# Immunovia Provides Complementary Information on the IMMray™ PanCan-d Verification and Validation Studies

**LUND, SWEDEN** – Immunovia, a diagnostic company that develops highly accurate blood tests for the early detection of cancer and autoimmune diseases, today announced a necessary clarification to supplement the information shared on 26 October 2020 (link to press release).

**About Blood Sample Inclusion Criteria**

It is standard practice to have specific inclusion criteria in place for the collection of blood samples for all diagnostic studies. Immunovia has always implemented this Quality Control process of samples and has worked very closely with the clinicians to create the criteria for the Verification and Validation studies. Samples that meet the quality requirements stipulated by the inclusion criteria are included in a study.

Inclusion criteria can be, for example, but not limited to (i) patients must not be under specific treatment, (ii) patients must not have been anesthetized in direct connection with the sampling, (iii) samples are lacking certain clinical data, etc.

**Immunovia's Verification Study Quality Control Process**

After the samples were received for the Verification study, Immunovia implemented the company's inclusion criteria. During this quality control process, which is normal for all studies, it was evident that some samples that did not meet the inclusion criteria. According to Standard Operating Procedure (SOP) for clinical studies, these samples do not go further in the testing process. These samples were then replaced with samples that were originally designated for the Validation Study. This was done to meet the required number of samples derived from the power calculation, the calculation done to determine how many samples will be needed to successfully complete the study.

It is important to note that the samples that do not fulfil the inclusion criteria are not, so called, "outliers". Outliers are identified after the test is performed, not during the inclusion QC process, and must be handled with the utmost caution not to affect the outcome in an incorrect way. This is also standard in all clinical studies and no samples were treated as outliers in the verification study.

The company´s timeline was affected by the delay in the completion of the sample collection for the Validation study due to the fact that sampling at the collection centers has recently significantly decreased due to COVID-19.

### 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 Immuntechnology 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.

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