PRESS RELEASE

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Immunovia completes analytical validation of its next-generation pancreatic cancer test

LUND (SWEDEN) – Immunovia (IMMNOV: Nasdaq Stockholm), the pancreatic cancer diagnostics company, today announces that the company has completed the analytical validation of its next-generation test designed to detect early-stage pancreatic cancer. The validation demonstrated excellent results across a comprehensive set of parameters, reinforcing the reliability and robustness of the test.

The biomarkers that make up Immunovia's next-generation test demonstrated excellent performance in a series of experiments. These experiments evaluated over 23 key performance attributes of the next-generation test according to guidelines set by the Clinical and Laboratory Standards Institute (CLSI) under the guidance of Immunovia's lab director, Lisa Ford, Ph.D. The experiments were designed to meet the stringent requirements of the Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists (CAP) accreditation standards, ensuring that the test meets the highest industry benchmarks.

Key highlights of the analytical validation include,

- **Precision:** The test demonstrated high precision and reproducibility across multiple testing runs, ensuring reliable results.
- **Linearity:** The test provided accurate readings at varying biomarker concentrations.
- **Sensitivity:** The assay exhibited high sensitivity, enabling detection of the target biomarkers even at low levels.
- **Stability:** The biomarkers remained stable under various conditions (e.g., different temperatures), maintaining their integrity and ensuring accurate measurement.
- **Robustness:** The test showed consistent performance across different batches of testing supplies and laboratory settings, confirming its robustness.

The analytical validation was conducted using an automated ELISA analyzer, which significantly enhances both performance and throughput compared to Immunovia's prior IMMray platform as well as standard manual ELISA tests.

“We are happy to announce that our analytical validation results confirm the strong performance of our next-generation test. This achievement validates the quality of our analytical method and marks an important milestone to provide a reliable, convenient test that could ultimately improve patient outcomes by enabling early detection of pancreatic cancer. We are excited to be moving to the next phase, clinical validation,” says Lisa Ford, Ph.D., Lab Director at Immunovia.

Following the successful completion of the analytical validation, Immunovia has initiated a large-scale clinical validation study to assess the accuracy of its next-generation test in detecting stage 1 and 2 pancreatic cancer. This clinical validation is expected to be completed by December 2024. The results will provide crucial insights into the test’s clinical performance, including its sensitivity and specificity.

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Immunovia in brief
Immunovia AB is a diagnostic company whose mission is to increase survival rates for patients with pancreatic cancer through early detection. Immunovia is focused on the development and commercialization of simple blood-based testing to detect proteins and antibodies that indicate a high-risk individual has developed pancreatic cancer. Immunovia collaborates and engages with healthcare providers, leading experts and patient advocacy groups to make its test available to individuals at increased risk for pancreatic cancer.

USA is the world’s largest market for detection of pancreatic cancer. The company estimates that in the USA, 1.8 million individuals are at high-risk for pancreatic cancer and could benefit from annual surveillance testing.

Immunovia’s shares (IMMNOV) are listed on Nasdaq Stockholm. For more information, please visit www.immunovia.com

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