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Hummingbird Diagnostics Publishes Study of miRisk as a Predictor of Immunotherapy Efficacy in Advanced-Stage NSCLC

- *Proprietary microRNA signature (miRisk) may support immunotherapy treatment decisions as a blood-based complementary diagnostic*
- *Results published in Journal of Thoracic Oncology Clinical and Research Reports*

HEIDELBERG, Germany, June 23, 2022 – Hummingbird Diagnostics GmbH, a leader in reading blood-based microRNAs for early disease detection and characterization, today announced a publication in the *Journal of Thoracic Oncology Clinical and Research Reports* that demonstrates their blood 5-microRNA signature (miRisk) to predict survival following immunotherapy in advanced non-small cell lung cancer (NSCLC) patients with high PD-L1 expression.

The study builds on results published in March 2022 in *npj Precision Oncology* [1] and addresses a current clinical dilemma; which advanced-stage NSCLC patients with high PD-L1 expression (≥ 50%) should be treated with immunotherapy (IO) alone versus immunotherapy in combination with chemotherapy (ICT)? Both are currently licensed therapies in international guidelines, yet no biomarkers exist to guide this decision. Optimizing this choice using principles of precision medicine will have significant impacts on patient survival and quality of life, by including toxic chemotherapy only when deemed necessary. Hummingbird's results demonstrate a significant association between overall survival (OS) and the miRisk score in IO treated patients and furthermore highlight its value as a predictive biomarker for type of treatment (IO or ICT). The score could identify high-risk patients who might benefit from treatment with ICT, as opposed to IO, and support treatment decisions as a blood-based complementary diagnostics.

"Patients with advanced, non-oncogene-driven, non-small-cell lung cancer (NSCLC) with high PD-L1 expression are eligible for treatment with immunotherapy. There is, however, an urgent medical need for biomarkers identifying cases that require additional combination with chemotherapy," says Timothy Rajakumar, MD PhD, Medical Director of Hummingbird Diagnostics and first author on the study. "The miRisk score represents an immune focused biomarker that is specifically predictive of response to immunotherapy and could serve as the foundation for a complementary diagnostic to guide therapeutic decisions and thereby allow physicians to more accurately choose between treating patients with IO alone vs. ICT."

The study was performed in collaboration with Professor Petros Christopoulos from the Thoraxklinik at Heidelberg University Hospital, as well as with Professor Martin Reck, Grosshansdorf. A valuable study cohort was assembled from a total of 155 whole blood samples, prospectively collected from patients with stage IV NSCLC with PD-L1 TPS ≥50%, before they had been initiated on treatment with IO or ICT. These samples

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were subject to small RNA sequencing and used to train and validate a 5-microRNA model to predict OS (miRisk). This model was significantly associated with OS and, most importantly, with the type of therapy (IO or ICT) therefore offering the promise to support clinical decisions surrounding choice of therapy.

Bruno Steinkraus, PhD, Chief Scientific Officer of Hummingbird Diagnostics remarked: "We believe our analysis will provide a blueprint for host-based integrative biomarker usage in a field of pressing medical need with the emergence of more complex immunotherapy regimens. Taken together with the relatively simple use of a peripheral whole blood test that does not require pipetting at point of care, we envision applicability of this technology to non-invasive therapy guidance for the IO or ICT decision in PD-L1 high patients."

The open-access article can be found online on the journal's website: https://www.jtocrr.org/article/S2666-3643(22)00093-5/fulltext

[1]Rajakumar T et al. A blood-based miRNA signature with prognostic value for overall survival in advanced stage non-small cell lung cancer treated with immunotherapy. NPJ Precis Oncol 2022; 6:19

About Hummingbird Diagnostics GmbH

Hummingbird is harnessing the predictive power of blood-borne miRNAs to provide insights into human health and disease. Analyzing miRNAs with Hummingbird's platform holds the potential for early disease detection, disease-specific prognostics, treatment response prediction, and the development of patient-centric therapies. To learn more, visit: https://www.hummingbird-diagnostics.com

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