

## Immunovia Shareholder Newsletter Q4 2016

Dear Immunovia Shareholders,

With the end of the year approaching and many of you looking forward to a well-deserved Christmas and New Year celebration, we at Immunovia would also like you to join us in celebrating an unprecedented year which we are sure you would agree has more than surpassed expectations. In this newsletter, we would like to give you a summary of the milestones and highlights of a highly successful 2016 and the outlook for what is shaping up already to be an equally productive 2017. In particular 2016 was an exciting year as we started implementing Immunovia's commercialization plan focussing on the goal of achieving reimbursement and national guideline status.

**2016, an unprecedented year of success for Immunovia:**

- **PANFAM-1 Prospective validation study** of the hereditary risk group for pancreatic cancer, which is pivotal to reimbursement and national guideline inclusion, started as planned at the end of 2016.
- **IMMray™ PanCan-d**, was successfully validated in an American patient cohort, confirming the unmatched 96% accuracy for asymptomatic pancreatic cancer patients stages I and II.
- **Collaboration with National Cancer Institute USA** was initiated with a focus on early detection of pancreatic cancer in the risk group of early onset diabetes type II patients over 50 years of age.
- **Intensive preparation for market entry concentrating on IMMray™ PanCan-d ISO 13485-2016** quality standards - Industrialization, verification, validation and upscaling production capacity.
- **Immunovia Scientific Advisory Board** in pancreatic cancer was formed involving Key Opinion Leaders and guideline authors from US and Europe.
- **Immunovia Board** strengthened with seasoned internationally experienced commercial leaders.
- **World Pancreatic Cancer Coalition** was formed and Immunovia is part of the coalition.
- **World Pancreatic Cancer Day** 17 November, 2016 was organized in Lund by Immunovia in collaboration with patient organizations from Sweden, PALEMA, and Denmark, Pancreasnaetverket.
- **IMMray™ Autoimmunity Program** was started in collaboration with Lund University and a large multinational company with preliminary results due to be communicated beginning of 2017.
- **Successful completion of preferential rights issue** of SEK 28.7 million, adding to previously completed SEK 189.9 million directed issue ensured the financial strength needed for the diabetes risk group surveillance clinical application.
- **Winner of European Small & Mid Cap Stars of Innovation Award 2016**, Immunovia is Europe's most innovative Small and Midcap company.

### **On the road to reimbursement: IMMray™ PanCan-d prospective clinical study for familial pancreatic cancer risk group, PANFAM-1 starts as planned**

The PANFAM-1 prospective study is the most important step towards achieving the two main goals for IMMray™ PanCan-d: reimbursement from healthcare payers and inclusion in national guidelines. The study is designed to monitor one thousand individuals with a genetic predisposition for pancreatic cancer over three years. This group, called familial pancreatic cancer (FPC), is already screened at reference cancer centers around the world as these individuals present the highest risk of developing the disease. In this 3 years-longitudinal prospective study, IMMray™ PanCan-d testing will be added to the existing high risk surveillance familial pancreatic cancer programs in USA and Europe. We anticipate that upon achieving successful results we will proceed with regulatory and reimbursement applications worldwide to establish

our test for early diagnosis of pancreatic cancer as a standard amongst pancreatologists for detecting pancreatic cancer in high-risk groups much earlier than possible today, thereby saving patient lives.

Thus, PANFAM-1 planning and preparations have been a major undertaking during 2016. We are very pleased to be able to announce the start of the prospective study in December 2016 as planned. During 2016 we have announced the participation of several key centers in our network, such as Mount Sinai in New York, Liverpool University Hospital in UK, FIBioHRC in Madrid to add to the existing Knight Cancer Institute collaboration. We are engaged in discussions with several other interested leading cancer centers from USA and Europe over participation in PANFAM-1 and will continue to report additional participants as they join our network going forward. Engaging key centers is also important commercially as they will be the first large customers for IMMray™ PanCan-d when the study is completed.

