BLUESTAR GENOMICS PRESENTS NEW DATA SHOWING ITS LIQUID BIOPSY TEST DETECTS PANCREATIC CANCER SIGNAL

Analytical performance data presented at the American Pancreatic Association meeting
The company also appointed seasoned industry leader Jim Vaughn as its chief commercial officer

SAN DIEGO, Calif. — (BUSINESS WIRE)—Nov. 5, 2021—Bluestar Genomics, an innovative company leading the development of next-generation liquid biopsy approaches to early cancer detection, today announced the presentation of new analytical performance data on its proprietary non-invasive pancreatic cancer test at the American Pancreatic Association (APA) annual meeting. Data from the study showed that the company's test detected a pancreatic cancer signal in people across various age groups, including patients with new-onset diabetes, occurring in 25% of new pancreatic cancer cases.

Bluestar Genomics' pancreatic cancer test uses a standard blood draw to assess whether an individual has an abnormal DNA signal associated with pancreatic cancer. This one-of-its-kind test would allow for early diagnosis of pancreatic cancer, one of the deadliest cancers in part because there are no existing screening methods to enable early detection. When found early, accurate detection of pancreatic cancer enables more timely, potentially curative surgical and therapeutic options for patients. People with new-onset diabetes are at high-risk of pancreatic cancer. Out of an estimated 60,000 patients diagnosed each year with pancreatic cancer in the U.S. alone, nearly 25% are found to have new-onset diabetes before a pancreatic cancer diagnosis.

"Along with our test's recent designation by the FDA as a breakthrough device, the findings from this study presented at APA underscore the opportunity we have to make a positive difference for patients by bringing this pancreatic cancer test to market," said Samuel Levy, Ph.D., chief executive and chief scientific officer at Bluestar Genomics and lead author of the study. "Based on these results, we are moving forward with completing the analytical validation in the coming months and making a CLIA laboratory developed test available next year."

Unlike other liquid biopsy cancer tests, this pancreatic cancer-focused test is performed with Bluestar Genomics' groundbreaking epigenomics technology platform that uses state-of-the-art machine learning coupled with a DNA-based 5-hydroxymethylcytosine (5hmC) biomarker as a precise screening method for detecting cancer at earlier stages. By combining a novel 5-hydroxymethylation enrichment assay with high-throughput sequencing, it is possible to generate powerful predictive models using machine learning to enable the detection of pancreatic cancer in patients with high accuracy.

Pancreatic cancer is the third-leading cause of cancer death in the U.S., surpassing common cancers such as breast and prostate. Bluestar Genomics' test has the potential to screen an estimated one million adults diagnosed annually with new-onset diabetes in the U.S. for the early detection and treatment of pancreatic cancer, which could enable better patient outcomes.

The study presented at APA included 917 patients, examining whole blood samples from 117 patients with pancreatic cancer and 800 non-cancer control patients, with and without new-onset diabetes. The predictive model was trained on samples using 5hmC signals from cell-free DNA. When applied to the validation set, 50% of which were early stage (stages I and II) disease, this model showed a median of 51.5% sensitivity and 98% specificity. Results from the study demonstrated pancreatic cancer signal detection in plasma-derived cell-free DNA using 5hmC profiles. Overall, these findings showed that the model performed consistently well between the training and independent validation datasets.

In addition to completing the analytical validation, Bluestar Genomics is planning a large clinical study to further validate the use of this test to detect pancreatic cancer in patients with new-onset diabetes.

With the commercialization efforts for the test focused on pancreatic cancer as well as a growing pipeline of other epigenomic assays, the company also announced that Jim Vaughn, R. Ph., has joined the company as its chief commercial officer. Vaughn brings more than 20 years of strategic leadership experience in commercializing molecular tests in oncology, including a breadth of expertise in sales, marketing, and reimbursement strategy. Most recently, Vaughn led efforts to successfully commercialize the Oncotype DX® portfolio at Genomic Health/Exact Sciences, where he was the global chief commercial officer.

"Liquid biopsy continues to show great promise in improving cancer patient survival," said Vaughn. "Our epigenomics approach is to focus on the highest-risk cancers with the greatest needs, starting with pancreatic and certain women's cancers. I look forward to leading our efforts to bring new-generation liquid biopsy tests to physicians and patients to enable curative therapies."

"The positive data at APA along with Jim's appointment as CCO provide confidence for the company to move forward with commercial planning for our first product, with the goal of developing a pipeline of tests employing our unique type of epigenomics analysis," said Levy.

About Bluestar Genomics
Bluestar Genomics is an early cancer detection company focused on the development and commercialization of non-invasive epigenomic tests to detect cancer through a standard blood draw, earlier than existing methods and when the disease is still treatable. The company uses its one-of-a-kind epigenomic platform that combines best-in-class bioinformatics and genomic technologies to analyze individuals' changing biology that is yet to produce symptoms. Leveraging its novel liquid biopsy technology, Bluestar Genomics is initially focused

on high-mortality cancers with the greatest need for early detection, starting with pancreatic and women's cancers. With locations in San Diego and the San Francisco Bay Area, Bluestar Genomics collaborates with top research institutions and is supported by multiple global healthcare and technology investors and pharmaceutical collaborations.
For more information, visit https://www.bluestargenomics.com.