

# PRESS RELEASE



August 16<sup>th</sup>, 2018, Lund, Sweden

## **Results from a multicenter retrospective study for IMMray™ PanCan-d conclude that due to variations in blood sampling processes from different biobanks Immunovia needs to do further optimizations to meet the expected performance**

**Immunovia AB (publ) (“Immunovia”) finalized today a retrospective study performed as part of the preparation for the certification and accreditation of the company’s commercial version of their IMMray™ PanCan-d assay for early detection of pancreatic cancer. Due to variations in different biobank blood sampling processes, Immunovia needs to do further optimizations to the test algorithms to meet the expected performance for its commercial version of the test. The further optimization work will delay the initiation of the sales of the IMMray™ PanCan-d until later part of 2019 and in aggregate render an extraordinary cost of less than SEK 5 million.**

The retrospective study analyzed more than 1000 blood samples from five different clinical collaborators, covering all the stages of pancreatic cancers combined with samples from the patients presenting early symptoms suggestive of pancreatic cancer and from healthy controls. The study was performed as part of the preparation for the certification and accreditation of Immunovia’s commercial version of IMMray™ PanCan-d.

The combination of retrospective samples from different biobanks, with varying sample collection procedures, introduced unforeseen variability in the test algorithm performance. To eliminate the distorting effect caused by the variability in blood sampling, a further optimization of the algorithms will be completed by Q1 2019. The successful optimization of the algorithms is followed by the compulsory verification and validation studies resulting in a delay of the launch of IMMray™ PanCan-d until the later part of 2019.

This study and other studies performed during the accreditation and certification preparations as well as the peer reviewed article in Journal of Clinical Oncology released Tuesday Aug 14<sup>th</sup>, 2018, continues to demonstrate solid evidence of the IMMray™ platform robustness and functionality, including low technical platform variabilities and low laboratory process variations.

The financial targets adopted by the Immunovia Board in March 2018 remains, with a corresponding delay in time. The Company’s goal is to reach SEK 250-300 million in turnover in 2022 based on “self-pay”-sales and a turnover of SEK 800-1,000 million in 2024 including self-pay and reimbursements in Europe and the US. These financial targets do not include the pipeline products in other cancers and autoimmunity.

All other product pipeline studies are moving forward as planned.

*“We are confident that the further optimizations of the algorithms will be the final adjustments we need to do before our commercial launch. I would like to point out that this variability in blood sampling process only affects the current study used for the algorithm development and verification phase at Immunovia. To eliminate any future blood sampling variability for the commercial version of*

*IMMray™ PanCan-d we are standardizing the blood sampling procedure, conforming to current de facto standards of blood sampling,” commented Mats Grahn, CEO, Immunovia.*

A telephone conference is scheduled on Friday August 17<sup>th</sup>, 2018, 08:00 am CET to answer questions and further describe the results and the plans.

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On the Immunovia website under Investors/Audio Gallery (<https://immunovia.com/investors/audio-gallery/>) there will be an MP3 file for those who want to listen to the conference call later, the file is available within two hours of the end of the conference call.

**For further information, please contact:**

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*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 17.35 CET on August 16, 2018.*

**About Immunovia**

Immunovia AB was founded in 2007 by investigators from the Department of Immunotechnology at Lund University and CREATE Health, the Center for Translational Cancer Research in Lund, Sweden. Immunovia’s strategy is to decipher the wealth of information in blood and translate it into clinically useful tools to diagnose complex diseases such as cancer, earlier and more accurately than previously possible. Immunovia’s core technology platform, IMMray™, is based on antibody biomarker microarray analysis. The company is now performing clinical validation studies for the commercialization of IMMray™ PanCan-d that could be the first blood based test for early diagnosis of pancreatic cancer. In the beginning of 2016, the company started a program focused on autoimmune diseases diagnosis, prognosis and therapy monitoring. The first test from this program, IMMray™ SLE-d, is a biomarker signature derived for differential diagnosis of lupus, now undergoing evaluation and validation. (Source: [www.immunovia.com](http://www.immunovia.com))

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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