

# PRESS RELEASE



March 29, 2021, Lund, Sweden

## Immunovia reports positive results of the blinded clinical validation of IMMray™ PanCan-d blood test in USA

### Stage I/II pancreatic cancers were detected with 98% specificity and 85% sensitivity in familial/hereditary risk group cohorts

**LUND, SWEDEN** —Immunovia today announced the successful completion of the last development milestone of IMMray™ PanCan-d blood test designed for early detection of pancreatic cancer (PDAC). The blinded validation study data demonstrated that Immunovia's IMMray™ PanCan-d biomarker signature and CA 19-9 detects early stage I&II pancreatic cancers with a test specificity/sensitivity of 98%/85% vs familial/hereditary controls (reference PanFAM clinicaltrials.gov) and with a specificity/sensitivity of 99%/85% vs healthy controls. All stages of PDAC were detected with a specificity of 98% and a sensitivity of 87% against familial/hereditary controls. The blinded validation study, performed by Immunovia Dx Laboratory in Marlborough USA, analysed 591 samples including 167 PDACs whereof 56 PDAC stage I&II, 203 high risk individuals, and 221 healthy controls. These samples have been freshly collected from 11 sites in the US and Europe: Mt Sinai School of Medicine, Beth Israel Deaconess Medical Center, University of Pittsburgh Medical Center, BioIVT, Discovery Life Sciences, Inc., Massachusetts General Hospital, and University of Pennsylvania in the US; Sahlgrenska University Hospital and Växjö Central Hospital in Sweden; Helsinki University Hospital in Finland; and Ramón y Cajal University Hospital, IRYCIS, CIBERONC in Spain.

MD, PhD, Thomas King, Medical Director Immunovia Dx Laboratory, Marlborough, USA commented: "IMMray™ PanCan-d showing specificities of 98% and 85% sensitivities for early stages of pancreatic cancer versus a cohort of familial/hereditary risk group are a historical breakthrough both for Immunovia and for improving pancreatic cancer survival. We will be filing for the Massachusetts State License and CLIA registration for Immunovia Dx Laboratory in USA as soon as practically possible before commercialization starts in USA".

Patrik Dahlen, CEO, Immunovia added: "This is a historical moment for Immunovia and we have all been working very hard since the very beginning with this one goal in mind: to provide an accurate and early blood test for pancreatic cancer. For the IMMray™ PanCan-d to now show 99% specificity for early stage pancreatic cancer in a large blinded study is a truly revolutionary advancement for healthcare systems in the way they will test and detect this deadly disease, and will result in great improvements for the patients and their families. It is simply fantastic for us to now enter commercialization in the US."

## **Webcasted teleconference**

These results will be presented Tuesday March 30, 2021, in a webcasted teleconference at 16.30 (CET).

**Presenters:** Thomas King, MD, PhD, Linda Mellby, PhD, Patrik Dahlen CEO, Immunovia

The presentations will be followed by a Q&A session. The webcasted teleconference will be held in English.

### **Dial-in details:**

SE: +46 856642651

US: +18558570686

UK: +44 3333000804

Pin code: 20761152#

**Webcast:** <https://financialhearings.com/event/13801>

Following the teleconference, a recording will be available on Immunovia's website ([www.immunovia.com](http://www.immunovia.com)).

*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 21:20 CET on March 29, 2021.*

### **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 phase. The company aims for a sales start at the end of Q1 2021 with subsequent commercial testing in Q2.

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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