Urica Therapeutics Announces Topline Data from the Phase 1 Clinical Trial Evaluating Dotinurad in Healthy Volunteers in the United States

Data from Phase 1 clinical trial in healthy volunteers show comparable pharmacokinetic, pharmacodynamic and safety profile between U.S. and Japanese healthy subjects

Initiating Phase 1b clinical trial in gout patients in the U.S. and expect to begin pivotal clinical trials in 2024

MIAMI, FL – June 29, 2023 – Urica Therapeutics, Inc. ("Urica" or the "Company"), a Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress") subsidiary company focused on the development and commercialization of pharmaceutical products to treat gout and other conditions associated with hyperuricemia, today announced topline data from the Phase 1 clinical trial evaluating dotinurad in healthy volunteers in the United States ("U.S.").

The randomized, placebo-controlled Phase 1 clinical trial evaluated the safety, tolerability, pharmacokinetics ("PK") and pharmacodynamics ("PD") of multiple doses of dotinurad in U.S. healthy subjects. Dotinurad was shown to be safe and well tolerated with no severe adverse events observed at any dose level. No drug-related adverse events were observed at doses of 1mg, 2mg, and 4mg, which are all approved and marketed doses in Japan. The PK profile in U.S. subjects was comparable to that of Japanese subjects with all tested doses for time to peak serum drug concentration, peak serum drug concentration and drug serum half-life.

Pharmacodynamic data from the Phase 1 trial were also comparable to the Japanese data where over 1,000 subjects were exposed to dotinurad, including rapid and significant serum uric acid ("sUA") reduction. Up to 90% of sUA reduction was observed within four days since the start of treatment. Increase of urine uric acid excretion was also observed following dotinurad treatment, which confirms its mechanism of action.

Jay D. Kranzler, M.D., Ph.D., Urica's Chairman and Chief Executive Officer, said, "We are encouraged that the data from our Phase 1 clinical trial in U.S. healthy volunteers show comparable pharmacokinetic, pharmacodynamic and safety profiles between U.S. and Japanese healthy subjects. Dotinurad has been marketed in Japan since 2020 and we are poised to leverage the extensive Japanese clinical and safety data to accelerate U.S. development and bring dotinurad to U.S. gout patients with continued unmet need to further lower serum uric acid levels and potentially reduce gout flares and tophi formation. We are initiating a Phase 1b clinical trial in gout patients in the U.S. this summer and expect to begin pivotal clinical trials in 2024."

About Dotinurad

Urica Therapeutics is developing dotinurad, a novel urate transporter (URAT1) inhibitor for gout with potential to address other conditions associated with hyperuricemia such as chronic kidney disease. Dotinurad can lower blood uric acid levels by selectively inhibiting URAT1 and uric acid reabsorption in the kidneys. Dotinurad (URECE® Tablets in Japan) was approved in Japan in 2020 as a once-daily oral therapy for hyperuricemia with or without gout. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in three Phase 3 clinical trials. Its efficacy demonstrated non-inferiority to Febuxostat, which has a black box warning in the U.S. for increased risk of cardiovascular death, while dotinurad was well-tolerated and safe with low risk for drug

interactions.[1,2,3] Over 1,000 patients have been treated with dotinurad in clinical trials. Eisai is currently running a Phase 3 trial with dotinurad in China.

About Gout

Gout is a serious, progressive, painful and debilitating inflammatory arthritis caused by deposits of uric acid crystal in and around the connective tissue of joints, tendons and bones due to hyperuricemia. There are nearly 20 million diagnosed gout patients in the U.S., Europe and Canada as of 2021,[4,5,6] and it is estimated that two to three million U.S. patients have inadequately controlled serum uric acid levels with existing urate-lowering therapies.[7,8]

About Urica Therapeutics

Urica Therapeutics, Inc. ("Urica") is a clinical-stage biopharmaceutical company that focuses on the development and commercialization of pharmaceutical products to treat gout and other conditions associated with hyperuricemia. Urica acquired the rights to develop and commercialize dotinurad, a potentially best-in-class URAT1 inhibitor, in the United States, United Kingdom, European Union, Canada, Middle East and North Africa (MENA) and Turkey from Fuji Yakuhin. Dotinurad has been approved to treat gout and hyperuricemia in Japan and is currently in a Phase 1 clinical trial in the United States. Urica was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, please visit www.uricatherapeutics.com.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has eight marketed prescription pharmaceutical products and over 30 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. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand 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 plc, City of Hope, Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentynl Therapeutics, Inc. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain "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. As used below and throughout this press release, the words "we", "us" and "our" may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs, ability to generate shareholder value, ability of our products to receive necessary approvals, including FDA, ability of our products and therapies to help patients and any other statements that are not historical facts. 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; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials, including disruptions that may result from hostilities in Europe; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain

additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; 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.

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