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Urica Therapeutics Expands Exclusive License Agreement with Fuji Yakuhin Co. Ltd. to Develop Dotinurad in Additional Territories Including Turkey and the Middle East and North Africa

MIAMI, Dec. 14, 2022 (GLOBE NEWSWIRE) -- Urica Therapeutics, Inc. ("Urica" or the "Company") (formerly known as UR-1 Therapeutics, Inc.), 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 that the Company has expanded its exclusive license agreement with Fuji Yakuhin Co. Ltd. ("Fuji") for the development of dotinurad to include the Middle East and North Africa ("MENA") and Turkey territories. The agreement builds upon the exclusive license agreement between Urica and Fuji previously announced in May of 2021 to develop dotinurad in the United States ("US"), United Kingdom, European Union and Canada.

Under the terms of the agreement, the Company acquired exclusive development and marketing rights in MENA and Turkey from Fuji. Fuji is eligible to receive upfront and royalty payments from the Company.

Jay D. Kranzler, M.D., Ph.D., Urica's Chairman and Chief Executive Officer, said, "We continue to have a very collaborative relationship with Fuji and we are pleased to expand the license agreement to include additional territories. MENA and Turkey have a combined population of over 550 million, with limited therapeutic options for the treatment of gout. We expect to leverage the substantial preclinical and clinical data generated to-date and work with local regulatory authorities across the territory to expedite the approval process for dotinurad within these territories in the near-term. We hope to advance these discussions quickly and file the relevant marketing applications as soon as possible."

Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor that is currently in a Urica-sponsored Phase 1 clinical trial in the US and being developed for the treatment of gout. Dotinurad (URECE® tablet in Japan) was approved and launched in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 1,000 Japanese patients treated for up to 58 weeks in Fuji's clinical program. Urica expects to leverage data from the three completed Phase 3 clinical trials in more than 500 Japanese patients in furthering the development and marketing of dotinurad

in the licensed territories.

About Dotinurad
In May 2021, Fortress announced an exclusive license agreement between its subsidiary, Urica Therapeutics, Inc. (formerly UR-1 Therapeutics, Inc.), and Fuji Yakuhin Co. Ltd. to develop dotinurad in North America and Europe. In November 2022, Urica licensed rights to dotinurad from Fuji for additional territories including MENA and Turkey. Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor for gout and possibly other hyperuricemic indications including chronic kidney disease and heart failure. It can lower blood uric acid levels by selectively inhibiting URAT1 and uric acid reabsorption in the kidneys. Dotinurad (URECE® tablet) was approved in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials. Its efficacy demonstrated non-inferiority to Febuxostat, which has a black box warning in the US for increased risk of cardiovascular death, and dotinurad was well-tolerated with apparent low safety risk and drug interaction.[1,2,3] Over 1,000 Japanese patients have been treated safely with dotinurad in clinical trials. Also, dotinurad is currently in Phase 3 clinical trials in China.

About Gout
Gout is a serious, progressive and debilitating inflammatory arthritis caused by deposits of uric acid crystal in and around the connective tissue of joints, tendons and the kidneys. There are nearly 20 million diagnosed patients with gout in the US, Europe and Canada as of 2021,[4,5,6] and it is estimated that two to three million US patients are unsatisfied with their urate-lowering therapy and their serum uric acid levels remain inadequately controlled.[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).

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 Research 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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