May 10, 2021

Fortress Biotech Announces Exclusive License Agreement With Fuji Yakuhin to Develop Dotinurad in North America and Europe

Agreement signed with Fuji Yakuhin to develop Dotinurad, a potential best-in-class urate transporter (URAT1) inhibitor for gout and potentially other hyperuricemic indications including chronic kidney disease and heart failure

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

NEW YORK, May 10, 2021 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress" or the "Company"), an innovative biopharmaceutical company, today announced that it has entered into an exclusive licensing agreement with Fuji Yakuhin Co. Ltd. ("Fuji") to develop Dotinurad in the United States, United Kingdom, European Union and Canada. Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor that was approved for the treatment of gout and hyperuricemia in Japan in 2020. Hyperuricemia has also been implicated in the progression of chronic kidney disease and heart failure, and Dotinurad may potentially play a critical role in helping treat these conditions.

Under the terms of the agreement, the Company acquired exclusive development and marketing rights in North America and Europe from Fuji. Fuji is eligible to receive upfront, development and commercial milestone and royalty payments from the Company. Fortress expects to leverage data from three completed Phase 3 clinical trials in more than 500 Japanese patients to develop and market Dotinurad.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We are excited to work with Fuji to develop Dotinurad for the treatment of gout and possibly other indications, and look forward to the opportunity to deliver potential best-in-class medicines to patients in need. With nearly 20 million gout patients in our territory, we believe there is a sizeable market for this opportunity."

About Dotinurad

Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor which can lower blood uric acid levels by selectively inhibiting URAT1 and uric acid reabsorption in the kidney. Three Japanese Phase 3 trials were completed and more than 500 patients with gout or hyperuricemia were dosed with Dotinurad for up to 58 weeks. Its efficacy was non-inferior to Febuxostat, which has a black box warning for increased risk of cardiovascular death, and it was well-tolerated with low safety risk and drug interaction.[1,2,3] Dotinurad was approved in Japan in 2020.

About Gout

Gout is a serious, progressive and debilitating inflammatory arthritis caused by painful, needle-like uric acid crystal deposits around the connective tissue of the joints and in the kidneys. There are nearly 20 million diagnosed gout patients in the US, Europe and Canada in 2021,[4,5,6] and it is estimated that more than 2 million US patients on urate-lowering therapy may remain inadequately controlled.[7,8]

About Fuji Yakuhin Co. Ltd.

Fuji is a pharmaceutical company with integrated manufacturing and sales systems consisting of ethical drug sales, placement drug sales, drugstore business, and the pharmaceutical manufacturing business that supports them. Regarding ethical drugs, Fuji has invented and developed two drugs with different mechanisms of action, Topiroxostat and Dotinurad, for gout and hyperuricemia.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was ranked in Deloitte’s 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has seven marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners 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 Alexion Pharmaceuticals, Inc., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children’s Research Hospital and Nationwide Children’s Hospital. 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 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; 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. 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.

Company Contacts:
Jaclyn Jaffe and Bill Begien
Fortress Biotech, Inc.
(781) 652-4500
ir@fortressbiotech.com

Investor Relations Contact:
Daniel Ferry
LifeSci Advisors, LLC
(617) 430-7576
daniel@lifesciadvisors.com

Media Relations Contact:
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

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.

Source: Fortress Biotech, Inc.