March 30, 2023

Fortress Biotech Reports Record 2022 Financial Results and Recent Corporate Highlights

Fortress expects to file a total of three new drug applications in 2023

Record consolidated net revenue of $75.7 million for full-year 2022

FDA accepted for filing the Biologics License Application for cosibelimab in patients with metastatic or locally advanced cutaneous squamous cell carcinoma; PDUFA goal date of January 3, 2024

Rolling NDA submission for CUTX-101 for the treatment of Menkes disease is expected to be completed in 2023

Topline results from the Phase 3 clinical program of DFD-29 to treat papulopustular rosacea expected in the first half of 2023; NDA submission expected in the second half of 2023

MIAMI, March 30, 2023 (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 financial results and recent corporate highlights for the full-year ended December 31, 2022.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "In 2022, we continued to advance our extensive portfolio of multiple clinical-stage programs, several of which are late-stage and pivotal. We also generated record consolidated net revenues of $75.7 million, much of which came from the sales of our eight marketed dermatology products. Our growth continues in 2023, as the U.S. Food and Drug Administration ("FDA") accepted for filing the Biologics License Application ("BLA") for cosibelimab earlier this month and we expect to have two New Drug Applications ("NDA") submitted to the FDA for CUTX-101 for Menkes disease and DFD-29 for rosacea this year. We also anticipate multiple clinical trial initiations, data readouts and regulatory filings across our other development-stage programs. Fortress has also established 25 acquisition companies with expert opinion leaders in multiple therapeutic areas over the past year. These expert opinion leaders will continue to work with our business development team to identify, evaluate and acquire potential best-in-class therapies to form the bases of these

new companies. We are focused on licensing assets with proof-of-concept clinical data available in areas with high unmet medical need, which potentially lowers the development uncertainty and associated risk. Our pipeline and structure allow for flexibility and diversified exposure with many product candidates and potentially long-term revenue streams. We expect to achieve multiple milestones this year, and we are confident in our long-term growth prospects as we continue to scale."

2022 and Recent Corporate Highlights[1]:

Marketed Dermatology Products and Product Candidates

- Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical"), our partner company, currently markets eight prescription dermatology products.
- Journey Medical's total net revenues were $73.7 million for the full-year 2022, which includes $71.0 million from their commercial portfolio, compared to full-year 2021 total net revenues of $63.1 million, representing growth of 17%.
- In January 2023, Journey Medical completed enrollment in its DFD-29 Phase 3 clinical program for the treatment of papulopustular rosacea. Topline data from the two DFD-29 Phase 3 clinical studies are expected to be announced in the first half of 2023. Journey Medical plans to submit the NDA for DFD-29 in the second half of 2023 and an FDA approval decision is anticipated in the second half of 2024.
    - In the Phase 2 clinical trials, DFD-29 (40mg) demonstrated nearly double the efficacy when compared against Oraycea® (European equivalent of Oracea®) on both co-primary endpoints. For the first co-primary endpoint, Investigator's Global Assessment ("IGA") treatment success, Oraycea had a 33.33% IGA treatment success rate, while DFD-29 achieved a 66.04% IGA treatment success rate. For the second co-primary endpoint, the change in total inflammatory lesion count, Oraycea had a 10.5 reduction in inflammatory lesions, while DFD-29 achieved a 19.2 reduction in inflammatory lesions.

Cosibelimab (Anti PD-L1 antibody)

- Our partner company, Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) ("Checkpoint"), submitted a BLA to the FDA for cosibelimab, its investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation, in January 2023. In March 2023, the FDA accepted for filing the BLA for cosibelimab and set a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024. In its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee meeting to discuss the application is not currently planned. According to U.S. prescription claims data, in 2021, approximately 11,000 cSCC patients were treated with systemic therapies. As PD-1 inhibitors comprised less than half of patient prescriptions, cSCC remains a disease with a need for more effective and tolerable treatment options, particularly for the significant number of cSCC patients with immunosuppressive conditions or autoimmune diseases. With its unique mechanism of action and compelling safety profile, we believe cosibelimab, if approved, would be uniquely positioned to provide an important new treatment option for cSCC patients that are currently underserved by available therapies.

