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ENB Therapeutics Presents Top-line Results from Phase 1b ENBOLDEN-101 Study in Platinum Refractory/ Resistant Ovarian Cancer at SITC 2023

- **ENB-003 in combination with KEYTRUDA® (pembrolizumab) demonstrated encouraging objective responses, disease control and progression-free survival in patients with metastatic platinum refractory/resistant ovarian cancer (PROC)**
- **Encouraging results support further development**
- **Expansion cohort in primary PROC and other refractory advanced cancers (ENB-003 + KEYTRUDA) to commence in 2024**

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NEW YORK--(BUSINESS WIRE)--ENB Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on oncology and immunology, today announced top-line results from the dual combination arm of the Phase 1b ENBOLDEN-101 study, evaluating ENB-003 in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced refractory cancers. The results show encouraging objective responses, disease control and extended progression-free survival in patients with platinum resistant/ refractory ovarian cancer (PROC). The poster, entitled, "ENB-003, an ETBR antagonist, in combination with pembrolizumab, shows promise in microsatellite stable platinum refractory/resistant ovarian cancer: Data from the ENBOLDEN-101 Phase 1B study" was presented on November 3, 2023 at a poster session at the SITC 2023 meeting, was held November 1-5, in San Diego, California, USA.

The data included 5 patients with metastatic microsatellite stable (MSS) PROC who had disease progression after one or more previous lines of treatment. Study treatment consisted of an initial 7-day run-in period of ENB-003 monotherapy, followed by repeated 3-week cycles of ENB-003 in combination with KEYTRUDA.

The data demonstrated that the treatment regimen was safe and well tolerated. The objective response rate (ORR) and disease control rate (DCR- patients exhibiting a response or stable disease) in MSS PROC was 40% and 80% respectively (N=5), including 2 patients with partial responses showing a 95% and 33% reduction in tumor burden respectively, as well as 4 patients with stable disease; 80% of PROC patients demonstrated shrinkage of target lesions overall. The 8-month progression-free survival rate was 60%. This compares favorably with a historical ~20% progression-free survival data at 6 months for single agent anti-PD1 and an ~8% ORR and an ~22% DCR.

"These data, demonstrate that ENB-003 in combination with KEYTRUDA is safe, with encouraging signs of clinical activity and support the combination's potential to become an effective immunotherapy regimen for MSS primary PROC – a disease that has responded very poorly to available treatments," stated Sumayah Jamal, MD-Ph.D., President, Chief

Scientific Officer, and Co-Founder of ENB Therapeutics. "We are extremely pleased with the top-line results from this ongoing study. We look forward to continuing our collaboration with Merck and anticipate initiating Part 2 of the study next year." For more information on this Phase 1/2a study, see NCT04205227.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About ENB-003

ENB-003 is a selective endothelin B receptor (ETBR) inhibitor that, in preclinical studies, enhances efficacy of CAR-T and anti-PD-1 in solid tumors 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 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 half of 2024. The trial will enroll MSS primary PROC, as well as MSS pancreatic cancer patients and patients with other advanced solid tumors 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 CAR-T in solid tumors and 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 drive the efficacy of CAR-T and anti-PD1 therapies in solid tumors. 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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