



Oxford BioTherapeutics Announces Partner Boehringer Ingelheim Received U.S. FDA Fast Track Designation for BI 764532 for the Treatment of Extensive Stage Small Cell Lung Cancer and Extrapulmonary Neuroendocrine Cancers

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

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

Fast Track designation accelerates BI 764532's path to U.S. FDA submission

Oxford, UK, San Jose, Calif., 3rd October 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 treatment of extensive stage small cell lung cancer (ES-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 is an investigational DLL3/CD3 IgG-like T-cell engager for treatment of patients with SCLC and other neuroendocrine tumors that is being developed by Boehringer Ingelheim. The discovery of BI 764532 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.

Encouraging data were presented from the Phase I first-in-human dose-escalation trial at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting. These Phase I data demonstrated a clinically acceptable safety profile and early efficacy in patients with DLL3-positive ES-SCLC and epNECs.

Christian Rohlf, Chief Executive Officer of OBT, commented: *"We are delighted about the accelerated clinical development of BI 764532, for which the DLL3 antigen was discovered using our OGAP® technology platform. This is tremendously exciting for OBT, as it shows the real impact this partnership has for patients in need. Receiving an ES-SCLC or epNEC diagnosis can be life changing and there is an urgent, unmet need for additional targeted immunotherapeutics to ensure that individuals impacted by these aggressive cancers get the care they need."*



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](#).

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