- In January 2022, Checkpoint announced positive topline results from its registration-enabling clinical trial evaluating the safety and efficacy of the anti-PD-L1 antibody, cosibelimab, administered as a fixed dose of 800 mg every two weeks in patients with metastatic cSCC. The study met its primary endpoint, with cosibelimab demonstrating a confirmed objective response rate ("ORR") of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the metastatic cSCC cohort using Response Evaluation Criteria in Solid Tumors version 1.1 criteria.
- In June 2022, we announced that the topline results of Checkpoint's pivotal trial of cosibelimab in metastatic cSCC were presented at the 2022 American Society of Clinical Oncology Annual Meeting. Data highlights included confirmed ORR by independent central review in the modified intent-to-treat population of 48.7% (95% CI, 37.0-60.4) and 13.2% of patients achieved a complete response in target lesions. Cosibelimab was generally well tolerated with no unexpected safety signals.
- Also in June 2022, we announced positive interim results from Checkpoint's pivotal trial of cosibelimab in locally advanced cSCC. As of the March 2022 data cutoff, the confirmed ORR by independent central review in 31 patients was 54.8% (95% CI: 36.0, 72.7).
- In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls ("CMC") and clinical/non-clinical). Based upon favorable interactions with the agency, the January 2023 BLA submission included both the metastatic and locally advanced cSCC indications.
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In May 2022, our subsidiary company Urica Therapeutics, Inc. ("Urica'") initiated a Phase 1 clinical trial to evaluate dotinurad in healthy volunteers in the United States. Dotinurad is in development for the treatment of gout. We anticipate topline data from the Phase 1 trial in the first half of 2023 and expect to be in pivotal clinical trials in early 2024.
- 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. The clinical program supporting approval included over 1,000 patients.
- In October 2022, Urica strengthened its leadership team by appointing 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 Urica's Board of Directors.
- In December 2022, Urica expanded its exclusive license agreement with Fuji Yakuhin Co. Ltd. ("Fuji") for the development of dotinurad to include the Middle East and North Africa and Turkey territories. The agreement builds upon the exclusive license agreement between Urica and Fuji previously announced in May 2021 to develop dotinurad in the United States, United Kingdom, European Union and Canada.
- Dotinurad was sourced by Fortress and is currently in development at Urica.

MB-106 (CD20-targeted CAR T Cell Therapy)

- In June 2022, we announced that the FDA granted Orphan Drug Designation to MB-106 for the treatment of Waldenstrom macroglobulinemia ("WM"), a rare type of B-cell

non-Hodgkin lymphoma (“B-NHL”). Our partner company Mustang Bio, Inc. (Nasdaq: MBIO) (“Mustang Bio”), which is developing MB-106, plans to treat additional WM patients in the Mustang Bio-sponsored Phase 1 portion of its multicenter trial to potentially support an accelerated Phase 2 strategy for WM.

- In October 2022, we announced that the first patient was treated in Mustang Bio’s multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106, for the treatment of relapsed or refractory B-NHL and chronic lymphocytic leukemia (“CLL”). In 2023, Mustang Bio anticipates dose escalation and reporting response data at major medical meetings.
- Additionally, in October 2022, we shared interim data from 28 patients treated in the ongoing Phase 1/2 investigator-sponsored clinical trial at Fred Hutch.
    - An ORR of 96% and complete response (“CR”) rate of 75% were observed in a wide range of hematologic malignancies including follicular lymphoma, CLL, diffuse large B-cell lymphoma and WM. Twelve patients have experienced CR for more than 12 months (10 ongoing), including four patients with CR for more than two years and the longest patient with CR at 33 months. Six patients with initial partial response at 28 days post-treatment improved to CR and all remain in ongoing CR. All three patients previously treated with CD19 CAR T cell therapy responded to treatment with MB-106.
    - A favorable safety profile for MB-106 as an outpatient therapy remains, with no cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome ≥ Grade 3 reported to date on this trial.
- MB-106 continues to generate compelling safety and efficacy data, and the product profile of this autologous CD20-directed CAR T is favorable compared to the approved autologous CD19-directed CAR Ts, which are generating an annualized run rate of $3 billion in net sales, based on reported sales in the third quarter of 2022.
- MB-106 was sourced by Fortress and is currently in development at Mustang Bio.

