First-in-Human Genolimzumab Phase 1 Study Initiated to Assess Safety and Preliminary Efficacy in Patients with Select Advanced Solid Tumors

March 30, 2017 12:00 PM EDT

CBT Pharmaceuticals (Australia) Pty Ltd Established

Santa Clara, CA – March 30, 2017 – CBT Pharmaceuticals, Inc. (CBT), a life sciences company focused on developing innovative oncology therapeutics, announced today that the first patient has been enrolled in the genolimzumab (CBT-501) Phase 1 study, the company's first clinical trial. The trial is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of genolimzumab in patients with advanced solid tumors, recurrent or refractory to standard of care therapies. The trial also aims to determine any dose limiting toxicities or biologically relevant dose and establish a recommended Phase 2 dose for future clinical studies. Once the dose and schedule is established, two or more select tumors will be evaluated for preliminary efficacy, and secondarily, progression free survival.

"The dosing of our first subject with genolimzumab is a significant milestone for the company and we are very pleased to begin the development of this important second generation PD-1 drug candidate intended to treat patients with cancer," Sanjeev Redkar, PhD, President and Chief Executive Officer of CBT Pharmaceuticals. "In the clinic, we hope to define the unique characteristics of this agent shown pre-clinically, and ultimately, differentiating it in a combination approach with other targeted agents, standard marketed therapies, and other immune-oncology agents."

CBT-501-01 Clinical Trial

The CBT-501-01 clinical trial will include a total of three cohorts at increasing doses. Select relapsed or refractory advanced solid tumors will be enrolled: colorectal, endometrial, gastric including gastroesophageal junction adenocarcinoma, head and neck (esophageal, nasopharyngeal), hepatocellular, non-small cell lung cancer, mesothelioma, ovarian, and renal cell carcinoma. This Phase 1, multi-center trial is a two-part, open-label clinical trial with a Dose Escalation Segment (3+3 design) followed by a Dose and Disease Expansion Segment. A total of approximately 50 subjects will be enrolled in participating centers in Australia. The first patient was enrolled at Linear Clinical Research in Australia.

"We are very excited to commence dosing on the first-in-human trial of CBT-501, which has been specifically developed with improved characteristics over existing PD-1 inhibitors," said Professor Michael Millward, lead investigator at the Linear Clinical Research, Foundation Chair of Clinical Cancer Research, University of Western Australia and Head of Medical Oncology at Sir Charles Gairdner Hospital, Perth, Australia.

For additional information regarding the trial, please visit www.clinicaltrials.gov, NCT03053466.

Genolimzumab Injection (CBT-501)

CBT-501 is a novel humanized IgG4 monoclonal antibody targeting the Programmed Death-1 (PD-1) membrane receptor on T lymphocytes and other cells of the immune system. CBT-501 has a comparable efficacy profile in *in vitro* and *in vivo* studies to marketed anti-PD-1 antibodies and has a favorable safety profile with very low undesirable antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) activity. The antibody (CBT-501, GB226) has been developed by Genor BioPharma Co. Ltd., a Walvax Company, who owns development and commercialization rights in China. CBT Pharmaceuticals, Inc. retains rest of the world (ROW) rights. An investigational new drug application has been approved by the China Food and Drug Administration (CFDA), and a Phase 1 trial will be initiated in China by Genor.

About CBT Pharmaceuticals

CBT Pharmaceuticals is a life sciences company developing innovative oncology therapeutics targeting the growth and proliferation of cancer cells. The company is advancing a pipeline of four development-stage assets including CBT-101, an oral c-Met inhibitor targeting the epithelial-mesenchymal transition (EMT) pathway in cancers and CBT-501, a novel humanized monoclonal antibody targeting the Programmed Death-1 (PD-1) membrane receptor of immune cells, as well as two investigational products – a preclinical multi-targeted kinase inhibitor that targets uncontrolled growth signaling pathways and a novel humanized Programmed Death Ligand-1 (PD-L1) antibody that restores the body's immune system to recognize and kill cancer cells. CBT is headquartered in California and has an Australian subsidiary, CBT Pharmaceuticals (Australia) Pty Ltd to manage all trials conducted in Australia. For additional information, please visit: www.cbtpharma.com

Contact:

Cammy Duong
MacDougall Biomedical Communications
Main: +1-781 591 3443
cduong@macbiocom.com
Contact CBT Pharmaceuticals, Inc.