CBT Pharmaceuticals Announces First U.S. Patient Dosed in Phase 1 Clinical Trial of c-Met inhibitor, CBT-101, for Advanced Solid Tumors with c-Met Dysregulation

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CBT Pharmaceuticals (CBT), a biopharmaceutical company focused on developing innovative oncology therapeutics harnessing the immune system and targeting specific molecular pathways to tame cancer, today announced that the first subject has been dosed in the Phase 1 multi-center study, CBT-101-01. CBT-101 is a specific oral inhibitor of the c-Met kinase. This is the company's first clinical trial in the United States (NCT03175224). Following identification of a dose for CBT-101, the trial is planned to expand into tumor specific cohorts.

"This is an important milestone for CBT and its employees. We are also extremely grateful to the patients and clinical researchers at premier U.S. institutions that will contribute to the evaluation of CBT-101," said Sanjeev Redkar, Ph.D., President and Chief Executive Officer. "CBT-101 has demonstrated strong inhibition of tumor growth in cell lines and patient derived models across multiple tumor types with c-Met fusions, mutations or amplifications. We anticipate the clinical results so that we can explore single agent development as well as combination approaches."

"The aberrant activation of c-Met has been demonstrated to be highly correlated with outcome in many cancer indications, including kidney, lung, gastric, esophageal and brain cancer and plays a major role in cancer pathogenesis including tumor growth, angiogenesis and metastasis, as well as the suppression of cell death," said Anthony El-Khoueiry, M.D., Associate Professor of Clinical Medicine and Phase 1 Program Director at USC Norris Comprehensive Cancer Center. "Through our research collaboration with CBT Pharmaceuticals and the cadre of investigators on this trial, we look forward to characterizing CBT-101 safety profile and dose, and defining a path for further development."

CBT-101-01 Clinical Trial

This is a Phase 1, multi-center, open-label, 2-part Dose Escalation Segment with a Dose and Disease Expansion Cohort study to assess the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of CBT-101 monotherapy in subjects with advanced solid tumors with c-Met dysregulation. These findings will be used to establish a recommended Phase 2 dose for future clinical trials. A total of approximately 68 subjects will be enrolled.

There are two other Phase 1 trials with CBT-101 (PLB1001) ongoing in China – one in Met-positive Advanced Non-Small Cell Lung Cancer and the other in PTPRZ1-MET Fusion Gene Positive Recurrent High-Grade Gliomas.

More information on all trials is available at ClinicalTrials.gov.

CBT-101 Oral Capsule (PLB1001)

CBT-101 is a novel small molecule drug that targets the epithelial to mesenchymal transition (EMT) pathway that is dysregulated in several tumors. It is a specific inhibitor of the c-Met receptor. CBT-101 has demonstrated tumor inhibitory effect in a variety of human primary c-Met amplified gastric, hepatic, pancreatic and lung cancer xenograft animal models with c-Met fusions, mutations or amplifications (AACR, 2017).

About CBT Pharmaceuticals, Inc.

CBT Pharmaceuticals is a biopharmaceutical company focused on developing innovative oncology therapeutics harnessing the immune system and targeting specific molecular pathways to tame cancer. The company is advancing a pipeline of four development-stage assets. CBT-101, an oral c-Met inhibitor targeting the epithelial to mesenchymal transition (EMT) pathway and CBT-102, an oral multi-targeted kinase inhibitor that targets uncontrolled growth signaling pathways. In addition, CBT has two novel humanized monoclonal antibodies that restore the body's immune system to recognize and kill cancer cells – CBT-501, targeting the Programmable Death-1 (PD-1) membrane receptor of immune cells, and CBT-502, targeting Programmable Death Ligand-1 (PD-L1). CBT is seeking partners for combination therapies with its PD-1 and PD-L1 antibodies. The company was founded in 2016 with headquarters in California. www.cbtpharma.com

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