multi-gene, amplification-based detection system that simultaneous analyzes over 150 miRNAs. Data were preprocessed, modeled and trained on 51 patients to derive a prediction algorithm, which was validated on 20 patients.

Results: Three months after the administration of the therapy, patients were examined for response and categorized into two groups, disease control (CR/PR) or disease progression (PD) based on RECIST 1.1. A prediction algorithm was derived based on the miRNA expression patterning of 51 patients using data-driven approach. When validated on 20 patients, the overall accuracy of the response prediction is 80%, with a PPV of 73% and a NPV of 89%.

Conclusions: Utilizing data-driven modeling, circulating miRNA classifier shows significant predictive power. Validation is currently being performed in patients undergoing treatment. We believe this would be one of the first evidence demonstrating circulating miRNAs as potential predictive biomarkers for immunotherapy response in advanced-stage cancer patients.

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321O Data-driven miRNA classifier as response predictor for immune checkpoint inhibitor treatment in advanced-stage cancer patients

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Background: The administration of immunotherapeutic antibodies against immune checkpoint proteins has shown great promises in the treatment of cancer patients. However, the response rate remains low, suggesting a strong need for predictive biomarkers. While PD-L1 is a commonly accepted biomarker, it is inadequate. Circulating microRNAs (miRNAs) have been shown as predictive biomarkers in various types of cancer therapies. We sought to determine whether miRNAs could predict response to immune checkpoint inhibitor in advanced-stage cancer patients.

Methods: In a prospective clinical study, miRNAs are isolated from the plasma of patients of various cancer types prior to immunotherapeutic treatment. Once reverse-transcribed into cDNA, expression profiling of miRNAs was performed using a