



IMMUNOVIA LAUNCHES ASSURE REGISTRY TO EVALUATE REAL-WORLD CLINICAL IMPACT OF PANCREASURE IN HIGH-RISK PANCREATIC CANCER SURVEILLANCE

Immunovia AB (Nasdaq Stockholm: IMMNOV), a pancreatic cancer diagnostics company, today announced the launch of ASSURE, a post-marketing registry evaluating the real-world clinical impact of its commercially available blood-based biomarker test, PancreaSure. The study is designed to capture clinical data on how PancreaSure influences clinician decision-making in pancreatic cancer surveillance. Data generated in ASSURE will support Immunovia's reimbursement efforts and clinician adoption of the test.

ASSURE is a prospective, multicenter, observational post-marketing registry measuring the real-world impact of PancreaSure, Immunovia's commercial biomarker test for early detection of pancreatic ductal adenocarcinoma (PDAC). The study will enroll high-risk individuals at 15–20 U.S. academic centers and health systems with established surveillance programs. Its primary aim is to measure how PancreaSure impacts physician decision-making: how clinicians adjust patient surveillance plans based on the test result. The study is expected to run through early 2029, with interim readouts approximately annually.

"Pancreatic cancer surveillance in high-risk individuals relies heavily on repeated imaging, and the patients' surveillance plans vary considerably across clinicians and sites. In this context, ASSURE will play an important role by generating novel insights on how blood-based biomarker testing fits into clinical surveillance – what it adds to clinical decision-making, how surveillance plans evolve once a result is available, and how patients experience the process. We will gather new practical reference points for how tests like PancreaSure can complement imaging and guide surveillance decisions," says Dr. Rajesh Keswani, MD, MS, Director of Endoscopy at Northwestern Memorial Hospital and lead investigator for ASSURE.

Physician decision impact is a recognized measure of clinical utility for payers and a driver of broader clinical adoption. Beyond the primary endpoint, ASSURE will capture test utilization patterns, downstream clinical actions (imaging, biopsies, specialty referrals), patient-reported outcomes (anxiety, satisfaction, decisional confidence), and health economic measures including cost per detected case.

"ASSURE is designed to show how PancreaSure performs where it matters most: in the everyday management of individuals at high risk of pancreatic cancer. From a commercial perspective, insights from ASSURE will be instrumental in driving wider access to PancreaSure – through increased commercial adoption and support for our ongoing Medicare reimbursement process," says Jeff Borcharding, CEO and President, Immunovia.

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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.