Quoin Pharmaceuticals Announces Receipt of Constructive Scientific Advice from EMA for QRX003 Development in Europe

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EMA Guidance Provides Clear Path Forward for Quoin's Netherton Syndrome Product in Europe

ASHBURN, Va., July 28, 2022 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the "Company" or "Quoin"), a clinical stage, specialty pharmaceutical company focused on rare and orphan diseases, announces that it has received comprehensive and constructive Scientific Advice from the European Medicines Agency (EMA) for the clinical and regulatory development of QRX003 in Europe, as a potential treatment for Netherton Syndrome (NS).

This Scientific Advice was received in response to a Briefing Submission document filed by Quoin to the EMA on May 26, 2022. Based on standard review periods for such submissions, which may also include an in-person meeting with the EMA, Quoin had anticipated receiving feedback from the EMA in mid-September. Instead, the EMA truncated the standard review period and provided this Scientific Advice to Quoin without the requirement for an in-person meeting.

Quoin CEO, Dr. Michael Myers, said, "We are very pleased to announce the receipt from the EMA of this comprehensive and constructive Scientific Advice for the clinical development of QRX003 in Europe. Incorporation of key elements of the EMA's guidance into our existing US development plan for QRX003 will potentially result in a more robust data set that may ultimately be used to seek regulatory approval in both the US and Europe.

"While we continue to expand our network of supply and distribution agreements for QRX003, which now spans 60 countries, following our most recent announcements for Canada and Greater China, we remain fully focused on the clinical and regulatory development of the product in our core markets of the US and Europe. Receipt of this Scientific Advice from the EMA will support our development activities in those regions."

QRX003 is currently in clinical testing in the US in a randomized, double blinded, vehicle-controlled study that is being conducted under an open U.S. Investigational New Drug (IND) Application which will assess two different doses of QRX003 topical lotion versus a vehicle lotion in Netherton patients. The test materials will be 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.

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.

In conjunction with the company's strategy of self-commercializing its portfolio of products in the U.S. and Europe, Quoin has established a global network of marketing partnerships for QRX003 in 60 countries that will help support its mission of ensuring that every patient, everywhere, can access Quoin's products, once approved.

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.

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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