To manage the multi-site global study logistics and documentation we have engaged one of the most well renowned and experienced CROs in the molecular diagnostics field. The CRO, Precision for Medicine Inc, headquartered in Bethesda, close to Washington DC USA, will also support us with regulatory expert advice, complementing the ongoing strategic collaboration with Jorge Leon of Leomics Inc.

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### **Pancreatic cancer community highly supportive: US validation study confirms the same unmatched 96% accuracy for asymptomatic Stage I & II patients as 2015 Scandinavian study**

A validation study using American blood samples was completed in collaboration with Knight Cancer Institute in Portland USA, as part of our longterm collaboration. The results of the study, showing 96% accuracy in detecting asymptomatic stage I and II pancreatic cancer, were reported in May, thereby validating the excellent results previously obtained in the large Scandinavian study. This was a very important milestone and raised interest in Immunovia significantly as these findings were presented at all major pancreatic cancer specialist meetings during 2016 including:

- American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer, May 12-15 2016
- The International Symposium on Pancreatic Cancer in Glasgow, UK, June 9-12 2016
- Sweden Life Science Summit with focus on Cancer in Tokyo, Japan, June 17 2016
- European Pancreatic Club, EPC 2016 in Liverpool, UK, July 6-9 2016
- American Pancreatic Association APA 2016 Annual Meeting, Boston US, October 26-29 2016
- Quality and Innovation in Pancreatic Diseases, Rome, Italy, November 10-13 2016

Looking forward, we have an ambitious plan for 2017 to participate at the most relevant conferences for pancreatic cancer in US, Europe and Japan. The event plan will be uploaded and updated continuously on Immunovia's website.

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### **Developing the diabetes connection: Exciting collaboration with NCI on IMMray™ PanCan-d for screening over-50's Type II Diabetes risk group –initiated**

90% of pancreatic cancers that occur are sporadic, making population screening unfeasible economically. To improve survival rates for this cancer that has the highest mortality rates of all cancers, a policy involving surveillance of individuals at risk has proved successful in several academic studies.

One of the highest risk groups that has gained a lot of attention during the last year are new onset Type II diabetes patients diagnosed after 50 years of age.

The increased focus was also driven by the 2013 Recalcitrant Act in the USA forcing the National Cancer Institute to concentrate on early detection of pancreatic and lung cancer. This was further enforced by the launch in January 2016 of the Moonshot initiative for Cancer intended to change cancer care radically in comparison with the current practice. The Moonshot initiative is driven by vice president Biden in a joint program involving government and industry. Establishing a test such as IMMray™ PanCan-d in this large NCI initiative is a very attractive, but also major undertaking which has prompted us to engage in collaboration with the large centers driven by National Cancer Institute in USA as well as

other reference centers in the EU. We are extremely pleased to be able to announce that initiation of this collaboration through a recently signed memorandum of understanding with the NCI. The ambition is to work within a consortium of 12 major health care systems providing patient samples from up to 10.000 diabetes patients over 3 years. These participating centers will be communicated as NCI's plans progress.

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### **Certifications and Accreditations continue apace**

Since the beginning of 2016, Immunovia has worked intensively to industrialize the IMMray™ PanCan-d assay as a major part of the development of the IMMray™ PanCan-d test and for the preparation of ISO 13485 certification and other related accreditations required for market entry.

During 2016, the regulatory quality standard ISO 13485 was updated to ISO 13485:2016 that introduces notable changes in risk management, software validation and design and development.

Lastly, in the preparation for the market introduction and the CE marking of IMMray™ PanCan-d, Immunovia has focused on developing the strategies for scaling up the production of the microarray while maintaining the same robustness and reproducibility as in the retrospective validation studies.

The assay industrialization, software verification and validation according to ISO 13485:2016 and production upscale are being performed in parallel. We are evaluating the impact of this increased workload and an updated time plan for the certifications and accreditations will be communicated at the end of Q1 2017.

