ENB Therapeutics Announces Orphan Drug Designation Granted by FDA for ENB-003 for the Treatment of Pancreatic Cancer

Tuesday, May 24, 2022 8:00 AM

ENB-003 is a first in class small molecule therapeutic selectively targeting the ETB receptor - a novel immune checkpoint

NEW YORK, NY / ACCESSWIRE / May 24, 2022 / ENB Therapeutics, Inc., a clinical stage biotechnology company pioneering a new and differentiated class of therapeutics targeting the endothelin B receptor (ETBR) inhibitor, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for its lead product candidate, ENB-003, for the treatment of pancreatic cancer. This is the second Orphan Drug Designation award for ENB-003, which has also been granted Orphan Drug Designation for melanoma.

"Immune checkpoint therapies have significantly improved the survival of patients with certain cancers; however, there remain a significant percentage of patients that exhibit no response to these therapies," said Sumayah Jamal, MD-PhD, President, Co-founder and CSO of ENB Therapeutics. "This is especially true for pancreatic cancer patients, where only about 3% of tumors are responsive to the leading anti-PD-1 therapy KEYTRUDA® (pembrolizumab). We believe that combining our ETRB inhibitor, ENB-003, with pembrolizumab, has the potential to overcome this resistance, and provide much needed additional treatment options for patients in a broader range of pancreatic tumors."

"Our Phase 1/2 trial will exclude patients with pancreatic tumors that have the molecular alterations known as high microsatellite instability (MSI-H) or defective DNA mismatch repair (dMMR). Thus, we are targeting truly pembrolizumab resistant patients to evaluate the potential for a ENB-003 + pembrolizumab combination as a potential treatment for this population with clear and significant unmet need," said Dr. Jamal.

FDA Orphan Drug Designation is granted to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the United States. This designation acts as a stimulus for the development of drugs for rare

diseases through several incentives, including assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees and the potential for seven years of post-approval marketing exclusivity after FDA approval.

About ENB-003

ENB-003 is a selective endothelin B receptor (ETBR) inhibitor that, in preclinical studies, enhanced the efficacy of immunotherapies such as anti-PD-1, anti-CTLA-4 and CAR T across multiple cancer types in preclinical studies. In an ongoing multi-center Phase 1/2 clinical trial, early efficacy signals suggest that ENB-003 overcomes resistance to the anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in heavily pre-treated drug resistant cancer patients. The Phase 2 portion of the ENB-003 + pembrolizumab combination study is expected to start in the first quarter of 2023. The trial will enroll melanoma patients with innate resistance to anti-PD-1 based immunotherapies, platinum refractory and platinum resistant ovarian cancer patients, as well pancreatic cancer patients that have failed standard of care.

About ENB Therapeutics, Inc.

ENB Therapeutics is a clinical-stage biopharmaceutical company developing a novel class of medicines, endothelin B receptor (ETBR) inhibitors, to overcome resistance to immune-based therapies such as the immune checkpoint inhibitors. ETBR causes uncontrolled cancer growth, drives cancers to spread through the body and prevents the immune system from detecting and killing cancer cells. ENB's lead product candidate, ENB-003 specifically blocks the ETBR and has the potential to enhance the efficacy of immune-based therapies. ENB-003 is currently being investigated in an ongoing Phase 1/2 clinical trial in collaboration with Merck.

Learn more by visiting the ENB Therapeutics website.

Forward Looking Statements

This press release may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding the clinical development of ENB-003 or any of ENB's other product candidates or programs; the design of ENB's clinical trials; the safety, durability, or efficacy of ENB-003; and the potential benefits of ENB-003 or any of ENB's other product candidates. ENB may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you

should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of ENB's product candidates; availability and timing of results from preclinical studies and clinical trials; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that trials and studies may be delayed and may not have satisfactory outcomes; expectations for regulatory approvals to conduct trials or to market product; risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to ENB's abilities to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and ENB expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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