

# PRESS RELEASE



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## **Immunovia Announces Completion of Analysis from the IMMray™ PanCan-d Verification Study**

### **Additional Sample Collection for Validation Study Hindered due to COVID-19 Infection Rate Increase, Causes Delay in Sales Launch**

**LUND, SWEDEN** – Immunovia, a diagnostic company that develops highly accurate blood tests for the early detection of cancer and autoimmune diseases, today announced that the Verification study analysis confirms the positive and technical performance of IMMray™ PanCan-d, in line with previous results, further substantiating the accuracy and robustness of the IMMray™ platform technology.

The results showed excellent accuracy of 94% in differentiating PDAC patients from healthy controls and 91% for differentiating early stages I/II of PDAC versus all controls. The controls were comprised of patients with non-specific but concerning symptoms, including type II diabetics and healthy individuals.

The Verification study is the step in the development process where samples are run on the final commercial product with the locked biomarker signature finalized in the previous Commercial Test Model Study. The verification study included samples collected from many different sites, mirroring the commercial setting.

“While we are very pleased with the positive technical outcome and the accuracy of the verification study, it was necessary to use some samples that had originally been allocated to the Validation process in order to increase the statistical significance of the results,” said Mats Grahn, CEO.

Furthermore, COVID-19 infections are once again on the rise across the US, UK, Germany and Spain. Patient flows at the sample collection centers have significantly decreased in recent weeks. This affects the previously agreed to sample collection rate and the collection of the additional samples needed to complete the Validation study in accordance with the previously communicated timeline of Q4 2020. Based on the current impact of COVID-19 on sample collection, the company aims for a sales start at the end of Q1 with subsequent commercial testing in Q2.

CEO, Mats Grahn, and incoming CEO, Patrik Dahlen will host a webcast to further discuss and hold a question and answer session today. The live webcast is scheduled to begin at 4:30 p.m. CET on October 26, 2020.

Event Details:

To join the webinar: Register for Webinar ([link](#))

### **About the Verification Study**

The study was performed in order to verify the IMMray™ PanCan-d commercial biomarker signature using known samples and to further validate its accuracy in differentiating PDAC (pancreatic ductal adenocarcinoma) stages I through IV vs. controls that best mirror the clinical, commercial setting

situation (i.e. healthy controls and patients with non-specific but concerning symptoms). All the samples were freshly collected through our Key Opinion Leaders (KOL) at pancreatic diseases reference sites in USA and Europe. The verification study precedes the final blinded validation study required for sales start.

### **About the Validation Study**

The study is performed in order to verify the IMMray™ PanCan-d commercial biomarker signature using blinded samples and to further validate its accuracy in differentiating PDAC (pancreatic ductal adenocarcinoma) stages I through IV vs. controls that best mirror the clinical, commercial setting situation (i.e. healthy controls and patients with non-specific but concerning symptoms). For the sales start in Immunovia Dx Lab in Marlborough USA, a CLIA-CAP accreditation is necessary and the blind validation study will contribute with data to this accreditation. All the samples are being freshly collected through our Key Opinion Leaders (KOL) at pancreatic diseases reference sites in USA and Europe. Once successfully completed, sales will begin, first to self-paying customers.

*This is information that Immunovia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 16:00 CET on October 26, 2020.*

### **For more information, please contact:**

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### **About Immunovia**

Immunovia AB is a diagnostic company that is developing and commercializing highly accurate blood tests for the early detection of cancer and autoimmune diseases based on Immunovia's proprietary test platform called IMMray™. Tests are based on antibody biomarker microarray analysis using advanced machine-learning and bioinformatics to single-out a set of relevant biomarkers that indicate a certain disease. Thus, forming a unique "disease biomarker signature".

The company was founded in 2007, based on cancer studies and ground-breaking research in the Department of Immunotechnology at Lund University and CREATE Health Cancer Center, Sweden.

The first product, IMMray™ PanCan-d, is undergoing clinical evaluation in some of the world's largest clinical studies for pancreatic cancer, PanFAM-1, PanSYM-1 and PanDIA-1 and is currently in the final validation for sales start Q1 2021. When validated, IMMray™ PanCan-d will be the first blood-based test for early diagnosis of pancreatic cancer on the market, with a potential to significantly improve patient survival and outcome.

Immunovia Dx Laboratories located in Marlborough, Massachusetts, USA and Lund, Sweden will provide laboratory testing services in two accredited reference laboratories.

Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm. For more information, please visit [www.immunovia.com](http://www.immunovia.com).

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