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Fortress Biotech Announces an Exclusive License Agreement for FB-607 for the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D)

A majority-owned and controlled subsidiary of Fortress entered into an agreement with Cedars-Sinai to license FB-607, which is currently being evaluated in an ongoing Phase 2 study for IBS-D

MIAMI, Nov. 10, 2026 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress" or the "Company"), an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty income, today announced that a majority-owned and controlled subsidiary of Fortress has entered into an exclusive licensing agreement with Cedars-Sinai to develop FB-607, a novel approach to potentially address the symptoms of irritable bowel syndrome with diarrhea ("IBS-D").

FB-607 is a proprietary enteric-coated, pH-sensitive coformulation of rifaximin and N-acetylcysteine ("NAC") and is designed to target the intestinal mucus layer and biofilms to improve outcomes for patients, including those who do not fully respond to rifaximin alone. The license agreement also enables the development of FB-607 for other indications, including hepatic encephalopathy.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We are excited to develop FB-607 for the treatment of IBS-D and potentially provide a therapeutic option for patients that continue to have significant unmet need. IBS-D alone affects an estimated 4.5 million U.S. adults, and we believe there is a sizeable market for this opportunity, as these patients struggle with chronic symptoms and frequent relapses that can make their day-to-day life challenging."

FB-607 is designed to potentially enhance clinical symptom relief and expand on the efficacy of monotherapy rifaximin, including in IBS-D patients with elevated hydrogen sulfide-producing bacteria, which have been associated with IBS-D. In a proof-of-concept study, the combination of rifaximin and NAC showed efficacy across several IBS-D endpoints including stool consistency, stool frequency, abdominal pain and bloating, as well as on breath testing. Additionally, in a toxin-induced rat model of IBS-D, rifaximin plus NAC normalized measured

cytokine levels and reduced elevated levels of *E. coli* and *Desulfovibrio*.

FB-607 is currently being evaluated in a multi-center, randomized, double-blind, placebo-controlled Phase 2 study (NCT06727422) to assess the safety, efficacy and pharmacokinetics in the treatment of patients with IBS-D. The study is evaluating two dose levels of FB-607 against placebo, with 14 days of treatment and follow-up through week 14. The endpoints will assess improvement in abdominal pain and stool consistency during the four weeks after treatment and additional endpoints will assess stool frequency and overall response.

About FB-607
FB-607 is a proprietary enteric-coated, pH-sensitive coformulation of rifaximin and NAC. This novel formulation is designed to use NAC's mucolytic properties to improve rifaximin's access to bacteria within the intestinal mucus layer. While rifaximin is commonly used to treat IBS-D, symptom relapse is common in these patients and some patients may require repeat treatment as limited solubility and penetration into the intestinal mucus may reduce access to the bacteria within that layer for rifaximin alone.

About Irritable Bowel Syndrome with Diarrhea (IBS-D)
Irritable bowel syndrome with diarrhea (IBS-D) is a chronic gastrointestinal disorder characterized by recurrent abdominal pain associated with frequent, loose or watery stools. An estimated 4.5 million adults in the United States are affected by IBS-D with a high rate of recurrence (derived from Rome IV IBS prevalence of 6.1% and an IBS-D share of 28.1%; Almario et al., Gastroenterology 2023). There are limited treatment options that adequately address both pain and bowel symptoms.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty income. The company has a portfolio of multiple marketed prescription pharmaceutical products and 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. Fortress' portfolio is being commercialized and developed for various therapeutic areas including oncology, dermatology, and rare diseases. Fortress' model is focused on leveraging its significant biopharmaceutical industry expertise and network to further expand and advance 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, City of Hope, Nationwide Children's Hospital, Columbia University, Dana-Farber Cancer Institute and Sentynl Therapeutics. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements
Statements in this press release that are not descriptions of historical facts are "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. The words "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology are generally intended to identify forward-looking statements.

These 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, financing and strategic agreements and relationships; our need for substantial additional funds and uncertainties relating to financings; uncertainty related to the timing and amounts expected to be realized from future milestone, contingent value right, royalty or similar future revenue streams, if at all; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of product candidates under development; the results of research and development activities; uncertainties relating to preclinical and clinical testing; our ability to obtain regulatory approval for products under development; our ability to successfully commercialize products for which we receive regulatory approval or receive royalties or other distributions from third parties; our ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates; 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.

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