# IO Biotech Announces Clinical Collaboration with MSD to Evaluate IO102-IO103 with KEYTRUDA® (pembrolizumab) as First-Line Treatment in Metastatic Melanoma Patients in a Phase 3 Trial

**- IO Biotech to initiate a Phase 3 combination trial of IO102-IO103 and KEYTRUDA, which is designed to be potentially registrational for IO102-IO103**

*Copenhagen, Denmark – September 14, 2021:* IO Biotech, a clinical-stage biopharmaceutical company developing novel, immune-modulating cancer therapies based on its T-win® technology platform, announced today that it has entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the US and Canada), through a subsidiary. The purpose of the collaboration is to evaluate IO Biotech's lead candidate, IO102-IO103, in combination with KEYTRUDA (pembrolizumab), MSD's anti-PD-1 (programmed death receptor-1) therapy, in patients with previously untreated, unresectable or metastatic (advanced) melanoma. IO102-IO103 is an investigational cancer vaccine designed to target the immunosuppressive mechanisms mediated by key immunosuppressive proteins such as Indoleamine 2,3-dehydrogenase (IDO) and PD-L1.

"We are pleased to collaborate with MSD to study the potential of our IDO and PD-L1 derived immune-modulating therapy in combination with KEYTRUDA as part of our broad, late-stage development program," said Mai-Britt Zocca, PhD, CEO and founder of IO Biotech. "Although therapies are available to treat metastatic melanoma, the clinical outcomes for patients with advanced disease remain poor and novel therapeutic options are desperately needed. We look forward to expanding our data set on IO102-IO103 with KEYTRUDA combination results, which we believe will support the potential approval of IO102-IO103 as a first-line therapy for melanoma and other difficult-treat-cancers."

The planned Phase 3 trial will be an open label, randomized clinical trial that will evaluate the combination of IO102-IO103 with MSD's anti-PD-1 therapy, KEYTRUDA, versus KEYTRUDA alone in patients with previously untreated, unresectable or metastatic (advanced) melanoma. Biomarker studies will also be conducted. Under the terms of the agreement, IO Biotech will sponsor the Phase 3 trial and MSD will supply KEYTRUDA.

In a Phase 1/2 clinical trial of 30 patients with metastatic melanoma, IO102-IO103, in combination with anti PD1 mAb, demonstrated an ability to induce meaningful tumor regression and establish durable antitumor response while achieving a manageable tolerability profile for patients. In this trial, we observed a confirmed overall response rate (ORR) of 73% and a complete response (CR) rate of 47%. Based on the results from this trial, IO102-IO103, in combination with pembrolizumab, was granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for treatment of unresectable/metastatic melanoma.

**About IO102-IO103/KEYNOTE-D18**
An open label, randomized Phase 3 clinical trial of IO102-IO103 in combination with pembrolizumab versus pembrolizumab alone in patients with previously untreated, unresectable or metastatic (advanced) melanoma.

Biomarker studies will be conducted in parallel to the above.

The clinical trials will be sponsored by IO Biotech. IO Biotech maintains global commercial rights to IO102-IO103.

**About IO Biotech**
IO Biotech is a clinical-stage biopharmaceutical company developing novel, immune-modulating cancer therapies based on its T-win® technology platform. The T-win® platform is a novel approach to cancer immunotherapy designed to activate naturally occurring T cells to target immunosuppressive mechanisms. IO Biotech is advancing in clinical studies its lead immuno-oncology candidate, IO102-IO103, targeting IDO and PD-L1, and through clinical and preclinical development its other pipeline candidates. IO Biotech is headquartered in Copenhagen, Denmark. For further information, please visit www.iobiotech.com

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