Oxford BioTherapeutics Announces Partner Boehringer Ingelheim Received U.S. FDA Fast Track Designation for BI 764532 for the Potential Treatment of Advanced or Metastatic Large-Cell Neuroendocrine Carcinoma of the Lung

BI 764532 is an investigational T-cell engager that redirects T cells towards cancer cells expressing the DLL3 protein

DLL3 antigen was discovered using OBT's proprietary OGAP® drug discovery platform

This is the third Fast Track designation for BI 764532

Oxford, UK, San Jose, Calif., 29 November 2023 – Oxford BioTherapeutics (OBT), a clinical stage oncology company with a pipeline of immuno-oncology and Antibody Drug Conjugate (ADC)-based therapies, today announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to BI 764532 for the potential treatment of advanced or metastatic large-cell neuroendocrine carcinoma of the lung (LCNEC-Lung) expressing DLL3 whose disease has progressed following at least one prior line of treatment including platinum-based chemotherapy.

BI 764532 is an investigational DLL3/CD3 IgG-like T-cell engager for potential treatment of patients with LCNEC-Lung that is being developed by Boehringer Ingelheim. The discovery of BI 764532 (OBT620) was enabled through a successful partnership initiated in 2013, leveraging OBT's proprietary OGAP® drug discovery platform for identification of the DLL3 antigen and Boehringer Ingelheim's longstanding expertise in oncology and development of biotherapeutics.

As of November 2023, the FDA granted Fast Track designation to BI 764532 for the potential treatment of extensive-stage small cell lung cancer (SCLC) whose disease has progressed following at least two prior lines of treatment including platinum-based chemotherapy, and of advanced or metastatic extrapulmonary neuroendocrine carcinomas (epNEC) whose disease has progressed following at least one prior line of treatment including platinum-based chemotherapy.

BI 764532 was also granted Orphan Drug designation by the FDA for the treatment of SCLC, and is currently being investigated in a Phase 2 study, 'DAREON™-5' (NCT05882058), in patients with relapsed/refractory extensive-stage SCLC and other relapsed/refractory NEC.

Christian Rohlff, Chief Executive Officer of OBT, commented: *"We are delighted about the clinical development to help address unmet needs for people living with small cell lung cancer and other neuroendocrine carcinomas. This is an important milestone for our teams and exciting news for the community"*

FDA's Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs.

***

About Oxford BioTherapeutics

Oxford BioTherapeutics (OBT) is a clinical stage oncology company with a pipeline of first-in-class immuno-oncology (IO) and antibody-drug conjugate (ADC) based therapies designed to fulfil 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 US 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 US and Europe. OBT's IO discovery process provides unique insights into the cancer-immune cell synapse and has identified several novel IO monoclonal and bispecific antibody candidates for cancer therapies.

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

Contacts
Investors:
Dr Christian Rohlff, CEO
christian.r@oxfordbiotherapeutics.com

Media:
MEDiSTRAVA Consulting
Sylvie Berrebi, Sandi Greenwood, Erica Hollingsworth
E : OBT@medistrava.com
T : +44 (0) 203 928 6900