



Biond Biologics Announces First Patient Dosed with BND-35 in Phase 1 Clinical Trial

BND-35 is a Novel and Unique Anti-ILT3/LILRB4 Antibody for Remodeling the Tumor Microenvironment

BND-35-001 trial includes unique combination arms with anti-EGFR (cetuximab) and anti-PD-1/PD-L1, in selected indications

Misgav, Israel, June 24, 2024 –Biond Biologics Ltd. ("Biond" or the "Company"), a private clinical-stage biopharmaceutical company developing novel immunotherapies for cancer and a platform for the intracellular delivery of biologics, today announced that the first patient has been dosed in a first-in-human clinical trial testing BND-35, a humanized ILT3/LILRB4 antagonist antibody.

The first patient was administered BND-35 as a monotherapy at the Institute of Oncology, Davidoff Center, Rabin Medical Center, Israel, one of the six Israel and US trial study sites. The phase 1, open-label, dose escalation study aims to explore the safety, tolerability, anti-tumor activity, pharmacokinetics and exploratory biomarkers for BND-35 as a monotherapy and in combination with two approved drugs, a PD-1/PD-L1 inhibitor or the anti-EGFR drug, cetuximab. The decision to test the combination of BND-35 with cetuximab was driven by supportive pre-clinical data and a deep understanding of the BND-35 mechanism of action. BND-35 augments antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity, which are mediated by binding of Fc receptors (FcR) on immune cells to antibodies as cetuximab and additional tumor targeting antibodies. Each arm of the trial includes the patient populations most likely to benefit from ILT3/LILRB4 blockade based on translational research findings.

“The BND-35 trial design introduces a novel combination therapy that targets the immunosuppressive cell milieu within the tumor microenvironment (TME),” commented Professor Salomon Stemmer, M.D., Head of Research, Development and Innovation and Deputy Director of Davidoff Center at the Rabin Medical Center, and a clinical investigator in the trial. “There’s a pressing need for innovative treatments for cancers that are resistant to existing therapies. Given its promising preclinical efficacy, we’re eager to assess BND-35’s potential in overcoming ILT3/LILRB4-mediated immunosuppression.”

"ILT3 is a unique receptor expressed on various suppressive myeloid cells within the TME and the binding of various ligands to ILT3 maintains the TME in an immunosuppressive state. BND-35 has been demonstrated to effectively block the interaction between ILT3 and its various ligands, thereby enhancing the immune system's ability to fight tumors, resulting in increased physiological anti-tumor



responses and enhanced tumor cell destruction by immune cells," stated Tsuru Peretz, project manager for the BND-35 program.

About ILT3/LILRB4 and BND-35

BND-35 is a novel anti-ILT3/LILRB4 antagonist antibody developed for the treatment of solid tumors. BND-35 binds ILT3/LILRB4 with high affinity and blocks its interaction with ligands present in the TME. In vitro and ex vivo studies have demonstrated that BND-35 as monotherapy or in combination with anti-PD-1/PD-L1 pathway inhibitors as well as with anti-EGFR agents, enhances the pro-inflammatory activity of various myeloid cells and inhibits the immunosuppressive activity of suppressive myeloid cells, thereby restoring T cell and NK cell activity.

BND-35-induced immune activity enhancement was demonstrated in a unique system of patient-derived tumoroids. In vivo, blocking ILT3/LILRB4 activity with BND-35, as monotherapy or in combination therapy, resulted in decreased tumor growth and induced a pro-inflammatory phenotype in tumor-resident T cells and myeloid cell populations. Further information about the trial is available in <https://www.clinicaltrials.gov/study/NCT06274437?term=BND-35&rank=1> (Trial Identifier: NCT06274437).

About Biond Biologics

Biond Biologics is at the forefront of developing cutting-edge therapies targeting novel oncology pathways and enabling the intracellular delivery of biologics. By exploring immunoregulatory pathways and pioneering intracellular delivery platforms, Biond Biologics aims to translate advanced science and innovative technologies into transformative drugs for diseases with significant unmet needs. The company fosters synergistic collaborations with leading biopharmaceutical entities to formulate groundbreaking medicines to patients worldwide.

In addition to BND-35, Biond Biologics' programs include BND-22 (SAR444881), a multi-cell checkpoint first-in-class ILT2 blocking antibody that was partnered with Sanofi. In addition, it is developing BND-67, a novel agent for attenuation of CD28 shedding, an immune-evasion mechanism discovered by Biond's scientists, which could overcome PD-1 pathway blockade resistance. Biond Biologics is also developing INspire – an innovative technological platform that enables the intracellular delivery of protein therapeutics, such as antibodies, proteins or enzymes, into cells.



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