



## IO Biotech Provides Business Update

- *Independent data monitoring committee recommends that the company's Phase 3 trial evaluating IO102-IO103 in combination with pembrolizumab in first-line advanced melanoma patients continue without any modifications; the trial is enrolling patients at more than 80 active sites globally.*
- *Encouraging initial data reported from 9 evaluable non-small cell lung cancer patients from the company's ongoing Phase 2 solid tumor basket trial evaluating IO102-IO103 in combination with pembrolizumab; the company anticipates additional data from this study in 2023.*
- *Agreed to support an investigator-initiated study with Johns Hopkins University evaluating the addition of IO102-IO103 to neoadjuvant pembrolizumab and adjuvant pembrolizumab prior to curative-intent surgical care for squamous cell carcinoma of the head and neck (SCCHN), expected to begin in the first half of 2023.*

New York, New York – January 9, 2023: IO Biotech (Nasdaq: IOBT), a clinical-stage biopharmaceutical company developing novel, immune-modulating cancer vaccines based on its T-win<sup>®</sup> vaccine platform, today provided a business update.

“Throughout 2022, the team at IO Biotech made major progress on multiple fronts – advancing our lead program into a global Phase 3 pivotal trial for patients with advanced melanoma, initiating a Phase 2 solid tumor basket study for IO102-IO103 in combination with pembrolizumab, and continuing research on our pipeline assets,” said Mai-Britt Zocca, Ph.D., President and Chief Executive Officer of IO Biotech. “At year end, we had more than 80 clinical trial sites in the United States, Europe, Australia, Israel and South Africa active in our Phase 3 trial, and we observed strong interest and accelerating enrollment trends in both the Phase 3 melanoma trial and the Phase 2 basket study for multiple solid tumors. Importantly, today we report encouraging initial data from the first 9 efficacy evaluable patients in the lung cancer cohort from our Phase 2 study with four patients achieving a partial response and four patients with stable disease.”

Dr. Zocca continued, “In 2023, we are focusing our full attention on clinical execution and advancing our clinical experience with IO102-IO103, through both our own clinical trials as well as various investigator-initiated studies. We now have four investigator-initiated studies underway in the United States and Europe, with an additional grant being finalized. The level of enthusiasm from leading cancer institutions around the world to work with our novel, investigational immune-modulating vaccine we believe is a testament to the potential broad applicability of an off-the-shelf cancer vaccine with a favorable safety profile.”



## Recent Highlights

- The independent data monitoring committee for the company's Phase 3 trial (IOB-013/KN-D18) evaluating IO102-IO103 in combination with pembrolizumab in first-line advanced melanoma patients convened its first meeting in December to review initial safety data from the trial and recommended that the trial continue without any modifications; the trial is enrolling patients at more than 80 active sites globally. The trial protocol calls for an interim analysis of overall response rate one year after 75% of the patients have been enrolled, which could allow for submission of a Biologics License Application for an accelerated approval in the US.
- The company recently agreed to support an investigator-initiated study with Johns Hopkins University evaluating the addition of IO102-IO103 to neoadjuvant pembrolizumab and adjuvant pembrolizumab prior to curative-intent surgical care for squamous cell carcinoma of the head and neck (SCCHN). The trial is expected to begin in the first half of 2023. The company is now supporting four investigator-initiated trials evaluating IO102-IO103 in combination regimens across a variety of cancer types.
- Encouraging initial data was reported today for the first time from 10 lung cancer patients in the company's Phase 2 basket study (IOB-022/KN-D38) evaluating IO102-IO103 in combination with pembrolizumab in patients with non-small cell lung cancer, head and neck cancer, or bladder cancer. Of the 10, 9 were efficacy evaluable per protocol having received at least one full cycle of treatment. Among the 9 evaluable patients, 4 patients had a partial response while 4 had stable disease; one patient had progressive disease. The safety profile observed to date in this study is consistent with prior clinical experience with IO102-IO103. The company anticipates reporting additional data from this study in 2023.

"These initial data suggest that the combination of IO102-IO103 with pembrolizumab is active," said David Gandara, MD, Co-Director, Center for Experimental Therapeutics in Cancer at UC Davis Comprehensive Cancer Center, the lead center for the study. "If these early data are sustained, I believe they would translate into a successful study and could support further development of this combination for patients with non-small cell lung cancer."

The company ended 2022 with approximately \$142.7 million in cash and cash equivalents (preliminary and unaudited) and anticipates this will be sufficient to fund operations into mid-2024.

## About the IOB-013/KN-D18 Phase 3 Clinical Trial

IOB-013/KN-D18 (Clinical Trials.gov: NCT05155254) is an open label, randomized Phase 3 clinical trial being conducted in collaboration with Merck of IO102-IO103 in combination with pembrolizumab versus pembrolizumab alone in patients with previously untreated, unresectable or metastatic (advanced) melanoma. Target enrollment is 300 patients from centers spread across the United States, Europe, Australia, Israel and South Africa. Biomarker



analyses will also be conducted. IO Biotech is sponsoring the Phase 3 trial and Merck is supplying pembrolizumab. IO Biotech maintains global commercial rights to IO102-IO103.

### **About IOB-022/KN-D38 Phase 2 Solid Tumor Basket Study**

IOB-022/KN-D38 is a non-comparative, open label trial to investigate the safety and efficacy of IO102-IO103 in combination with pembrolizumab in each of the following first-line indications: NSCLC, SCCHN, and UBC. The clinical trial is sponsored by IO Biotech and conducted in collaboration with Merck. IO Biotech maintains global commercial rights to IO102-IO103.

### **About IO102-IO103**

IO102-IO103 is an investigational cancer immunotherapy designed to target the immunosuppressive mechanisms mediated by the key immunosuppressive proteins indoleamine 2,3-dioxygenase (IDO) and PD-L1.

### **About IO Biotech**

IO Biotech is a clinical-stage biopharmaceutical company developing novel, immune-modulating cancer vaccines based on its T-win<sup>®</sup> vaccine platform. The T-win platform is a novel approach to cancer vaccines designed to activate T cells to target the most important immunosuppressive cells in the tumor microenvironment. IO Biotech is advancing in clinical studies its lead cancer vaccine candidate, IO102-IO103, targeting IDO and PD-L1, and through preclinical development its other pipeline candidates. IO Biotech is headquartered in Copenhagen, Denmark and has US headquarters in New York, New York.

For further information, please visit [www.iobiotech.com](http://www.iobiotech.com)

### **Forward-looking Statement**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including regarding current or future clinical trials, their progress, enrollment or results, or the company's financial position or cash runway, are based on IO Biotech's current assumptions and expectations of future events and trends, which affect or may affect its business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Except to the extent required by law, IO Biotech undertakes no



obligation to update these statements, whether as a result of any new information, future developments or otherwise.

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