

Oncology Research: New Opportunities for Menarini and OBT

Oncology Alliance between Menarini & Oxford BioTherapeutics Progresses Second Candidate MEN1309 into the Clinic, an Antibody Drug Conjugate for the Treatment of Solid Tumors and NHL

Oxford, UK; 12 September 2017 - Menarini Ricerche (Menarini Group) and Oxford BioTherapeutics (OBT), an international biotechnology company, announce today that they have initiated a multicenter first-in-human clinical study to evaluate MEN1309, an antibody drug conjugate for the treatment of metastatic solid cancers, as well as for the treatment of non-Hodgkin's lymphoma.

The phase I study of MEN1309 will be conducted in major European oncology centers in Italy, Spain, Belgium and the UK. MEN1309 is a fully-human monoclonal IgG1 antibody coupled to DM4, a maytansinoid toxin targeting the tumour antigen CD205. In patient derived models and xenografts, MEN1309 showed strong anti-tumor activity in triple-negative breast (TNBC), pancreatic, and bladder cancers, as well as diffuse large B-cell lymphoma (DLBCL), a type of non-Hodgkin lymphoma (NHL), consistent with the expression of CD205 seen in these cancer types.

"MEN1309 could become an innovative treatment option for many cancer patients" said **Andrea Pellacani (General Manager, Menarini Ricerche)**. "We are very pleased with the progress of our strategic oncology alliance with Oxford BioTherapeutics. Menarini has a long-standing commitment to advancing the treatment of cancer, and we look forward to accelerating our shared pipeline with OBT in clinical development."

This open label trial will start by enrolling patients with solid tumors in the first dose escalation phase, followed by a second dose escalation in NHL. The subsequent expansion cohorts phase will aim at identifying the recommended phase II dose in specific indications among solid tumors and NHL. In addition, the trial will investigate the correlation of the clinical response with target antigen expression.

"We are delighted to initiate clinical development of the second oncology programme in our partnership with the Menarini Group," said **Christian Rohlf, Oxford BioTherapeutics' CEO**. "By bringing together OBT's world-class discovery capabilities with Menarini's clinical development and manufacturing expertise, the partnership is successfully advancing exciting programs aimed at large unmet clinical need in oncology."

Under the collaboration, Menarini is responsible for the clinical development, up to the clinical proof of concept study, and then for the full development and regulatory approval in its territories: Europe, Asia, and Latin America. OBT is responsible for full development, approval and commercialization in North America and Japan.

MEN1112, the first program from the collaboration for the treatment of Acute Myeloid Leukemia (AML), is currently progressing through the phase I dose escalation trial in relapsed/ refractory AML patients.

About the Menarini Group

Menarini Group is an Italian pharmaceutical company, 12th in Europe out of 5,255 companies, and 36th company in the world out of 20,862 companies, with a turnover of more than 3.5 billion Euro and more than 16,700 employees. The Menarini Group has always pursued two strategic objectives: research and internationalization, and has a strong commitment to oncology research and development. As part of such commitment to oncology, Menarini is developing 2 investigational new drugs in addition to MEN1112 and MEN1309: the dual PIM and FLT3 kinase inhibitor MEN 1703, and the PI3K inhibitor MEN 1611, in development for the treatment of a variety of hematological and/or solid tumors. Menarini is active commercially in the most important therapeutic areas with products for cardiology, gastroenterology, pneumology, infectious diseases, diabetology, inflammation, and analgesia.

For further information please visit www.menarini.com

About Oxford BioTherapeutics

Oxford BioTherapeutics is a clinical stage oncology company with a pipeline of immuno-oncology and antibody-drug conjugate based therapies. OBT's immuno-oncology (IO) discovery process provides unique insight into the cancer - immune cell synapse, and has identified several novel IO candidates for cancer therapy. Oxford BioTherapeutics has a strong oncology specialist management team and board with significant experience in developing immuno-oncology and antibody-based therapies. The company is based in Oxford, UK, and San Jose, CA.

For further information, please see www.oxfordbiotherapeutics.com