

PRESS RELEASE



April 21, 2021, Lund, Sweden

Immunovia presents update on US market size for IMMray™ PanCan-d in the familial/hereditary risk group

LUND, SWEDEN — Immunovia today announced an updated assessment of the total market size for familial/hereditary pancreatic cancer risk group in the US. New estimations show that 315,000 – 350,000 individuals have a familial/hereditary risk for pancreatic cancer and would qualify to be enrolled in pancreatic cancer surveillance programs.

Immunovia's bloodtest IMMray™ PanCan-d for early detection of pancreatic cancer is to be used for surveillance testing of high risk individuals. The recent blinded validation study showed that IMMray™ PanCan-d and the tumor marker CA 19-9 detect stage I & II pancreatic cancer with 85% sensitivity and 98% specificity in familial/hereditary pancreatic cancer risk group.

Updated guidelines from US Preventive Services Task Force (USPSTF), National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and the International Cancer of the Pancreas Screening (CAPS) Consortium all conclude that the general population should not be screened for pancreatic cancer. Instead, it is recommended to follow-up on individuals with a family history of pancreatic cancer, individuals with one first degree relative (FDR) with a confirmed germline mutation that poses an increased risk for pancreatic cancer and enrolling high-risk individuals for pancreatic cancer into surveillance programs.

The updates of the guidelines has led the company to re-examine the potential market size for surveillance of high-risk individuals in the familial/hereditary risk group.

There will be approximately 60,000 new pancreatic cancer cases this year in the US. Based on public and published data, 10% of all new pancreatic cancer cases are attributed to a familial or hereditary link. Given the number of historically documented cases per year, and the fact that the average US family has two children and a surveillance window of 30 years (surveillance programs enroll persons at 50 – 80 years of age), the estimation concludes that 315,000 – 350,000 individuals have a familial/hereditary risk for pancreatic cancer. Consequently, these individuals would qualify to be enrolled in a pancreatic cancer surveillance program, using the IMMray™ PanCan-d test.

Furthermore, recent data demonstrates that individuals with 1 First Degree Relative (FDR) have a 9-fold risk for developing pancreatic cancer. The addition of these individuals in surveillance program would increase the enrollment to over 3 million high risk individuals. This suggestion is not yet in any guidelines. However, NCCN and ASCO already propose systematic germline testing for persons with 1 FDR.

“We anticipate that a cost-effective and non-invasive method like the IMMray™ PanCan-d test will be a key component to enable a dramatic increase in number of individuals enrolled in surveillance programs. The maximum potential market size for Immunovia, in terms of number of tests assuming twice a year surveillance, today range from 630,000 – 700,000 tests annually, following current recommendations and guidelines. In the future, these numbers could potentially grow to over 6

million tests per year – provided that the new suggestions are converted to guidelines,” said Patrik Dahlen, CEO Immunovia.

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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 22:10 CET on April 21, 2021.

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. The final validation study was completed in Q1 2021. Commercial testing will begin in Q2 after the accreditation of Immunovia Dx Laboratory in Marlborough, Massachusetts, USA.

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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