Biond Biologics Announces First Patient Dosed in Phase 1 Clinical Trial of BND-22, a Novel Immune Checkpoint Inhibitor Targeting the ILT2 Receptor

Preclinical data demonstrated broad anti-tumor effect of BND-22 through the targeting of ILT2-mediated "do not eat me" signals in macrophages and by activating NK and $CD8^+$ lymphocytes

The phase 1 study will evaluate the safety, tolerability, and anti-tumor activity of BND-22 in advanced cancer patients with tumor types known to express the immunosuppressive protein HLA-G

As previously announced, Biond has entered into a strategic collaboration with Sanofi for the development of BND-22 (SAR444881)

Misgav, Israel, April 26, 2021 – **Biond Biologics Ltd.** ("Biond" or the "Company"), a private clinical-stage biopharmaceutical company, developing novel immunotherapies for cancer and a platform enabling the intracellular delivery of biologics, today announced that the first patient has been dosed in the first-in-human, phase 1 clinical trial of BND-22 (SAR444881), an Ig-Like Transcript 2 (ILT2) receptor blocking antibody.

The first patient was administered BND-22 at the Oncology Research Unit of the Tel Aviv Sourasky Medical Center, Tel Aviv, Israel, one of the six US and Israel trial sites planned to initially participate in the phase 1, open-label, dose escalation study exploring the safety, tolerability, pharmacokinetics (PK), anti-tumor activity, and exploratory biomarkers for BND-22 activity in patients with select advanced solid tumors.

"BND-22 represents a novel approach to cancer immunotherapy targeting both adaptive and innate immune cells," said Ravit Geva, M.D., Research Unit Head and Deputy Director, Division of Oncology at the Tel Aviv Sourasky Medical Center, and a clinical investigator in the trial. "There continues to be an urgent need to develop new treatments for patients with cancers refractory to standard of care therapy. BND-22 has demonstrated compelling preclinical activity, and we look forward to further investigate the potential of ILT2 blockade in this Phase 1 study."

"The entry of BND-22 into the clinic is a significant milestone for Biond as it represents the achievement of an important aspect of the company's vision to progress our novel medicines into clinical evaluation while using our drug discovery, development, and translation capabilities" said Tehila Ben Moshe, Ph.D., Co-Founder and Chief Executive Officer of Biond. "BND-22, a multi-cell checkpoint inhibitor, was studied extensively by our scientific team for several years and was found to have the potential to improve upon current treatment paradigms, either as a monotherapy or in combination. Based on in-depth translational studies of real-world patient samples we have designed the Phase 1 trial to focus on patient populations we believe are most likely to respond to ILT2 blockade. We look forward to the results of the BND-22-001 trial as we strive to improve the treatment of cancer patients with dire needs for new therapies."

Biond announced on January 12th, 2021 an exclusive worldwide license agreement with Sanofi, for the development and commercialization of BND-22. Under the terms of the agreement, Biond will lead the first-in-human, phase 1 study of BND-22, evaluating its safety and tolerability as a single agent and in combination with approved cancer therapeutics as well as exploring the association between BND-22 anti-tumor activity and select tumor and blood-based biomarkers; Sanofi will assume clinical development and commercialization responsibilities thereafter.

About BND-22

BND-22 is a humanized IgG4, antagonist antibody targeting the ILT2 receptor in development for the treatment of solid tumors. ILT2, a member of the ILT family of immuno-modulating receptors, is an inhibitory receptor expressed on both innate and adaptive immune cells that binds major histocompatibility complex (MHC) class I molecules including HLA-G, an immunosuppressive protein expressed by multiple tumor types.
BND-22 has been shown in preclinical studies to have a broad anti-tumor effect by targeting ILT2-mediated "do not eat me" signals in macrophages and by activating NK and $CD8^+$ lymphocytes. The program is supported by a comprehensive biomarker strategy designed to guide patient enrollment in advanced clinical trials.

BND-22-001 is the first-in-human clinical trial of BND-22. It is a Phase 1/2 multicenter, open-label, dose escalation and expansion study enrolling advanced cancer patients with solid tumor types known to express HLA-G. Following dose escalation and determination of BND-22' recommended Phase 2 dose, the study design allows for the expansion of patient cohorts to evaluate the anti-tumor activity of BND-22 in specific tumor types. BND-22-001 is planned to be expanded to also evaluate the safety and anti-tumor activity of BND-22 in combination with other therapies. For more information about the trial, including participating medical centers, please visit 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 by uncovering immunoregulatory pathways and by enabling the intracellular delivery of biologics. Biond aims to translate high quality science and out-of-the-box, disruptive thinking into transformational drugs for diseases with high unmet needs. The company's vision is to deliver innovative medicines to patients while fostering synergistic long-term collaborations with leading biopharmaceutical companies.

Biond's leading development programs include BND-22, a multi-cell checkpoint inhibitor targeting ILT2, and BION-206, a novel agent developed for overcoming PD-1 blockade resistance by targeting soluble CD28; an immune evasion mechanism discovered by Biond scientists. The company is also developing BND-35 – an ILT3 blocking antibody, that targets suppressive myeloid cells in the tumor microenvironment.
In addition to its pipeline of immunotherapy agents, Biond is developing INspire – an innovative technological platform that enables the intracellular delivery of protein therapeutics, such as antibodies or enzymes, into 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. The lead investors in the company are Israel Biotech fund ("IBF") and Harel Insurance. For more information, visit www.biondbio.com.

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