

PRESS RELEASE



June 3, 2019, Lund, Sweden

Immunovia announces excellent results across all symptomatic risk groups from IMMray™ PanCan-d optimization work

IMMray™ PanCan-d blood-based test for early detection of pancreatic cancer now set for Q3 2020 launch

LUND, SWEDEN - Immunovia AB (publ) (“Immunovia”) today announced that the optimization work for the commercial version of IMMray™ PanCan-d, designed for early detection of pancreatic cancer (PDAC), has been successful and significantly improved the performance of the test. The test now shows accuracies higher than 90% and even up to 98% in differentiating PDAC of stage I through IV versus the large symptomatic risk groups, i.e. patients with non-specific but concerning symptoms, including type II diabetics, results which has never been reported before in the pancreatic cancer field.

“We are extremely pleased to share the results from the optimization work. All of us at Immunovia have worked very hard and have achieved very satisfying accuracies in our target risk groups with conditions that best mirror commercialization. This is a milestone achievement for the company and a crucial step towards early detection of pancreatic cancer,” commented Mats Grahn, CEO, Immunovia.

“This is not only a milestone for us, but also a major breakthrough in the global quest for a reliable non-invasive blood test for early detection of cancer. This study, performed in collaboration with Prof Stephen Pereira of the University College of London, is the first to achieve such results with these high-risk patients. This collaboration, also known as PanSYM-1 pilot study ([PR Nov. 2 2017](#), [PR April 10 2019](#)), covered a large group of patients with non-specific but concerning symptoms, attending secondary care centers and endoscopy / gastrointestinal units, including the new onset type II diabetics,” concluded Mr. Grahn.

“We agree that these results mark a major step towards diagnosing pancreatic cancer at a resectable stage,” stated Professor Steve Pereira. “Being able to include our cohort of symptomatic PDAC patient samples instead of just healthy individuals mirrors for the first time the “real world” situation we are faced with in clinics. Having a non-invasive blood test to differentiate non-PDAC from PDAC individuals with a high probability at an early stage will be invaluable,” concluded Professor Pereira.

About the Optimization Results

The study was performed to differentiate PDAC (pancreatic ductal adenocarcinoma) individuals from healthy individuals, as well as to differentiate non-PDAC symptomatic individuals, including diabetics from PDAC ones. The study was set up to mirror the clinical, commercial testing situation and included a total of 937 samples comprising 150 PDAC-, 570 symptomatic controls and 217 healthy individuals.

After the optimization of the pre-analytical conditions and the algorithms, IMMray™ PanCan-d could detect the PDAC samples of stage I through IV from the non-PDAC symptomatic and healthy ones

with accuracies higher than 90% and up to 98% differentiating the different stages and control groups, including for the first time type II diabetics.

Additionally, tests were performed in parallel on all the samples with CA19-9, the only tumor marker recommended by American Society of Clinical Oncology, to monitor patient after surgical resection. Immunovia's IMMray™ PanCan-d biomarker signature in combination with CA19-9 improved accuracies even further. These preliminary combination results will be further confirmed in the next steps of the development of IMMray™ PanCan-d.

The optimization study was conducted with the highest quality fresh samples available and made possible through Immunovia's extensive key opinion leader collaboration network, particularly with Prof. Stephen Pereira, Professor of Hepatology and Gastroenterology at University College Hospital London (UCL) Institute for Liver and Digestive Health. UCL is the home of the ADEPTS Study (Accelerated Diagnosis of neuro Endocrine and Pancreatic Tumours) funded by Pancreatic Cancer UK and a major proponent of the UK's NHS long term plan to improve rates of cancer detection.

Next steps

As previously communicated, the next steps, the Commercial Test Model Study Test, Verification and Validation remain the same and the timeline is outlined below:

Milestone timeline for the remaining steps to market:

Start Date	Milestone	Details	Results
Present - Aug 2019	Preparing for Commercial Test Model study	Finalizing Contracts and Deliveries of the Fresh Samples Making Final Preparations for the Test Model study	
Sep 2019	Commercial Test Model Study	Commercial Signature Fine Tune Algorithm Lock Signature and Algorithms Up to 1200 Samples	Year End 2019
Q1 2020	Verification Study	Locked Signature and Algorithms Known Samples Up to 600 Samples	Q2 2020
Q2 2020	CLIA/CAP Validation Study	Locked Signature and Algorithms Blinded Samples Up to 600 Samples	Q3 2020
Q3 2020	Sales Start IMMray™ Dx Lab Marlborough USA		

Immunovia's CEO, Mats Grahn will host a **telephone conference (in English) on June 3, 2019, 17:00 CET** to answer questions and provide additional details, including a slide presentation. Please call in a few minutes in advance.

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Weblink: <https://tv.streamfabriken.com/immunovia-2019-06-03>

There will be an archived reply of the live call available on Immunovia's IR page: <https://immunovia.com/investors/audio-gallery/> for those who want to listen to the telephone conference afterwards. The file will be available within two hours after the conference has ended.

For more 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 3.00 p.m. (CET) on June 3, 2019.

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. (Source: www.immunovia.com)

Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm. For more information, please visit 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 by 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%.

About the ADEPTS study

The ADEPTS Study (formally referred to as TRANSBIL: TRANSLational research in BILiary tract and pancreatic diseases) is a UCL (London) based early biomarker study which aims to detect pancreatic cancer in patients at a much earlier stage. It aims to develop a prospective biobank and an early diagnostic tool that can differentiate early PDAC (pancreatic ductal adenocarcinoma), PNETs (pancreatic neuroendocrine tumours) and high-risk pancreatic lesions from benign disease, by combining a risk factor / early symptom electronic clinical decision support tool (e-CDST) with novel panels of blood biomarkers of early disease. This diagnostic tool may then be used for surveillance of high-risk populations and triage of patients with non-specific symptoms concerning for pancreatic cancer.

Source: <https://www.ucl.ac.uk/surgery/research/situ-trials/adepts-study-information>

The study has four work packages focused on improving early symptom identification (WP1), development of a biomarker panel for PNETs (WP2), prospective blood sample collection from symptomatic patients (WP3) and stakeholder / health economic analysis (WP4).

About UCLH and Rapid Diagnostic Centers

Rapid diagnostic centers (RDCs) are being piloted in ten areas as part of NHS England's drive to catch cancer early and speed up diagnosis for people with cancer.

Each of the centers will operate in a different way to ensure they meet the needs of their local communities. However, all have the same purpose – to diagnose cancers early in people who do not have 'alarm symptoms' for a specific type of cancer.

People with vague, non-specific symptoms, such as unexplained weight loss, appetite loss or abdominal pain are often referred multiple times for different tests for different cancers, but these new centers will help end this cycle.

Rapid diagnostic centers are for patients with so-called 'vague' symptoms that could indicate cancer. These patients need to access appropriate tests quickly to improve early diagnosis. UCLH is one of the lead centers of the RDC initiative.

Source: <https://www.england.nhs.uk/2018/04/new-one-stop-shops-for-cancer-to-speed-up-diagnosis-and-save-lives/>

A network of at least 20 rapid diagnostic centers will be working by 2020, with further centers rolling out across the country before 2030.

Source: [Theresa May, Oct 2018](#)

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