Oxford BioTherapeutics receives US FDA IND Clearance for OBT076

An experimental first in class ADC medicine for high risk Her2 negative breast cancer, gastric, lung, bladder and ovarian cancer patients - US phase I clinical trial to be initiated.

Oxford, UK and San Jose, Calif., December 21, 2018 – Oxford BioTherapeutics Ltd. ("OBT"), a clinical stage oncology company with a pipeline of immuno-oncology and antibody drug conjugate based therapies, announces that it has received US Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA) for OBT076, an experimental antibody drug conjugate (ADC) for the treatment of women with high risk HER2 negative breast cancer, as well as other solid tumors expressing this target antigen including gastric, lung, bladder and ovarian cancer. The phase I study will be performed at a number of leading clinical centres across the United States.

"With our highly experienced expert investigators, we hope to bring this new innovative treatment option to this high unmet medical need patient population with high risk Her2 negative breast cancer", said OBT's Chief Medical Officer, Dr Rahim A Fandi. "We also aim to develop OBT076 for other solid tumors expressing the target antigen. OBT076/MEN1309 has already been shown to be well tolerated in an on-going phase 1 trial conducted in Europe under the sponsorship of Menarini Ricerche. OBT076/MEN1309 is an ADC drug, which is designed to target CD205 positive tumours and to reverse immune tolerance in patients with high risk breast cancer and other solid and liquid tumours. This is a great achievement by OBT's team."

OBT Chief Executive Officer, Dr. Christian Rohlff said, "The FDA's acceptance of the IND for OBT076 is an important milestone in OBT's US product development strategy. We plan to conduct studies in the US that will extend the potential of this first-in-class molecule, beyond the cancer indications currently under evaluation in the Menarini Ricerche sponsored European trial, under the name MEN1309, to patients with other cancer types with a clear need for better treatment options. OBT076 is expected to play a key role in OBT delivering on its commitment to help patients with cancer, in particular those with high risk breast cancer. The start of this trial will herald an exciting start to 2019 for OBT."

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 being developed 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 pDC correlates with an adverse outcome, suggesting their contribution in the progression of breast cancer[1] 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 DLBCL.

OBT076 is currently also being tested in a multi-centre first-in-human clinical study under the name MEN1309 in major European oncology centres in Italy, Spain, Belgium and the UK in triple negative breast cancer (TNBC), pancreatic, and bladder cancers, as well as diffuse large B-cell lymphoma (DLBCL) under the sponsorship of Menarini Ricerche via a strategic alliance with OBT. The European first in human trial is successfully progressing the dose escalation phase that commenced by enrolling patients with solid tumors and has recently extended the enrolment to patients with NHL. The subsequent expansion cohorts' phase of this European trial will aim to identify the recommended phase II dose in specific sold tumor indications as well as NHL.

[1]Treilleux, Isabelle, et al. "Dendritic cell infiltration and prognosis of early stage breast cancer." *Clinical Cancer Research* 10.22 (2004): 7466-7474.

About Oxford BioTherapeutics

Oxford BioTherapeutics 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 fulfil 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 AML blasts, is currently in a phase I dose escalation trial for relapsed/refractory Acute Myeloid Leukemia 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

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