



IMMUNOVIA PUBLISHES DATA ON PANCREASURE IN HEREDITARY AND FAMILIAL HIGH-RISK INDIVIDUALS

Immunovia AB (IMMNOV: Nasdaq Stockholm), a pancreatic cancer diagnostics company, today announced that a new analysis of PancreaSure® test performance has been published in the peer-reviewed *Journal of Clinical Medicine*. The analysis evaluated PancreaSure in individuals at high risk for pancreatic cancer due to an inherited genetic mutation, a family history of pancreatic cancer, or both. In this population, the PancreaSure test demonstrated 77.5% sensitivity in detecting Stage I and II pancreatic cancer cases and 93.6% specificity. These individuals form the initial intended-use population for PancreaSure. The data will support Immunovia's efforts to secure payment from commercial insurers.

The analysis pooled data from the CLARITI and VERIFI validation studies, limited to individuals at elevated risk of pancreatic ductal adenocarcinoma (PDAC) due to a pathogenic germline variant (PGV), a family history, or both. PancreaSure detected Stage I and II PDAC with 77.5% sensitivity* and 93.6% specificity**. Importantly, sensitivity was consistent across stages: 80.0% in Stage I and 75.6% in Stage II. Performance in Stage I cases is crucial, as this is when detection has the greatest potential to increase survival.

Performance was also consistent across the two causes of high-risk status: 84.8% sensitivity and 94.5% specificity in individuals with a genetic mutation only, and 79.2% sensitivity and 93.7% specificity in those with a family history of pancreatic cancer only. The difference between the two groups was not statistically significant.

"The new analysis demonstrates that PancreaSure performs well in those with inherited or familial risk, the group targeted in our initial commercial strategy. We are especially pleased to see the PancreaSure test detect 80% of Stage I pancreatic cancers in this group since patients diagnosed at Stage I have significantly better 5-year survival. We look forward to sharing this peer-reviewed, published data with clinicians and commercial payers," says Jeff Borcharding, CEO and President, Immunovia.

An estimated 1.1 million Americans carry PGVs linked to pancreatic cancer and approximately 275,000 have two or more first-degree relatives with the disease. Both groups are recommended for routine surveillance and form PancreaSure's initial addressable market, which has grown as guidelines from the National Comprehensive Cancer Network and others have extended surveillance recommendations to more individuals with genetic risk factors. A further 7.8 million Americans have at least one first-degree relative with pancreatic cancer but fall outside current surveillance recommendations unless a PGV is also present. Many are nonetheless concerned about their own risk and represent an additional opportunity for a blood-based test such as PancreaSure.

"A substantial population in the US carries an increased risk of developing pancreatic cancer due to heredity and family history. Detecting the disease early allows us to act quickly, when the chances of survival are highest. We therefore welcome new solutions, such as blood-based tests, that create opportunities for individuals at high risk to be monitored less invasively," says Dr. Walter G. Park, MD, a board-certified gastroenterologist and pancreatologist at Stanford Health Care and Medical Director, Pancreas Clinic at Stanford Hospital & Clinics.

Immunovia has previously announced data supporting its Medicare coverage application, which is limited to the subset of high-risk individuals with clinical abnormalities including cystic lesions, main duct lesions consistent with main duct intraductal papillary mucinous neoplasms (MD-IPMNs), diabetes, and chronic/recurrent pancreatitis. The new analysis covers the full hereditary and familial group, inclusive of patients with and without clinical abnormalities.

** Sensitivity: The proportion of people with the condition correctly identified as positive, meaning how well the test detects cancer in those who have it.*

*** Specificity: The proportion of people without cancer correctly identified as negative, meaning how well the test clears those who do not have disease.*

The full article

Gonda T, et al. The PancreaSure multianalyte blood test performs well at distinguishing early-stage pancreatic ductal adenocarcinoma from high-risk controls: a retrospective secondary analysis. J Clin Med. 2026;15(19):7355. doi:10.3390/jcm15197355

For more information, please contact:

Jeff Borcharding
CEO and President
jeff.borcharding@immunovia.com

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.