Oxford BioTherapeutics Initiates Dose-Escalation Portion of U.S. Phase I Clinical Trial for OBT076 in Patients with Advanced Solid Tumors

Dose-escalation starting at a dose based on results from a European study sponsored by partner, Menarini Ricerche.

Phase I program includes two U.S. expansion cohorts: (1) High risk cohort of HER2 negative, Hormone receptor positive (HER2-/HR+) chemotherapy-failure breast cancer; and (2) a basket trial in multiple pretreated solid tumors.

OXFORD, United Kingdom and SAN JOSE, Calif., Jan. 09, 2020 (GLOBE NEWSWIRE) -- Oxford BioTherapeutics Ltd. (“OBT”), a clinical stage oncology company developing antibody-based immuno-oncology therapies emerging from the Company’s proprietary target discovery platform, today announced the initiation of the dose-escalation portion of its U.S. Phase I program for OBT076, a CD205 targeting antibody-drug conjugate (ADC), in patients with advanced solid tumors. Dose-escalation is the first part of the Phase I program that includes two U.S. expansion cohorts: high-risk HER2-/HR+ chemotherapy-failure breast cancer and a basket trial that will enroll patients with a variety of CD205-overexpressing advanced solid tumors. Dosing in the study will initiate near anticipated therapeutic dose levels based on results from the Company’s European development partner, Menarini Ricerche (“Menarini”).

“OBT076 binds to a novel target, CD205, identified by our OGAP® target discovery platform, that is highly expressed on the surface of both cancer cells and tumor-associated immunosuppressive cells such as in HER2-/HR+ breast cancer,” said Christian Rohlff, Ph.D., Chief Executive Officer of OBT. “Our Phase I program is designed to leverage results obtained by our European partner, Menarini, to initiate dose escalation at a level where tolerability has been established, which is expected to expedite completion of the dose escalation phase of the trial. In addition, OBT has developed a CLIA-certified patient selection assay that we developed in conjunction with OBT076, which will be highly beneficial in identifying patients with CD205-overexpressing tumors to enroll in the expansion phase of the trial and potentially in more advanced clinical trials.”

Abderrahim (Rahim) Fandi, M.D., Ph. D, Chief Medical Officer of OBT said, “Our U.S. clinical program is truly innovative because OBT076 can potentially reverse immune tolerance by simultaneously destroying tumor associated immune cells and the tumor itself. Safety data collected by Menarini enables us to more rapidly and effectively move toward the second portion of the program, where we will target high risk HER2-/HR+ chemotherapy-failure breast

cancer patients, which call for new treatment approaches due to limited existing treatment options and more rapid disease progression."

The dose-escalation phase of the clinical trial is an open-label, multicenter study that will investigate the safety, tolerability and pharmacokinetic profile of OBT076 in patients with advanced or refractory solid tumors. The expansion cohorts in HER2-/HR+ breast cancer and the basket trial will begin once a maximum tolerated dose has been established in the dose escalation phase.

"HER2-/HR+ breast cancer is a common phenotype for which chemotherapy is generally effective," said Gary Schwartz, M.D., Chief of Hematology/Oncology at NewYork-Presbyterian/Columbia University Irving Medical Center, Deputy Director of the Herbert Irving Comprehensive Cancer Center, Professor of Oncology at Columbia University Vagelos College of Physicians and Surgeons, and investigator of the clinical trial. "However, more than 30% of these patients respond poorly to treatment and face limited treatment options. There is a high unmet need for an innovative drug that is effective in this subset of HER2-/HR+ patients. I look forward to seeing the results of this Phase I program."

Solmaz Sahebjam, M.D., Director of the Clinical Research Unit and leader of the Phase 1 Clinical Trial Program at Moffitt Cancer Center, added, "The proposed mechanism of action of OBT076 provides for a unique new approach to treat CD205-positive solid tumors in areas of high unmet need by aiming to kill the tumor and re-engage the patient's immune system at the same time in patients with breast, bladder, lung, ovarian and gastric cancers. The totality of results from this phase 1 trial should provide us with significant information on this new mechanism, and the team at Moffitt Cancer Center is excited to make a contribution to this valuable effort."

Dr. Schwartz and Dr. Sahebjam report no financial or other conflicts of interest related to this trial.

About OBT076

OBT076, is an antibody drug conjugate (ADC) comprising a fully human antibody targeting CD205, coupled to the DM4 toxin from Immunogen. OBT076 is in development for a number of CD205-driven tumors including HER2 negative breast cancer, gastric cancer, triple-negative metastatic breast cancer, bladder cancer and pancreatic cancers as well as Non-Hodgkin Lymphoma (NHL). Infiltration of primary localized breast tumors by immunosuppressive cells correlates with an adverse outcome (PFS and OS[1]), suggesting they contribute to the progression of breast cancer and several other solid and liquid cancers. CD205 is overexpressed in subsets of HER2 negative breast cancer, triple negative breast cancer, gastric cancer, lung cancer, bladder cancer, pancreatic cancer, ovarian cancer and multiple liquid cancers including diffuse large B-cell lymphoma (DLBCL).

OBT076 has been tested in a multicenter first-in-human clinical study under the name MEN1309 in major European oncology centers in Italy, Spain, Belgium and the UK under the sponsorship of Menarini Ricerche via a strategic alliance with OBT.

About Oxford BioTherapeutics

Oxford BioTherapeutics (“OBT”) is a clinical stage oncology company; based in Oxford, UK and San Jose, USA; with a pipeline of first-in-class immuno-oncology (IO) and antibody-drug conjugate (ADC) based therapies designed to fulfill major unmet patient needs in the field of cancer. OBT's IO discovery process provides unique insights into the cancer - immune cell synapse and has identified several novel IO candidates for cancer therapy.

OBT's first clinical program MEN1112/OBT357, an antibody-dependent cell-mediating cytotoxicity (ADCC) candidate targeting Bst1/CD157-expressing Acute Myeloid Leukemia (AML) blasts, is proceeding in ARMY-1 study, of an open-label Phase I trial for relapsed/refractory AML in Europe under the sponsorship of Menarini Ricerche, a company of the Menarini Group.

OBT’s pipeline and development capabilities have been validated through multiple strategic partnerships including with world leaders in antibody development (such as Amgen, Alere, BioWa, Medarex (BMS), Immunogen, Nerviano and WuXi) and with leading Italian pharmaceutical company Menarini, which fully funds the clinical development of two programs in the EU to completion of Phase II proof-of-concept. OBT retains full commercial rights to these programs in North America and Japan. Additionally, two pre-clinical stage programs are partnered with Boehringer Ingelheim. OBT has a strong oncology focused management team and board with significant experience in developing IO and antibody-based therapies.

For more information on Oxford BioTherapeutics, please visit www.oxfordbiotherapeutics.com.

[1] Clinical Cancer Research, Vol. 10, 7466–7474, 2004

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