Biond Biologics Announces Initiation of a Phase 2 Study of BND-22 in Combination with anti-PD-1 therapy

Trial will identify response and predictive biomarkers for the combination of BND-22, a first-in-class anti-ILT2 antibody with anti-PD1 therapy

Misgav, Israel, August 3, 2025 – **Biond Biologics Ltd.** ("Biond" or the "Company"), a private, clinical-stage biopharmaceutical company developing novel immunotherapies for cancer and autoimmunity, today announced the launch of a Phase 2 study of BND-22 (SAR444881) in combination with anti-PD-1 therapy in patients with locally advanced or metastatic NSCLC previously treated with immune-oncology (IO) therapies, and anti–PD-1/PD-L1 naïve patients with MSS-CRC or ovarian cancer (ClinicalTrials.gov Identifier: NCT06651593).

The new study is led by Dr. Aung Naing from The University of Texas MD Anderson Cancer Center and is expected to enroll patients whose tumors are known to express HLA-G, which is the ligand of ILT2 receptor, and that was found to be correlated with response to treatment with BND-22. The primary objective of the study is to identify biomarkers related to the mechanism of action of BND-22 alone and in combination with an anti-PD-1 therapy and predictive biomarkers related to response, survival and resistance. Secondary study objectives include efficacy of BND-22 and its combination with anti-PD-1 therapy, and safety/tolerability. Biond retains worldwide development and commercialization rights to BND-22.

"The foundation of the biomarker study is supported by the results of the first-in-human Phase 1/2 dose-escalation study of BND-22 which demonstrated a favorable safety profile and encouraging anti-tumor activity both as monotherapy and in combination with approved therapies. Dose-dependent activation of ILT2-expressing T cells, NK cells and monocytes were observed, with several confirmed clinical responses in heavily pre-treated patients," said Dr Natalia Ashtamker, VP Clinical Development at Biond. "This study is an important step toward precision development of BND-22, our multi-cell checkpoint inhibitor, and by combining it with PD-1 blockade and deeply profiling patient samples, we aim to accelerate BND-22 into registrational trials for the tumors most likely to benefit. Additionally, we continue to treat responders from the Phase 1/2 trial that are still benefiting from BND-22. We are excited to collaborate with MD Anderson on this biomarker-rich study, which will guide the design of future registrational programs".

About BND-22

BND-22 is a humanized IgG4 antagonist antibody targeting the ILT2 receptor, developed for the treatment of solid tumors. ILT2 is an inhibitory immuno-modulating receptor expressed on both innate and adaptive immune cells. It binds to major histocompatibility complex (MHC) class I molecules, including HLA-G, an immunosuppressive protein expressed by various tumor types.

Preclinical studies have demonstrated that BND-22 exerts broad anti-tumor effects by disrupting ILT2-mediated "do not eat me" signals in macrophages and activating NK and CD8+ lymphocytes.

BND-22-001, a Phase 1/2 multicenter, open-label, dose-escalation, dose-expansion and dose optimization study enrolled patients with advanced solid tumors known to express HLA-G. The first-in-human Phase 1 study (BND-22-001, NCT04717375), designed to evaluate the safety and tolerability of BND-22, both as a monotherapy and in combination with the approved cancer therapies cetuximab and pembrolizumab. The phase 2 included evaluations of BND-22 as monotherapy in cholangiocarcinoma and in combination with cetuximab in patients with non-small cell lung cancer (NSCLC) and colorectal cancer (CRC).

https://clinicaltrials.gov/ (Trial Identifier: NCT04717375).

About Biond Biologics

Biond Biologics is a drug discovery and development company focused on developing innovative therapies for novel oncology targets identified through research of immunoregulatory pathways.

Biond's clinical pipeline includes BND-22 (SAR444881), a phase 2, first-in-class antibody that acts as a multi-cell checkpoint inhibitor targeting the ILT2 receptor. BND-22 enhances the anti-tumor activity of both innate and adaptive immune cells by blocking the interaction between ILT2 and HLA-G, for the treatment of solid tumors. Biond is also developing BND-35, a unique anti-ILT3/LILRB4 blocking antibody that drives the suppressive tumor microenvironment to become more pro-inflammatory. BND-35 also augments the Antibody dependent cellular cytotoxicity (ADCC) and Antibody dependent cellular phagocytosis (ADCP) activity of tumor-targeted antibodies. BND-35 is being evaluated in a FIH, Phase 1 trial dose escalation as of May 2024. Biond is also developing BND-67, a first-in-class antibody, that specifically prevents the shedding CD28 from T cells. Blocking CD28 shedding drives prolonged T cell activation and enables safe and sustained immune responses. This unique approach can overcome resistance in patients treated with T cell-targeting therapies, such as anti-PD1/PDL1 blockers and T cell engagers. BND-67 is expected to enter a phase 1 trial in 2026.

Biond was founded in 2016, by Tehila Ben Moshe, Ph.D., Ori Shilo, and a team of accomplished scientists and drug developers from the Israel biopharmaceutical industry. www.biondbio.com.

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