

# PRESS RELEASE



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## **Immunovia Announces Achieving a Major Milestone with the Successful Completion of the IMMray™ PanCan-d Commercial Test Model Study with High Accuracy**

### **IMMray™ PanCan-d commercial test for Early Stage Detection of Pancreatic Cancer remains on track for sales start Q3 2020**

**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 Commercial Test Model study was successful, showing a 95% accuracy, and the company is on track for commercialization of the IMMray™ PanCan-d commercial biomarker signature. The signature, together with CA19-9, confirmed the same high accuracy from the optimization study done earlier this year ([link to PR, June 3, 2019](#) and the [webinar presentation, Sept 2019](#)), in differentiating early stages of PDAC versus patients with non-specific but concerning symptoms, including type II diabetics and healthy individuals.

“It is an amazing time for Immunovia. Achieving these fantastic results with IMMray™ PanCan-d commercial signature was the last major technical milestone before we start the final validation as planned and start sales in Q3 next year. An accurate and early blood test for pancreatic cancer is a revolutionary advancement in the way the world healthcare systems test for and detect this deadly disease and will make significant improvements in patient outcome and survival,” commented Mats Grahn. CEO, Immunovia.

#### **About the Commercial Test Model Study Results**

The study was performed in order to finalize the IMMray™ PanCan-d commercial biomarker signature and to 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 patients with non-specific but concerning symptoms, including type II diabetics as well as healthy individuals.

The study included a total of 1113 samples comprising 315 PDAC, 488 symptomatic controls and 310 healthy individuals. All these samples were freshly collected through our Key Opinion Leaders (KOL) at seven pancreatic diseases reference sites in USA and Europe. The sites contributing with samples in this study were: UCL Institute for Liver and Digestive Health, London UK; University of Pittsburgh, Division of Gastroenterology, Hepatology & Nutrition, Pittsburgh, USA; New York University Langone Health, Perlmutter Cancer Center, New York, USA; Beth Israel Deaconess Medical Center (BIDMC), Pancreas and Liver Institute, Boston, USA; Ramon y Cajal Institute for Health Research (IRYCIS), Madrid, Spain; Växjö Central Hospital, Department of Transfusion Medicine, Sweden, Hallands Hospital Varberg, Department of Transfusion Medicine, Sweden.

IMMray™ PanCan-d commercial signature in combination with CA 19-9 tumor marker was able to detect the PDAC samples of stage I through IV vs all controls with 96% accuracy. Additionally, the accuracy for detecting PDAC early stages I and II was 95% thus confirming that Immunovia's IMMray™ PanCan-d combined with CA 19-9 enables accurate early detection of pancreatic cancer through a simple blood test.

## Next Steps

As previously communicated, the next steps are Verification Study and Validation Study. The timelines to sales start remain on track for Q3 2020. A detailed overview is outlined below:

## Steps to Market:

Start Date	Milestone	Details	Results
Q1 2020	Verification Study	Locked Signature and Algorithms Known Samples  500 Samples	Q2 2020
Q2 2020	CLIA/CAP Validation Study	Locked Signature and Algorithms Blinded Samples  500 Samples	Q3 2020
Q3 2020	Sales Start IMMray™ Dx Lab Marlborough USA		

The date and log in information for the webinar to share and discuss more details of the Commercial Test Model Results will be announced in January 2020.

*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 11:20 CET on December 19, 2019.*

## 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 entering the final validation for sales start Q3 2020. 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's shares (IMMNOV) are listed on Nasdaq Stockholm. For more information, please visit [www.immunovia.com](http://www.immunovia.com).

#### **About Pancreatic Cancer**

Pancreatic Cancer is one of the most deadly and difficult to detect cancers, as the signs and symptoms are diffuse and similar to other diseases. There are more than 40,000 deaths and over 50,000 new cases diagnosed each year in the U.S. alone, and the five-year survival rate for pancreatic cancer is currently 5-9 %. It is predicted to overtake colorectal cancer to become the second leading cause of cancer death in 2020. However, because resection is more successful in stage I/II, early diagnosis can significantly improve pancreatic cancer patients' 5-year survival rates from 5-9 % to up to 49%.

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