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Urica Therapeutics Appoints Seasoned Biotech Executive Jay D. Kranzler, M.D., Ph.D., as Chairman and Chief Executive Officer

Company also strengthens Board of Directors with addition of Stanford Professor Vibeke Strand, M.D., MACR, FACP

MIAMI, Oct. 03, 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 chronic kidney disease, today announced the appointments of Jay D. Kranzler, M.D., Ph.D., as Chairman and Chief Executive Officer and Vibeke Strand, M.D., MACR, FACP, Adjunct Clinical Professor, Division of Immunology/Rheumatology, Stanford University, to its Board of Directors.

Lindsay A. Rosenwald, M.D., Fortress' Chairman and Chief Executive Officer and Board Member of Urica, said, "We are pleased to welcome Jay as Chairman and Chief Executive Officer of Urica and Vibeke to the Board. Jay has been an important advisor to Fortress over the past few years. His extensive experience across all aspects of drug development will add significant value as Urica advances dotinurad for the treatment of gout and possibly other hyperuricemic indications including chronic kidney disease and heart failure. We are equally thrilled to add Vibeke to the Board given her vast knowledge in rheumatology. Her clinical research and regulatory strategy expertise will be invaluable as dotinurad continues to progress through clinical development. We look forward to the anticipated announcement of topline data from our Phase 1 trial in the second half of 2022."

Dr. Kranzler has been a Founder, Chief Executive Officer, Board Member and Advisor to leading life science companies for over 30 years. Dr. Kranzler joins Urica to guide and expedite the development of its lead product candidate, dotinurad, a potential best-in-class urate transporter (URAT1) inhibitor that is currently in Phase 1 clinical trials and positioned for the treatment of gout in the United States. Dotinurad (URECE® tablet in Japan) 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.

“I am gratified to be extending my engagement with Fortress to lead its newest subsidiary and manage development of such a promising technology. With an experienced team, we are well positioned to replicate the exceptional clinical efficacy and safety profile that dotinurad has already demonstrated in Japanese trials and clinical use,” said Dr. Kranzler. “With success, we hope to expand treatment options for the nearly 10 million patients suffering from gout in the Unites States, in addition to the 10 million patients in our other licensed territories, and possibly explore efficacy in other hyperuricemic indications, while creating value for shareholders.”

Dr. Kranzler has served in operational and consulting capacities for multiple large pharmaceutical companies, small biotechnology companies, investment banks and investors. He has developed drugs, medical devices and diagnostics, and is an inventor on multiple key patents. Dr. Kranzler serves as an Adjunct Professor at New York University Stern School of Business and at the New York University Langone School of Medicine. Previously, Dr. Kranzler was Vice President and Global Head of External R&D Innovation and Worldwide R&D Strategic Investments at Pfizer. His entrepreneurial career includes his role as Founder and Chief Executive Officer of Cypress Bioscience, where he was credited for the development of Savella™ (milnacipran) for the treatment of fibromyalgia. He also served as Chief Executive Officer of Cytel Corporation and was a Founder of Perception Neuroscience, which was acquired by ATAI Life Sciences. Dr. Kranzler started his career at McKinsey & Company where he was a key member of the team that established the firm’s pharmaceutical practice. He is currently a Board Member of Avenue Therapeutics (Nasdaq: ATXI), Baergic Bio, Pastorus, Navitas and ImmunoBrain Checkpoint. Dr. Kranzler graduated from Yale University School of Medicine with M.D. and Ph.D. degrees with a focus in psychopharmacology.

Dr. Vibeke Strand has served as an adjunct clinical professor in the Division of Immunology and Rheumatology at Stanford University School of Medicine since 1993. For several decades, she has led a consulting practice offering clinical research and regulatory strategy expertise to pharmaceutical and biotech with a focus on translating basic research into rational design of randomized controlled trials, evaluation of their results and defense of novel products in rheumatology to the U.S. Food and Drug Administration and European Medicines Agency. She has participated in the successful development of DMARDs, biologics and JAK inhibitors in an array of rheumatoid conditions and biosimilars. Dr. Strand has authored more than 500 publications, is a Fellow of the American College of Physicians, Master of the American College of Rheumatology and member of the Cosmos Club. She received her B.A. from Swarthmore College and her M.D. from University of California San Francisco School of Medicine.

“I look forward to working with Urica and my fellow board members as we advance the development of dotinurad, an innovative therapy that holds the potential to address the needs of multiple patient populations requiring more effective treatment,” said Dr. Strand.

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. 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 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 U.S. 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 chronic kidney disease. Urica acquired the rights to develop and commercialize Dotinurad, a potentially best-in-class URAT1 inhibitor, in the United States, United Kingdom, European Union and Canada 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 nine 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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References

1. Clin Exp Nephrol. 2020 Mar;24(Suppl 1):71-79.
2. Clin Exp Nephrol. 2020 Mar;24(Suppl 1):62-70.
3. Clin Exp Nephrol. 2020 Mar;24(Suppl 1):80-91.
4. Rheumatology (Oxford). 2019 Dec 1;58(12):2177-2180.
5. Semin Arthritis Rheum. 2017 Feb; 46(4): 451–456.
6. GlobalData. Gouty Arthritis (Gout): Competitive Landscape in 2021.
7. Arthritis Rheumatol. 2019 Jun; 71(6): 991–999.
8. J Rheumatol. 2016 Oct;43(10):1897-1903.

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