Quoin Pharmaceuticals Files U.S. and International Patent Applications for Novel Topical Rapamycin Formulations to Treat Rare Disease Indications

March 4, 2025

- *Target Indications Include Microcystic Lymphatic Malformations, Venous Malformations and Angiofibromas*
- *Proprietary Invisicare Delivery Technology Designed to Optimize Local Skin Penetration*
- *Company Plans to Submit Investigational New Drug Applications and Initiate Clinical Testing This Year*

ASHBURN, Va., March 04, 2025 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the “Company” or “Quoin”), a late clinical stage, specialty pharmaceutical company focused on rare and orphan diseases, today announced it has filed U.S. and International patent applications for novel topical rapamycin (sirolimus) formulations as potential treatments for a number of rare diseases including microcystic lymphatic malformations, venous malformations and angiofibromas. The products are being developed using Quoin’s in-licensed proprietary Invisicare delivery technology. There are currently no FDA approved treatments for either microcystic lymphatic malformations or venous malformations.

The proprietary Invisicare delivery technology, which Quoin has exclusive rights to for all orphan rare skin disease applications, is designed to optimize penetration of rapamycin deep into dermis where it can be most effective clinically. The Invisicare technology is also being utilized in Quoin’s QRX003 topical lotion, which is in late-stage clinical testing as a potential treatment for Netherton Syndrome, a rare genetic disease. Quoin believes QRX003 has the potential to become the first approved treatment for this disease.

“As we continue to advance the clinical development of Quoin’s lead product, QRX003, for Netherton Syndrome, we are pleased to announce the filing of this patent and the initiation of the development of our novel formulations as potential treatments for these additional rare skin diseases. By combining the known clinical activity of rapamycin with this optimized delivery system, we believe our novel topical formulations may have the potential to effectively treat these diseases. We have seen other topical formulations of rapamycin underperform in clinical settings across a number of indications, which we believe may be as a result of suboptimal delivery of the drug at the target sites. The Invisicare technology is designed to overcome these limitations. We are now moving forward with our plans to submit IND applications for at least two of these target indications this year and to formally initiating clinical development as soon as possible ” said Dr. Michael Myers, Chief Executive Officer of Quoin.

Quoin is currently enrolling patients in three clinical trials being conducted under its open Investigational New Drug (IND) application, evaluating its QRX003 topical lotion as a potential treatment of Netherton Syndrome. To date, Quoin remains the only company actively recruiting subjects into multiple NS clinical trials that are being conducted under an open IND.

To find out more about Quoin’s clinical studies relating to Netherton Syndrome, please visit http://www.nethertonsyndromeclinicaltrials.com/.

About Microcystic Lymphatic Malformations
Microcystic lymphatic malformation is one subtype of lymphatic malformation (LM), a congenital malformation of the lymphatic vessels in soft tissues, including the skin. LM is classified into the macrocystic type, cysts larger than 2 cm with clear margins (previously known as cystic hygromas), and the microcystic type, consisting of cysts smaller than 2 cm, that appear diffuse, and grow without clear borders (previously known as lymphangioma circumscriptum). When the two types concur it is called the combined type. Microcystic lesions are commonly found inside the mouth, throat, and in the tongue, parotid gland and submandibular gland. Symptoms include deformity, and problems with breathing and feeding. The exact cause is unknown but is likely related to a malformation of the lymphatic system at six to ten weeks of gestation, when some lymphatic tissue fails to communicate with the lymphatic and venous system.[1] Lymphatic malformations occurring in 1 in 6000 to 16,000 patients. [2]

About Venous Malformations
Venous malformation (VM) is the most common type of congenital vascular malformation (CVM) with an incidence of 1 to 2 in 10,000 and a prevalence of 1%. They can cause significant morbidity, pain and discomfort to patients as they can lead to serious local and systemic complications. Although present at birth, they are not always clinically evident until later in life and tend to grow in concert with the child and without spontaneous regression. VMs are composed of ectatic venous channels found usually in the head, neck, limbs, and trunk and are thought to be sporadic in most cases, though familial inheritance patterns exist. Accurate diagnosis has been a limiting factor in VM management. An increased emphasis has been placed on creating comprehensive classification systems for diagnostic and therapeutic purposes of this chronic condition. Doppler ultrasound (US) and magnetic resonance imaging (MRI) are key imaging methods used to characterize and diagnose VMs. Treatment options include surgery, sclerotherapy, and ablative therapies. [3]

About Angiofibroma
Cutaneous angiofibroma is a benign skin tumor characterized by fibrovascular tissue and presents as a group of lesions with varied clinical appearances but consistent histological features. These benign fibrous neoplasms exhibit a proliferation of stellate and spindled cells, thin-walled blood vessels with dilated lumina in the dermis, and concentric collagen bundles. These growths typically manifest as small, firm, reddish, or flesh-colored papules, most commonly on the face (often referred to as fibrous papules or adenoma sebaceum), particularly around the nose and cheeks.[4]

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, go to: www.quoinpharma.com.

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. 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 new U.S. and International patent applications for novel topical rapamycin (sirolimus) formulations as potential treatments for a number of rare diseases including microcystic lymphatic malformations, venous malformations and angiofibromas; Invisicare delivery technology being designed to optimize penetration of rapamycin deep into dermis where it can be most effective clinically; the potential efficacy of QRX003 as a treatment for Netherton Syndrome; the progress or success of Quoin's ongoing clinical trials; combining rapamycin with the Invisicare technology delivery system having the potential to effectively treat these diseases; plans to submit IND applications for at least two of these target indications this year and initiating clinical development as soon as possible; and Quoin's products in development collectively having 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's ability to protect its assets with the new patent applications; the Company's ability to obtain regulatory approvals for the commercialization of its product candidates or to comply with ongoing regulatory requirements; the Company's ability to deliver a safe and effective treatment for Netherton Syndrome; the Company may be unable to submit applications and initiate clinical development as and when planned; and other factors discussed 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.

For further information, contact:

Quoin Pharmaceuticals Ltd.
Michael Myers, Ph.D., CEO
mmyers@quoinpharma.com

Investor Relations
PCG Advisory
Jeff Ramson
jramson@pcgadvisory.com (646) 863-6341

---

[1] Microcystic lymphatic malformation | About the Disease | GARD

[2] Genetic and Molecular Determinants of Lymphatic Malformations: Potential Targets for Therapy - PMC

[3] Venous malformations: clinical diagnosis and treatment - PMC

[4] Cutaneous Angiofibroma - StatPearls - NCBI Bookshelf