# PRESS RELEASE

June 27, 2022, Lund, Sweden

## PanFAM-1 Results Partly Inconclusive

**LUND, SWEDEN** – Immunovia today announced results from the PanFAM-1 study. The PanFAM-1 study is a prospective, multi-center, investigational study, designed to assess the performance of the IMMray™ PanCan-d test in early detection of pancreatic ductal adenocarcinoma (PDAC) in high-risk populations. The IMMray™ PanCan-d test met its primary endpoint of test specificity comparable to imaging in the study. Sensitivity, however, could not be evaluated due to the low number of PDACs among study participants.

"We aimed for more tangible results of the PanFAM-1 study, which are partly inconclusive due to a variety of factors related to the execution of the clinical trial compared with original study design. The PanFAM-1 clinical study was also impacted by the COVID pandemic, when many hospitals were closed for the routine surveillance or screening of patients, as many others in the industry have experienced", said Philipp Mathieu, CEO and President of Immunovia AB.

Analysis of the sensitivity of IMMray™ PanCan-d in the PanFAM-1 study was confounded by the unexpectedly low 0.2% prevalence of PDAC in the PanFAM-1 cohort, which was lower than the c.1% prevalence in this risk group observed in other studies[1, 2] and was lower than the prevalence assumed in the study design. In addition, the execution of the study was compromised by the following factors:

- The COVID pandemic significantly impacted the recruitment and monitoring of patients
- Insufficient number of serial blood draws and/or imaging for each patient
- Failure to provide a quality/accuracy assessment of imaging results

Philipp Mathieu, CEO and President of Immunovia AB, continues: "We are very grateful to the patients, clinicians and hospitals who participated in this study. In close collaboration with key opinion leaders and participating study sites we are currently analyzing the important learnings from PanFAM-1 which together with our ongoing discussions with payers will inform the way forward in establishing further clinical validation in this risk group."

Analysts, investors and media are invited to a webcast and teleconference, today Monday, June 27, at 13:00 pm CET for a presentation of the outcome and learnings from the PanFAM-1 study. For details, see the end of the press release.

**PanFAM-1, background and details**
PanFAM-1 was the first prospective, multi-center trial initiated by Immunovia in 2016, with the goal of evaluating the performance (sensitivity and specificity) of the IMMray™ PanCan-d test in individuals at high risk for developing familial or hereditary pancreatic ductal adenocarcinoma (PDAC) in comparison to conventional imaging.

Individuals enrolled in PDAC surveillance programs were planned to receive imaging and clinical evaluation at least once per year consistent with the study center's protocol (MRI, EUS or CT) and had a blood draw every 6 months. As an observational study, blood samples were frozen and stored until the IMMray™ PanCan-d test was clinically validated.

Samples were collected at 23 sites in the US (14) and Europe (9), with 3,457 blood samples collected from 1,255 participants between January 2016 and November 2021. Sites in the U.S. contributed over 2,300 blood samples from two third of the study participants, with a median observation period of 1-2 years. The IMMray™ PanCan-d results for US participants were in line with those reported for the US PanFAM-1 subjects in the blind validation (88.8% negative, 9.5% borderline, and 1.7% positive) [Clinical and Translational Gastroenterology, 2022; doi.10.14309/ctg.0000000000000468].

Statistical comparison of specific imaging findings and IMMray™ PanCan-d results is ongoing to examine trends in IMMray™ PanCan-d results relative to specific germline mutations, family histories, and imaging findings at the direction of the Principal Investigators in this study. Independent analysis of the PanFAM-1 results was conducted by Biostatisticians at the Biostatistical and Epidemiological Data Analysis Center (BEDAC) at Boston University School of Public Health.

[1] Overbeek KA, Levink IJ, Koopmann BDM et al. Long-term yield of pancreatic cancer surveillance in high-risk individuals. Gut. 2022;71:1152-1160.
[2] Overbeek KA, Goggins MG, Dbouk M et al. Timeline of development of pancreatic cancer and implications for successful early detection in high-risk individuals. Gastroenterol. 2022;162:772-785.

## Details for webcast and teleconference

Analysts, investors and media are invited to a webcast and teleconference today, Monday June 27 at 13:00 pm CET. The presentation slides will be available at www.immunovia.com.

The presentation will be held in English and be followed by a Q&A session. You are welcome to join via webcast or phone, see details below.

**Telephone numbers and webcast**
Ring any of the numbers below to participate via telephone. Please dial in a few minutes before the presentation starts.

Sweden: +46 8 50 51 00 31
United Kingdom: +44 207 107 06 13
United States: +1 631 570 56 13

**Link to the webcast:** https://creo-live.creomediamanager.com/806a27cb-a49a-4fa9-b7e7-3ac9fd7a4795

To ask questions, it is necessary to dial in. A recording of the presentation will be available on Immunovia's website.

**For more information, please contact:**
Philipp Mathieu
CEO and President
philipp.mathieu@immunovia.com

Tobias Bülow
Senior Director Investor Relations and Corporate Communications
tobias.bulow@immunovia.com
+46 736 36 35 74

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 08:30 CET June 27, 2022.

**About Immunovia**
Immunovia AB is a diagnostic company with the vision to revolutionize blood-based diagnostics and increase survival rates for patients with cancer.

Our first product, IMMray™ PanCan-d is the only blood test currently available specifically for the early detection of pancreatic cancer. The test has unmatched clinical performance. Commercialization of IMMray™ PanCan-d started in August 2021 in the USA and IMMray™ PanCan-d is offered as a laboratory developed test (LDT) exclusively through Immunovia, Inc. For more information see: www.immunoviainc.com

Immunovia collaborates and engages with healthcare providers, leading experts and patient advocacy groups globally to make this test available to all high-risk pancreatic cancer groups.

The USA, the first market in which IMMray™ PanCan-d is commercially available, is the world's largest market for the detection of pancreatic cancer with an estimated value of more than USD 4 billion annually.

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

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