



## **Biond Biologics to Regain Full Rights to BND-22, a Novel Immune Checkpoint Inhibitor Targeting the ILT2 Receptor**

**Following positive results from the Phase 1 dose escalation study, BND-22 (SAR444881) is now being tested in Phase 2 trials as monotherapy for patients with cholangiocarcinoma and in combination with cetuximab in patients with non-small cell lung cancer (NSCLC) and colorectal cancer (CRC).**

**Misgav, Israel, March 3, 2025** – **Biond Biologics Ltd.** (“Biond” or the “Company”), a private clinical-stage biopharmaceutical company developing novel therapies for cancer, today announced that it would regain full rights to BND-22 (SAR444881) from Sanofi. Sanofi is returning the rights of BND-22 as part of their broader R&D prioritization to focus on programs that support the company’s strategy. Biond and Sanofi, are working together to complete full transfer of the BND-22 program to Biond.

In January 2021, Biond entered into an exclusive worldwide license agreement with Sanofi for the development and commercialization of BND-22. As part of the agreement, Biond collaborated with Sanofi to initiate a 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 1 dose-escalation study was successfully completed and demonstrated a favorable safety profile across all patient groups. More specifically, data showed that BND-22 was well-tolerated and exhibited anti-tumor activity in heavily pretreated patients. Consistent with preclinical findings, a dose-dependent upregulation of activation markers was observed in monocytes and ILT2-expressing T and natural killer (NK) cell subsets. Notably, several confirmed clinical responses to both monotherapy and combination therapies regimens, were reported during the dose-escalation phase. These findings highlight the potential of BND-22 to address critical unmet needs in oncology.

Building on these encouraging results, Sanofi initiated enrollment for a Phase 2 dose-optimization and expansion study (BND-22-001, NCT04717375). The study was designed to evaluate BND-22 as monotherapy for patients with cholangiocarcinoma and in combination with cetuximab for patients with non-small cell lung cancer (NSCLC) or colorectal cancer (CRC). For more information about the trial, please visit <https://clinicaltrials.gov/> (Trial Identifier: NCT04717375).

“As part of the agreement between Biond and Sanofi, Biond will regain full rights to BND-22, including access to the clinical data generated by Sanofi,” said Dr. Tehila Ben Moshe, Biond’s CEO and co-founder. “Sanofi has been an outstanding partner, and together, we have made remarkable progress in advancing the clinical development of BND-22. We remain committed to the continued development of BND-22 program, whether independently or in partnership with strategic collaborators”.

“We are encouraged by the data demonstrated so far for BND-22 in the dose-escalation and dose-expansion study”, said Dr. Natalia Ashtamker, Biond’s VP of Clinical Development. “We intend to continue treating patients who are benefiting from BND-22 treatment in the BND-22-001 study



and are looking forward to the initiation of a Phase 2 biomarker study of BND-22 in combination with anti-PD-1 therapy”.

### **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 study 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). Additionally, a future Phase 2 biomarker trial will explore BND-22 in combination with an anti-PD-1 agent in NSCLC, CRC and ovarian cancers.

<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. In parallel, it is developing a dedicated platform to facilitate the intracellular delivery of payloads, including biologics.

Biond’s clinical pipeline includes BND-22, a multi-cell checkpoint inhibitor targeting ILT2, and 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 cancer-targeted therapies. BND-35 blocks the interaction between ILT3 and various ligands, including fibronectin, which can serve as a biomarker for patient selection. BND-35 entered a Phase 1 trial in May 2024. Biond is also developing BND-67, a first-in-class antibody, that specifically prevents the shedding of 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. BND-67 is expected to enter a phase 1 trial in 2026. In addition to its pipeline of immunotherapy agents, Biond is also developing INspire, a revolutionary platform that allows pH-specific delivery of various molecules, including biological drugs and small molecules into cancer cells.

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](http://www.biondbio.com).



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