton Syndrome patients.

This multicenter, open label study will be being conducted under Quoin’s currently open U.S. Investigational New Drug (IND) Application and will assess QRX003 topical lotion in Netherton patients who are currently receiving treatment including systemic therapy for symptomatic relief. QRX003 will be applied once daily over a twelve-week period, to pre-designated areas of the patient’s body. A number of different clinical endpoints will be assessed in the study.

The active ingredient in QRX003 is a broad-spectrum serine protease inhibitor, whose mechanism of action is intended to down-regulate the hyperactivity of skin kallikreins, leading to a more normalized rate of skin shedding. If proven to be safe and effective, long term daily application of QRX003 could lead to the development of a more normally functioning skin barrier and a significant improvement in the quality of life of Netherton patients.

Quoin CEO, Dr. Michael Myers, said, “We are very pleased to announce our plan to initiate this second clinical study in Netherton patients under our open IND application. While there are no currently approved therapeutic treatments for Netherton Syndrome, we are aware that a subset of patients is being treated off-label with systemic biologics, including systemic therapy, that provide some symptomatic relief but do not address all symptoms, nor the underlying cause of the disease.

“We firmly believe that, if approved, QRX003 has the potential to become the standard of care for Netherton patients. Assessing the safety and efficacy of the product as adjuvant treatment with a systemic biologic could potentially generate valuable clinical data that may facilitate better treatment options for patients and their physicians.”

Quoin’s currently ongoing Netherton Syndrome trial is a randomized, double blinded, vehicle-controlled study which is being conducted under a U.S. Investigational New Drug (IND) Application and is assessing two different doses of QRX003 topical lotion versus a vehicle lotion in Netherton patients. The test materials are applied once daily over a twelve-week period, to pre-designated areas of the patient’s body. Based on discussions with the U.S. Food and Drug Administration (FDA), a number of different clinical endpoints will be assessed in the study.

About Quoin Pharmaceuticals Ltd.

Quoin Pharmaceuticals Ltd. is a 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 four 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, Scleroderma, Epidermolysis Bullosa and others. For more information, visit: www.quoinpharma.com or LinkedIn for updates.

About Netherton Syndrome

Netherton Syndrome is a rare and sometimes fatal skin disease for which there is no approved treatment, and no cure. It is caused by a mutation of the SPINK5 gene which leads to uncontrolled skin shedding, resulting in a highly porous and ineffective skin barrier. Symptoms are present at birth and include red, scaly skin. Other symptoms include outbreaks of red, circular scaly rashes, thin, fragile hair (bamboo hair), and immune reactions such as hay fever, asthma, severe pruritus (itchy skin), and eczema. Dehydration and infection are common and can be serious or fatal. Babies tend to grow slowly and have poor weight gain. Netherton Syndrome is inherited in an autosomal recessive pattern.

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. 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. 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 20-F filed with the SEC on April 14, 2022, 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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