CBT Pharmaceuticals Initiates the APOLLO Oncology Clinical Trials Program

September 18, 2018 12:00 PM EDT

First Patient Dosed in Initial Immunotherapy Combination Trial Utilizing CBT's Proprietary Assets

Pleasanton, CA, and Hangzhou, China, 18 September 2018

— CBT Pharmaceuticals (CBT), a U.S. and China-based innovative biopharmaceutical company committed to becoming a leader in the discovery and development of oncology combination therapies, today announced the initiation of the APOLLO Oncology Clinical Trials Program. The APOLLO series of trials will evaluate and investigate whether CBT's proprietary assets can work in concert with other agents to improve single agent immunotherapy response rates, and, ultimately, to confer clinical benefit to patients with cancer. In Greek, the verb 'apollymi' means "to destroy," and in Greek mythology, Apollo is the god of healing.

The APOLLO program has been initiated with the dosing of the first patient in the initial trial in the series: a Phase 1/2 open label, multi-center dose escalation and expansion study in which CBT's proprietary c-Met inhibitor (bozitinib; CBT-101) will be administered concomitantly with anti PD-1 cancer immunotherapies. Utilizing biomarkers to identify patients likely to benefit from the combination, the trial will investigate whether the combination will improve single agent immunotherapy response rates as a result of the immunosuppressive tumor microenvironment due to tumor associated neutrophils (TANs).

"Initiating our APOLLO Oncology Clinical Trials Program and dosing the first patient is a major milestone for CBT as we advance our mission to improve the lives of cancer patients through combination treatment regimens," stated Sanjeev Redkar, PhD, Co-Founder and President. "The APOLLO program is designed to investigate our proprietary assets alongside each other and is focused on understanding the science and genetics to identify the appropriate patients likely to benefit from the regimen. We are grateful for the support of our investigators in running our series of trials."

The initial study is a two-arm clinical trial targeting locally advanced or metastatic disease: CBT-101 with CBT-501 (genolimzumab; anti-PD-1) in hepatocellular carcinoma (HCC), or CBT-101 and nivolumab in renal cell carcinoma (RCC). CBT-101 targets the epithelial to mesenchymal transition (EMT) pathway, and CBT-501 is CBT's IgG4 humanized monoclonal antibody against the PD-1 membrane receptor on immune cells. Nivolumab (OPDIVO®; Bristol-Myers Squibb Company) is approved for advanced kidney cancer.

Dr. Alex Powell, MBBS, FRACP, Affinity Oncology, Hollywood Private Hospital in Perth, Western Australia, added, "One of the newer paradigms for treating cancer patients is combining immunotherapy agents as this synergistic approach may provide improved outcomes. In this first trial in the series, we believe that giving a c-Met inhibitor concomitantly with an anti PD-1 therapy may produce a positive added response in patients with HCC and RCC where monotherapy treatment has proven effective. Affinity Oncology, and the entire Australia and New Zealand team, is thrilled to partner with CBT on this combination approach."

The primary objective of the Phase 1 portion of the trial will be to identify any dose limiting toxicities, evaluate overall safety, and assess the tolerability of CBT-101 and CBT-501 for HCC and CBT-101 and nivolumab for RCC. The Phase 2 primary objective is to assess preliminary efficacy by objective response rate (ORR) and duration of response (DOR) per irRECIST (Immune-related Response Evaluation Criteria In Solid Tumors). Secondary objectives include: determination of the recommended Phase 2 dose, determination of the pharmacokinetic (PK) parameters of CBT-101 and CBT-501 when administered in combination, assessment of clinical benefit rate, progression free survival, and overall survival at 6, 12, 18 and 24 months. Whole blood, serum, plasma and peripheral blood mononuclear cells will be collected to assess TANs. For additional information regarding the trial, please visit clinicaltrials.gov identifier: NCT03655613.

About Hepatocellular Carcinoma and Renal Cell Carcinoma

Hepatocellular Carcinoma (HCC)

Liver cancer is the sixth most common cancer in the world, and hepatocellular carcinoma (HCC) is the most common type of liver cancer. HCC occurs most often in people with chronic liver diseases, such as cirrhosis caused by hepatitis B or hepatitis C infection. While it is estimated that there will be approximately 42,000 new cases and 30,000 deaths from liver and intrahepatic bile duct cancer in the United States in 2018, about 83% of liver cancer cases occur in less developed countries. The highest incidence of liver cancer is in Asia and Africa.

Renal Cell Carcinoma (RCC)

Renal Cell Carcinoma (RCC) is the most common type of kidney cancer that begins in the lining of the renal tubules in the kidney. The renal tubules filter the blood and produce urine. Kidney cancer is the 12th most common cancer in the world with 338,000 new cases diagnosed in 2012. About 59% of kidney cancer cases occurred in more developed countries with the highest incidence in Northern America and Europe. It is estimated that there will be approximately 65,000 new cases and 15,000 deaths from kidney and renal pelvis cancer in the United States in 2018.

Sources on file.

About CBT Pharmaceuticals, Inc.

CBT Pharmaceuticals, Inc. is an innovative biopharmaceutical company committed to becoming a global leader in the discovery and development of oncology combination therapies that harness the immune system and target specific molecular pathways to tame cancer. The company's existing pipeline consists of five development-stage assets including three novel, humanized monoclonal antibodies that restore the body's immune system to recognize and kill cancer cells, and two targeted therapies against uncontrolled growth signaling pathways. For more information, please contact us and follow us on Twitter @CBTpharma.

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