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Fortress Biotech and Subsidiary Urica Therapeutics Announce First Patients Dosed in Crystalys Therapeutics' Global Phase 3 Trials of Dotinurad for the Treatment of Gout

MIAMI, Oct. 21, 2025 (GLOBE NEWSWIRE) -- Urica Therapeutics, Inc. ("Urica" or the "Company"), a Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress") subsidiary, today announced that Crystalys Therapeutics, Inc. ("Crystalys"), in which Urica maintains an equity position, dosed first patients in its two randomized, double-blind, multicenter global Phase 3 trials, the RUBY study (NCT07089875) and the TOPAZ study (NCT07089888), evaluating dotinurad, a next-generation, once daily oral, URAT1 inhibitor with potential for best-in-class safety and efficacy for the treatment of gout.

These Phase 3 clinical studies are designed to evaluate the safety and efficacy of dotinurad compared to an active control arm (physician-determined stable dose of allopurinol) in adults with hyperuricemia associated with gout (RUBY) and adults with tophaceous gout (TOPAZ).

Lindsay A. Rosenwald, M.D., Fortress' Executive Chairman, President and Chief Executive Officer, said, "Initiating the Phase 3 clinical trials represents a significant step forward in potentially expediting the development and regulatory approval of dotinurad in the United States and Europe for millions of people suffering from gout. We look forward to seeing the Crystalys team continue to execute on the clinical development program and achieve significant value inflection in the future."

Dr. Rosenwald continued, "The initiation of these pivotal clinical trials marks another important milestone for Fortress, building on the significant momentum achieved over the past year. This includes two U.S. FDA approvals — Emrosi™ and UNLOXCYT™ (cosibelimab-ipdl) — and the acquisition of our subsidiary, Checkpoint Therapeutics, by Sun Pharma, for an aggregate upfront payment totaling ~$355 million and ~$60 million payable in a contingent value right (CVR), of which Fortress received approximately $28 million upfront, with the potential for an additional CVR payment of up to $4.8 million and a 2.5% royalty on future net sales of UNLOXCYT to Fortress. We remain focused on unlocking value across our diversified portfolio of commercial and clinical-stage assets, while pursuing strategic business development opportunities to drive future growth."

Through the sale of dotinurad to Crystalys in 2024, Urica owns a minority equity position in Crystalys and is eligible to receive a 3% royalty on future net sales of dotinurad. Urica is a majority-owned and controlled subsidiary of Fortress.

About the RUBY Study
The RUBY study (NCT07089875) is a Phase 3, randomized, double-blind, multicenter study to evaluate the safety and efficacy of dotinurad in approximately 500 patients with hyperuricemia associated with gout. Study participants will be given dotinurad orally once a day for up to 64 weeks.

About the TOPAZ Study
The TOPAZ study (NCT07089888) is a Phase 3, randomized, double-blind, multicenter study to evaluate the safety and efficacy of dotinurad in approximately 250 patients with tophaceous gout. Study participants will be given dotinurad orally once a day for up to 76 weeks.

About Gout
Gout is the most common form of inflammatory arthritis. It is a condition that is very debilitating for patients and characterized by sudden, severe attacks of pain, swelling, redness and tenderness in one or more joints. This disease arises from excess uric acid in the body, known as 'hyperuricemia,' which causes buildup of uric acid crystals and inflammation, leading to tophaceous gout in people with chronic or undertreated disease. Despite available therapies that aim to reduce uric acid levels below the target 6 mg/dL, a major treatment gap remains between first-line xanthine oxidase inhibitors (XOIs) and last-line uricase therapy. Currently, no suitable second-line options exist in the U.S. or E.U., leaving a critical unmet need for patients who fail to respond to first-line treatments.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty income. The company has eight marketed prescription pharmaceutical products and multiple programs in development at Fortress, at its majority-owned and majority-controlled partners and subsidiaries and at partners and subsidiaries it founded and in which it holds significant minority ownership positions. Fortress' portfolio is being commercialized and developed for various therapeutic areas including oncology, dermatology, and rare diseases. Fortress' model is focused on leveraging its significant biopharmaceutical industry expertise and network to further expand and advance the company's portfolio of product opportunities. Fortress has established partnerships with some of the world's leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including AstraZeneca, City of Hope, Nationwide Children's Hospital, Columbia University, Dana Farber Cancer Center and Sentynl Therapeutics. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements
Statements in this press release that are not descriptions of historical facts are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other

comparable terminology are generally intended to identify forward-looking statements. These forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include risks relating to: our growth strategy, financing and strategic agreements and relationships; our need for substantial additional funds and uncertainties relating to financings; uncertainty related to the timing and amounts expected to be realized from future milestone, contingent value right, royalty or similar future revenue streams, if at all; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of products under development; the results of research and development activities; uncertainties relating to preclinical and clinical testing; our ability to obtain regulatory approval for products under development; our ability to successfully commercialize products for which we receive regulatory approval or receive royalties or other distributions from third parties; our ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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