ENB Therapeutics Announces Successful Completion of the First Dosing Cohort in Phase I Clinical Trial of ENB-003 in Combination with Pembrolizumab

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

NEW YORK, NY / ACCESSWIRE / June 15, 2020 / ENB Therapeutics, INC., a biotechnology company pioneering a new and differentiated class of therapeutics targeting the ETB receptor (ETBR), today announced the successful completion of the first dosing cohort in a Phase I dose escalation of ENB-003 in combination with pembrolizumab. The Phase I trial includes a monotherapy run-in followed by combination therapy. Doses of ENB-003 administered to date appear well-tolerated and the safety review committee has approved the dose escalation. ENB-003 is a selective and potent inhibitor of the ETBR receptor which is overexpressed in over 40% of all tumor types and blocks T-cell trafficking, thus creating "cold" tumors which have a high unmet need.

"We are pleased that the doses of ENB-003 administered to date in combination with pembrolizumab appear to be very well tolerated and that our safety committee has approved moving on to the next higher dose," said Sumayah Jamal, MD-PhD, President, Co-Founder and CSO of ENB Therapeutics, Inc. "We are very excited to have cleared this initial safety hurdle in the first clinical trial of a selective ETBR inhibitor (ETBRI) for cancer immunotherapy. ETBRIs have demonstrated preclinical proof of concept for overcoming anti-PD1 resistance across multiple cancer types. We believe that ENB-003, when combined with pembrolizumab in the anti-PD1 resistant patient population, may result in enhanced anti-tumor activity and immunologic effects."

The Phase I/II multi-center, open-label trial of ENB-003 is currently enrolling patients with advanced solid tumors in indications associated with ETBR expression. The Phase I dose escalation of ENB-003 in combination with pembrolizumab is primarily designed to assess safety and tolerability and to determine a recommended Phase II dose (RP2D). Following selection of an RP2D, we expect to initiate a Phase II dose expansion portion with the primary objective of evaluating the clinical ability of ENB-003 to enhance responsiveness to pembrolizumab in patients who have previously failed pembrolizumab therapy or have tumors associated with pembrolizumab resistance.

About ENB Therapeutics

ENB Therapeutics is a clinical-stage biopharmaceutical company developing a novel class of medicines, ETBR inhibitors, to overcome resistance to immune-based therapies such as the immune checkpoint inhibitors. ENB's lead product candidate, ENB-003 is being investigated in an ongoing Phase I/II clinical trial in collaboration with Merck. For more information, visit www.enbpharma.com

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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