



Press release

Biomunex Pharmaceuticals announces the start of a Phase 1 clinical trial for its first-in-class bispecific antibody for the treatment of cancer

- This first-in-man trial conducted by Onward Therapeutics, under the license and co-development agreement, is a Phase 1 clinical trial for the evaluation of a bispecific antibody generated from Biomunex' proprietary BiXAb® platform.
- The Phase 1 study is evaluating the safety, tolerability, pharmacokinetics, immunogenicity and preliminary anti-tumoral activity of a “first-in-class” bispecific antibody targeting two immune checkpoints (OT-A201), given as monotherapy or in combination in patients with either solid tumors or hematological malignancies.
- The enrollment of the first patient in this clinical trial demonstrates the potential of the BiXAb platform to generate clinical candidates. It also triggered the first clinical milestone payment by Onward Therapeutics to Biomunex.

Paris (France) and Cambridge, MA, USA, January 24th, 2024 - Biomunex Pharmaceuticals (Biomunex), a French biopharmaceutical company that develops cutting-edge immunotherapies through the discovery and development of bi- and multi-specific antibodies, generated from the BiXAb platform, for the treatment of cancer, announced today the enrollment in 2023 of the first patient in a Phase 1 clinical trial conducted by Onward Therapeutics SA (Onward Therapeutics).

In preclinical studies, this antibody generated from Biomunex' proprietary, best-in-class, bi- and multi-specific antibody platform, BiXAb, has demonstrated not only good pairing, low aggregation, high stability, excellent manufacturability but also excellent specificity and safety, and displayed important in vivo anti-tumoral activities at different doses.

The clinical trial takes place within the framework of [the license and co-development agreement signed in 2021 by Biomunex with Onward Therapeutics](#), a global biotechnology company focused on development for cancer treatment, and thus triggered a milestone payment tied to the start of a Phase 1 clinical trial. Under the terms of the agreement, Biomunex has already received an upfront payment and is also eligible for further clinical, regulatory and commercial milestone payments, as well as tiered royalties on global net sales and other potential payments.

"We are delighted to announce this clinical trial for the evaluation of one of the antibodies generated thanks to our unique BiXAb platform, with Onward Therapeutics," said Dr. Pierre-Emmanuel Gerard, founder, President and CEO of Biomunex. "The achievement of this key milestone supports the scientific and technological relevance of our BiXAb platform to identify, generate and develop rapidly and efficiently novel bispecific antibodies. With this clinical trial, we hope to demonstrate the potential major impact of our antibodies in cancer patients, particularly in those with significant unmet medical needs."

This Phase 1 clinical trial is a European multicenter and open-label study that is divided in two parts.

The first part is a dose escalation stage of the BiXAb candidate as single agent in patients with selected advanced/metastatic solid tumors or relapsed/refractory hematological malignancies, that will mainly evaluate safety and tolerability and will determine the maximum tolerated and recommended Phase 2 doses. The second part is an expansion stage that will further evaluate the safety and preliminary anti-tumoral activity of the candidate as monotherapy or in combination in selected solid tumors and hematological malignancies.

"We are convinced of the potential of this "first-in-class" bispecific antibody, capable of simultaneously targeting two immune checkpoints, based on our proprietary BiXAb platform, to provide better anti-tumor effects with a favorable therapeutic window and potentially become a true novel immunotherapeutic option for various cancers, both solid and liquid", added Dr. Simon Plyte, Chief Scientific Officer of Biomunex. "This clinical evaluation of our BiXAb format paves the way for the successive development of our first-in-class BiXAb-MAIT engager approach that we will rapidly advance to the clinic".

About Biomunex Pharmaceuticals : www.biomunex.com

Biomunex Pharmaceuticals is a biopharmaceutical company based in Paris (France) and Cambridge, MA, USA, led by an international and experienced team. Biomunex is focused on the discovery and development of breakthrough immunotherapeutic approaches, based on solid data and proven biological and clinical evidence, to address unmet medical needs in oncology.

Biomunex has created and developed BiXAb, a robust, 'Plug and Play', next-generation bi- and multi-specific antibody technology platform, using a proprietary computational modeling approach, with a very robust IP and patent portfolio. The BiXAb platform, which allows the generation of bispecific antibodies from any pair of monoclonal antibodies in a simple, fast and cost-effective manner, has been validated through licensing agreements and collaborations with the pharmaceutical and biotech industry, with Sanofi then Onward Therapeutics.

Biomunex is also the leading company worldwide developing an immuno-oncology approach that allows, through bispecific antibodies from its BiXAb platform, to specifically target, engage and redirect MAIT cells, a subpopulation of T cells naturally present throughout the body, most specifically in mucosal and barrier tissues, to kill cancer cells, for the treatment of solid tumors.

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