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### **Strong links forged with Scientific Advisory Board and Patient Organisations**

The most important influencers of advances in medical practices, such as national guidelines, are Key Opinion Leaders. During 2016 we have built an impressive Scientific Advisory Board who are now actively working with us. These include:

- Dr. Marco Del Chiaro, Leading European Surgeon from Karolinska Institute, Author of European Guidelines for Cystic Tumors of the Pancreas, Stockholm, Sweden
- Professor Margaret Tempero, UCSF, Leading US gastrointestinal cancer expert and chairman of the NCCN Guideline committee for pancreas cancer
- Professor Aldo Scarpa, World leading cancer diagnostics expert, Verona, Italy
- Prof. Diane Simeone, Director of the Multidisciplinary Pancreatic Tumor Program and the HPB Surgical Fellowship at the University of Michigan Medical Center, USA

To ensure the introduction of IMMray™ PanCan-d into clinical practice close collaboration with patient organizations is crucial. We have continued the collaboration with PANCAN US, the largest US based patient organization, which also formed during 2016 a world coalition of more than 50 pancreatic cancer patient organizations. Immunovia joined World Pancreatic Cancer Coalition as a sponsor of the inaugural meeting in May 2015 in Orlando, Florida, USA.

At the coalition meeting, 17 November was proclaimed as the World Pancreatic Cancer Day 2016. During this day, all the patient support organizations arranged events around the world to raise awareness and understanding about pancreas cancer in their respective countries. Immunovia in collaboration with the Swedish and Danish patient organization arranged a very successful event in Lund, Sweden, with the participation of politicians, patients, relatives, health care personnel and many others who wanted to support the fight against this dreadful disease.

We will continue to work closely with patient organizations, support them in their efforts and we will organize seminars and workshops together with them during 2017.

### Another key market identified – the Immunovia Autoimmunity and SLE initiative

In the beginning of 2016, we announced that Immunovia and Lund University had started several retrospective clinical validation studies of Systemic Lupus Erythematosus (SLE) biomarker signatures. In addition, Immunovia engaged in a collaboration with a multinational life science company to validate the new SLE diagnostics test.

An important study that will determine our ability to differentiate between SLE and other common autoimmune diseases has been running during this year. The study is under initial analysis and we will be able to communicate the results in the beginning of 2017.

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### Financial strength

In the autumn Immunovia announced completion of preferential rights issue of SEK 28.7 million, adding to a SEK 189.9 million directed issue for total of 218,6 MSEK. New and existing institutional investors participated, including funds from Handelsbanken, Öhmans, Alfred Berg, Ålandsbanken, and Banque Internationale Luxembourg. This gives the company a strong financial position and the ability to act on the opportunity to address the enormous clinical need and market possibility that arise analyzing the new onset diabetic patients for pancreatic cancer, since they have up to 10 times an increased risk of acquiring this deadly disease.

Immunovia also announced our intention to apply during 2017 for listing on Nasdaq Stockholm's Main Market.

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### Industry recognition - Winner of European Small & Mid Cap Awards 2016, Stars of Innovation

Immunovia was nominated by the European stock markets community as one of the three most innovative small to mid-companies in Europe 2016.

In November, we were delighted when the prestigious European jury announced Immunovia as the European winner of the 2016 Stars of Innovation Prize.

Therefore in summary, 2017 will certainly be another exciting year with a focus on the ground-breaking PANFAM-1 study and developing our NCI collaboration for the over-50's Type II diabetes risk group. I strongly believe we have the scientific, human and, thanks to your support, financial resources in place to continue our exciting journey towards giving clinicians the tools they need for early detection of pancreatic cancer and potentially other cancers and autoimmune diseases. Thereby enabling successful intervention and saving patients' lives.

### Thank you for your continued support of Immunovia!

Wishing you all a happy and prosperous 2017,

*Mats Grahn CEO and the Immunovia team*



*Photo from World Pancreatic Cancer Day. Lund, Sweden, November 17, 2016.*