Oxford BioTherapeutics to Present Initial Positive Data from Phase I Trial at ASCO 2022

- *Initial data from Phase 1 dose escalation part of the trial, assessing OBT076 in adult patients with advanced solid tumors, indicated that OBT076 was generally well tolerated with no dose-limiting toxicities observed; optimal dose selected at 3.0 mg/kg.*

- *OBT076 showed preliminary signs of clinical activity as a monotherapy, with objective responses including long lasting stable disease in six patients (with gastric, ovarian and lung, esophageal and thyroid cancers), in chemotherapy and checkpoint inhibitor (CPI) refractory patients.*

- *Company has advanced OBT076 into single agent expansion cohorts in both checkpoint- and chemotherapy-naïve and resistant patients.*

- *OBT to expand clinical studies to include US and European centers.*

Oxford, UK and San Jose, California - May 27, 2022 - Oxford BioTherapeutics (OBT), a clinical stage oncology company with a pipeline of immuno-oncology and Antibody Drug Conjugate (ADC)-based therapies, today announced it will present preliminary clinical data from its ongoing Expansion Phase I Trial (NCT04064359) of its experimental CD205-directed ADC, OBT076, at the American Society of Clinical Oncology (ASCO) Annual Meeting 2022 being held 3-7 June in Chicago, IL.

The presentation will highlight the initial findings from the completed dose escalation and ongoing expansion trial investigating monotherapy with OBT076, indicating a favorable tolerability profile at the optimal dose for clinical activity, with objective response including the achievement of stable disease in advanced cancer patients, refractory to checkpoint inhibitor (CPI) and chemotherapies.

“We are pleased to share these data showing promising preliminary signs of clinical activity and a favorable tolerability profile for our experimental CD205-directed ADC, OBT076, in patients with advanced and chemotherapy-refractory cancers,” **said Christian Rohlff, PhD, Chief Executive Officer (CEO) of Oxford BioTherapeutics.** “The results support our excitement around OBT076 as a therapeutic product capable of harnessing the immune system to treat patients with advanced, difficult to treat cancers as monotherapy at an optimal dose of 3.0 mg/kg. At this dose, seven of eighteen advanced cancer patients derived clinical benefit, of which one experienced major improvement in metastatic lesions after cycle 3.

Based on these encouraging results, we are advancing OBT076 into the next stage of clinical development as both a single agent and in combination with CPIs for the treatment of multiple solid tumor indications, with the goal of improving outcomes for patients with difficult-to-treat cancers.”

Summary of the Data to Be Presented at ASCO

The purpose of the dose escalation portion of the ongoing OBT076 trial, to be presented at ASCO, is to evaluate primary objectives of safety and tolerability, and secondary objectives of pharmacokinetics (PK), pharmacodynamics (PD) and antitumor activity of OBT076 as a monotherapy in patients with advanced solid tumors having high expression of target protein CD205. CD205 is a type I transmembrane glycoprotein, with unique characteristics that make it an ideal target for ADC therapy.

As of the data cut-off (January 31, 2022), the trial had enrolled 18 patients with advanced solid tumors with at least 1 metastatic site in the dose escalation part of the study (Part 1) and two patients in the ongoing expansion basket trial enriched in indications where preliminary efficacy has been shown (Part 2). The patients received OBT076 intravenously (IV) once every three weeks (Q3W) followed by Granulocyte Colony Stimulating Factor (GCSF) 8 days following dosing with OBT076. In part 1 of the study, doses of 1.6, 2.5, 3.0 and 3.5 mg/kg were evaluated. Dose limiting toxicity (DLT) was defined as neutropenia.

PK data showed that Cmax of 40.000-90.000 ng/ml was achieved between 2.5 and 3.5mg/kg. In Part 1, seven patients derived clinical benefit despite being in disease progression at trial entry of which one experienced major improvement with complete disappearance of ascites and metastatic adenopathy after cycle 3. At a dose of 3.0 mg/kg, OBT076, as a single agent, showed a favorable safety profile with manageable neutropenia and antitumor activity in gastric, ovarian and lung cancer. No DLTs were observed at this dose.

“I am highly encouraged by these initial results from the OBT076 trial, particularly the clinically meaningful responses to treatment with OBT076 as a monotherapy in chemotherapy-refractory patients with gastric, ovarian and lung cancers,” **said Abderrahim Fandi, M.D. PhD., Chief Medical Officer of Oxford BioTherapeutics.** “I look forward to the full analysis of the trial and further clinical development of OBT076 as a therapeutic for solid tumors where there is significant unmet need in these difficult to treat cancers.”

The e-poster and abstract are accessible on the ASCO conference website. The abstract and presentation details are as follows:

- **Title:** *Phase 1 study of OBT076, first in class anti-DEC205 ADC, in patients with advanced/metastatic solid tumors: safety, efficacy and PK/PD results*
- **Session:** Developmental Therapeutics - Molecularly Targeted Agents and Tumor Biology
- **Abstract #:** 3028
- **Date & Time:** Sunday, June 5, 2022 at 8:00 -11:00 AM CDT
- **Authors:** Olivier Rixe, Shou-Ching Tang, Solmaz Sahebjam, Monica Mita, Alain Mita, Lee Rosen, Arnima Bisht, Abderrahim Fandi, Christian Rohlff, Rutika Mehta.

OBT076 Further Clinical Development Plans

Based on these preliminary results, OBT plans to advance OBT076 into Phase 1b trials assessing the safety of OBT076 as a monotherapy as well as in combination in both checkpoint-naïve and resistant patients with solid tumors. Subsequent disease-specific Phase 2a trials are planned in non-small cell lung, ovarian and gastric cancer patients. OBT is also planning for later-stage trials of OBT076, including in combination with CPI.

About Oxford BioTherapeutics

Oxford BioTherapeutics is a clinical stage oncology company based in Oxford, UK and San Jose and Morristown NJ 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 cancer therapeutics. These include bispecific, Chimeric Antigen Receptor T Cell (CAR-T), Antibody Drug Conjugate (ADC) and Antibody Dependent Cell-mediated Cytotoxicity (ADCC) therapeutics.

OBT's first clinical program, OBT076, initiated expansion in a U.S. Clinical Trial in 2021 in patients with advanced or refractory solid tumors, including gastric, bladder, ovarian and lung cancer, where CD205 is overexpressed. Infiltration of tumors by immunosuppressive cells correlates with adverse outcomes (lower progression free and overall survival), suggesting that this process contributes to the progression of several cancers.

OBT's proprietary OGAP® target discovery platform is based on one of the world's largest proprietary cancer membrane proteomic databases, with data on over 5,000 cancer cell proteins providing unique, highly-qualified oncology targets, of which three programs are in clinical development in the USA and Europe.

A major differentiator between OBTs discovery platform and other approaches is the retention of the link between individual patient samples through to the design of therapeutic antibodies and diagnostic patient selection tools, increasing the overall successful transition into clinical development.

OBT's pipeline and development capabilities have been validated through multiple strategic partnerships including with Boehringer Ingelheim and our cell therapy research collaboration with Kite Pharma as well as other world leaders in antibody development (such as Amgen, Immunogen, WuXi, Medarex (BMS), Alere (Abbott), BioWa, and Nerviano). 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

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