



CBT Pharmaceuticals Initiates Phase 1b Clinical Trial for Anti-PD-1 Antibody CBT-501-01 (genolimzumab injection) in Patients with Advanced Solid Tumors

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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 continuation of the CBT-501 (genolimzumab injection) Phase 1 clinical trial with the initiation of the Phase 1b segment of the study in patients with select advanced or relapsed/recurrent solid tumors. CBT-501 is a novel IgG4 humanized monoclonal antibody against the Programmable Death-1 (PD-1) membrane receptor on immune cells.

Following a meeting by the trial's Safety Review Committee (SRC), the SRC determined that the safety data to date demonstrates CBT-501 is well tolerated and recommended a dose and schedule to advance the program. The Phase 1b segment will evaluate four tumor types, each expected to enroll approximately 20 patients. The ongoing clinical trial is being conducted in Australia.

"We are pleased that our PD-1 drug candidate, CBT-501, has demonstrated encouraging pharmacokinetics, pharmacodynamic engagement, a well-tolerated safety profile, and encouraging activity in advanced stage cancer patients," stated Sanjeev Redkar, PhD, President and Chief Executive Officer. "We expect the Phase 1b to further evaluate the safety profile of CBT-501 and its utility as a single agent in a number of homogenous tumor types. Results from this study may lead to a Phase 2 trial utilizing CBT-501 as a single agent or in combination with chemotherapy, radiation, targeted therapies, or other cancer immunotherapy agents."

For additional information regarding the trial, please visit [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03053466) identifier: [NCT03053466](https://clinicaltrials.gov/ct2/show/study/NCT03053466).

About CBT-501 (genolimzumab Injection)

CBT-501 is a novel IgG4 humanized monoclonal antibody against the Programmable Death-1 (PD-1) membrane receptor on immune cells. It has a comparable efficacy profile in in vitro and in vivo studies to the marketed anti-PD-1 antibodies, nivolumab and pembrolizumab, and has a favorable profile with very low antibody-dependent cell-mediated cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC) activity. In China, CBT-501 is referred to as GB226 where it is being developed by CBT partner Genor BioPharma Co. Ltd. Visit clinicaltrials.gov for additional information on the ongoing clinical trials: NCT03053466, NCT03374007, and NCT03502629.

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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