AN ANTI-CD205 ADC FOR SOLID TUMORS AND NHL DEVELOPED THROUGH PRECISION ONCOLOGY APPROACH

MEN 1309

MEN1309, developed in collaboration between Menarini and Oxford BioTherapeutics, is an antibody drug conjugate (ADC) consisting of a monoclonal antibody conjugated to a maytansin derivative, a potent cytotoxic agent DM4, against CD205 in clinical development for non-Hodgkin lymphoma (NHL) and solid tumors.
**MEN 1309**

**MEN 1309** targets both non-Hodgkin lymphoma and solid tumors. Lymphomas are traditionally divided into Hodgkin’s lymphoma (which accounts for about 10% of all lymphomas) and non-Hodgkin lymphoma which represents a wide spectrum of illnesses that vary from the most indolent to the most aggressive malignancies.

Overall, the chance that a man will develop NHL in his lifetime is about 1 in 42; for a woman, the risk is about 1 in 54.

Solid tumors are an heterogeneous population of diseases. One of the main indications in which **MEN1309** is in development is Triple Negative Breast Cancer (TNBC). TNBC accounts for the 15% of breast cancers and is more likely to recur than the other 2 subtypes, with 85% 5-year breast cancer-specific survival for stage I triple-negative tumors vs 94% to 99% for hormone receptor positive and ERBB2 positive.

**MEN 1309** molecular target is highly expressed in a wide range of solid tumors and lymphomas.

**MEN 1309** has shown IMPRESSIVE antitumor activity in clinically relevant models.

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**“Open-Label, Multicenter, Phase I Dose Escalation Study of MEN1309, a CD205 Antibody-Drug Conjugate, in Patients With CD205-Positive Metastatic Solid Tumors and Non-Hodgkin Lymphoma”** NCT03403725

The main aim of this study is finding the dose that is well-tolerated and suitable to be administered in subsequent clinical trials in patients. The clinical trial is also looking at the effectiveness of the study drug.

The clinical trial consists of two sequential parts:

Part 1 involves patients with CD205-positive metastatic solid tumors to determine the highest dose of the study drug that can be used safely in these types of cancer.

Part 2 involves patients with CD205-positive non-Hodgkin Lymphoma and will test doses of **MEN1309** which have demonstrated to be adequately tolerated in patients with solid tumors.