Epigenomic platform detects early-stage pancreatic cancer

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Bluestar Genomics has published study results in the peer-reviewed journal *Nature Communications* demonstrating the power of the company's platform to detect pancreatic cancer in its early stages, addressing the unmet need of more than 60,000 patients diagnosed with the disease each year in the United States alone. The epigenomic platform analyzes a simple blood draw and identifies the presence of pancreatic cancer in patients' DNA circulating in their blood, enabling

non-invasive, precise detection of the disease, which could lead to more timely treatment and improved patient survival.

"Pancreatic cancer is a deadly disease with no current screening methods for the larger population," said Samuel Levy, Ph.D., chief executive and chief scientific officer at Bluestar Genomics, and the senior author of the study. "The *Nature Communications* publication demonstrates that our technology provides a crucial foundation for the development of a screening test that will set a new standard for liquid biopsies and the future of cancer screening."

Published results from a study of 307 patients, including both men and women ages 40 or older, showed that Bluestar Genomics' technology identified distinctive patterns in thousands of genes that could serve as a biomarker for blood-based pancreatic cancer detection to enable the development of a future cancer screening test. The study includes application of the detection strategy to novel samples not included in the development set, providing validation that holds promise for early-stage detection in larger patient groups.

"Pancreatic cancer is the third-leading cause of cancer death in the U.S. and the absence of a robust screening test in clinical care means that this cancer is often detected at an advanced stage, leaving patients with fewer treatment options," said Kelly Bethel, M.D., chief medical officer at Bluestar Genomics. Gulfem Guler, Ph.D, the lead author of the study and Bluestar Genomics' lead scientist on pancreatic cancer research further stated, "This publication demonstrates that the utilization of our epigenetics platform can identify tumor biology in plasma earlier, which can bring the possibility of earlier treatment options to patients, potentially increasing their survival."

In pancreatic cancer patients, circulating tumor cells and circulating tumor DNA are shed into the blood and can be easily obtained through a

blood draw, providing a unique potential for early diagnosis, forecasting disease prognosis, and monitoring of therapeutic response.

Unlike current diagnostic methods that rely on disease tissue to characterize the condition, Bluestar Genomics' blood-based 5hmC assay is able to detect signals of disease in a patient's plasma via DNA-based changes found in gene and gene regulatory regions.

This study's results strongly suggest that a clinical test employing newly identified biomarkers may promote more effective early-stage pancreatic cancer screening, which has significant value since many patients do not show symptoms until the disease has advanced to a late stage. Based on the results and inspired by the collaboration with its research and patient advocate partners, Bluestar will continue its development work required to commercialize a test in the coming years.

More information: Gulfem D. Guler et al, Detection of early stage pancreatic cancer using 5-hydroxymethylcytosine signatures in circulating cell free DNA, *Nature Communications* (2020). DOI: 10.1038/s41467-020-18965-w

Provided by Bluestar Genomics

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