$1 Billion Oncology Alliance between Menarini Group & Oxford BioTherapeutics Initiates First-in-Human Study of Enhanced Antibody for Treatment of Acute Myeloid Leukemia

OXFORD, UK and BERLIN, GERMANY—25 November 2014 – Oxford BioTherapeutics and Berlin Chemie/ Menarini Biotech/ Menarini Ricerche (belonging to Menarini Group) announce today that they have initiated the first-in-human clinical study of OBT357 (MEN1112), a novel enhanced antibody for the treatment of acute myeloid leukemia (AML). This is the first of five development programs between the two companies to enter the clinic in a $1 billion strategic oncology alliance.

The phase I study of OBT357/ MEN1112, a defucosylated, recombinant, humanized antibody targeting an undisclosed antigen expressed on AML blasts and the AML stem cell compartment, will be conducted in major European leukemia treatment centers in Belgium, France, Germany and Italy. The open label trial will enroll patients with relapsed or refractory AML in a first dose escalation phase for safety assessment, and the expansion cohort phase for determination of the recommended phase II dose. In addition, the trial will include correlation analyses of clinical response and target antigen expression. Preliminary results are expected in 2016.

“The initiation of the first clinical program in our co-development collaboration with Menarini is an important strategic milestone,” said Dr Christian Rohlff, Oxford BioTherapeutics’ CEO. “Oxford BioTherapeutics has built a strong pipeline of innovative cancer therapeutics by combining leading antibody-based technologies with its world-class discovery capabilities, and we look forward to accelerating further candidates into the clinic as part of our major oncology alliance with Menarini.”

Commenting on the announcement, Andrew Slade, Menarini Biotech Chairman, said, “I have been very impressed with how the two companies have worked together to achieve this milestone. It bodes well for the rest of the collaboration.”

Oxford BioTherapeutics and the Menarini Group established their strategic partnership in October 2012, covering the development and commercialization of five of Oxford BioTherapeutics’ proprietary antibody-based cancer therapies. In October 2013, the companies designated OBT357 (MEN1112) targeting AML as the first clinical development candidate in the partnership. Under the collaboration, Menarini contributes preclinical, clinical and manufacturing expertise, supported by an investment of up to $1 billion, plus potential milestone payments of a similar magnitude and royalties on future sales, in exchange for commercial rights to the treatments in Europe, Asia and Latin America. Oxford BioTherapeutics retains commercial rights in North America and Japan. The partnership was recently identified as the second largest antibody and antibody-drug conjugate technology platform deal globally during the past five years*.

*September 2014 biopharma dealmakers; published in September 2014 editions of Nature Biotechnology and Nature Reviews Drug Discovery

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About Oxford BioTherapeutics

Oxford BioTherapeutics is developing a range of innovative antibody-drug conjugates (ADCs) for the treatment of cancer. The company's ADCs are based on its proprietary OGAP® targeting platform, and incorporate novel antibody and cancer toxin technologies accessed from leading companies in the field. Oxford BioTherapeutics’ network of collaborations provides a unique range of complementary ADC technologies, allowing the company to select the optimal combination for each target identified by its OGAP® system. OGAP® incorporates one of the world's largest proprietary proteomic databases, with data on over 5,000 cancer cell proteins providing unique, highly-qualified oncology targets that are selected for optimal ADC activity.
About the Menarini Group

The Menarini Group is the number one Italian pharmaceutical company in the world, 17th in Europe out of 5,291 companies, and 37th company in the world out of 19,042 companies, with a turnover of more than 3 billion Euro and nearly 17,000 employees. The Menarini Group has always pursued two strategic objectives: Research and Internationalisation. It is present in the most important therapeutic areas including: cardiovascular products, gastroenterology.

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