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Fortress Biotech Announces First Patient Dosed in Phase 1 Clinical Trial Evaluating Dotinurad for the Treatment of Gout in the United States

Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor in clinical development at Fortress' subsidiary company, UR-1 Therapeutics

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

MIAMI, May 31, 2022 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on efficiently acquiring, developing and commercializing or monetizing promising therapeutic products and product candidates, today announced that its subsidiary company, UR-1 Therapeutics, Inc. ("UR-1"), dosed the first patient in a Phase 1 clinical trial evaluating Dotinurad for the treatment of gout in the United States.

The principal objective of this Phase 1 clinical trial is to study the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses of Dotinurad in Western subjects. Subjects will be randomized into a placebo-controlled crossover clinical trial design to evaluate a wide range of Dotinurad doses.

Lindsay A. Rosenwald, M.D., Fortress' Chairman and Chief Executive Officer, said, "The successful dosing of the first patient in this Phase 1 clinical trial to evaluate Dotinurad for the treatment of gout is an important milestone for UR-1 and Fortress and we expect to announce topline data in the second half of 2022. Our goal is to leverage the exceptional clinical efficacy and safety profile of Dotinurad to create a superior treatment option for the nearly 10 million patients suffering from gout in the U.S. If approved in the U.S., Dotinurad has the potential to be the most potent oral therapy for lowering serum uric acid levels with an excellent safety and efficacy profile vis-à-vis earlier generations of URAT inhibitors. There is also further potential to evaluate this product candidate in other diseases, including chronic kidney disease and heart failure."

About Dotinurad
In May 2021, Fortress announced an exclusive license agreement between its subsidiary, UR-1, 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 was non-inferior to Febuxostat, which has a black box warning for increased risk of cardiovascular death, and was well-tolerated with low safety risk and drug interaction.[1,2,3] Over 1,000 Japanese patients have been treated safely with Dotinurad.

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 UR-1 Therapeutics
UR-1 Therapeutics, Inc. (“UR-1”) is a clinical-stage biopharmaceutical company that focuses on the development and commercialization of pharmaceutical products to treat gout and chronic kidney disease. UR-1 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. UR-1 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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