CUTX-101 (Copper Histidinate for Menkes disease)

- Our subsidiary, Cyprium Therapeutics, Inc. (“Cyprium) has completed two pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). In the studies, a 79% reduction in risk of death was observed in patients treated within four weeks of birth compared with an untreated historical control cohort of patients, and median overall survival (OS) was 177.1 for CUTX-101 compared to 16.1 months historical control, with a hazard ratio (HR) of (95% CI) = 0.208 (0.094, 0.463) $p<0.0001$. A 75% reduction in the risk of death was also observed in patients treated after four weeks of birth compared with untreated historical control subjects and median OS was 62.4 and 17.6 months, respectively; HR (95% CI) = 0.253 (0.119, 0.537); $p<0.0001$.
- In 2021, Cyprium signed a Development and Asset Purchase Agreement with Sentynl Therapeutics, Inc. (“Sentynl”), a wholly owned subsidiary of Zydus Lifesciences Ltd., for CUTX-101 to treat Menkes disease. Cyprium is responsible for the development of CUTX-101 and Sentynl will be responsible for commercialization of CUTX-101, as well as progressing newborn screening activities.
- In December 2021, Cyprium initiated the rolling submission of an NDA to the FDA for CUTX-101, which is ongoing and expected to be completed in 2023.
- In March 2022, Cyprium announced positive data on CUTX-101 were presented as a “Top-Rated Abstract” and poster at the 2022 American College of Medical Genetics

and Genomics Clinical Genetics Meeting. The abstract can be viewed here.
- Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.
- CUTX-101 was sourced by Fortress and is currently in development at Cyprium.

CAEL-101 (Light Chain Fibril-reactive Monoclonal Antibody for AL Amyloidosis)

- On October 5, 2021, AstraZeneca plc ("AstraZeneca") acquired Caelum Biosciences, Inc. ("Caelum") for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress, net of Fortress' $6.4 million portion of the $15 million, 24-month escrow holdback amount and other miscellaneous transaction expenses. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all potential milestone payments, which together with the upfront payment, would total up to approximately $212 million.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).[2]
- AstraZeneca has estimated that it expects the FDA to accept its BLA submission for review during calendar year 2024.
- CAEL-101 (anselamimab) was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

Triplex (Cytomegalovirus ("CMV") vaccine)

- We expect that the Phase 2 clinical trial of Triplex for adults co-infected with HIV and CMV will complete enrollment in the second half of 2023 with topline data anticipated in 2024. The study aims to show potential reduction in intensity of highly active antiretroviral therapy treatment (HAART) which is used in up to 1.7 million treated HIV patients.
- In August 2022, we announced that Triplex received a grant from the National Institute of Allergy and Infectious Diseases that could provide over $20 million in non-dilutive funding. This will fund a 420 patient multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation and is expected to begin enrollment this year. The company believes this data set could ultimately be used to support approval of Triplex in this setting.
- Triplex is currently the subject of four clinical trials including: adults undergoing stem cell transplant; adults co-infected with CMV and HIV; and in combination with a CAR T cell therapy for adults with NHL.
- Triplex was sourced by Fortress and is currently in development at our subsidiary company, Helocyte, Inc.

AJ201

- In March 2023, we announced that our partner company, Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue"), entered into an exclusive license agreement with AnnJi Pharmaceutical Co., Ltd. for intellectual property related to AJ201, a first-in-class clinical asset currently in a Phase 1b/2a study in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease. Kennedy's Disease is a debilitating rare genetic neuromuscular disease primarily affecting men.