PRESS RELEASE

October 8, 2018, Lund, Sweden

Immunovia announces strategic focus centered on IMMray™ blood-based biomarker signatures for rheumatoid arthritis within autoimmunity

LUND, Sweden — Encouraged by the promising discovery study results previously reported, Immunovia´s prime focus in autoimmunity testing will be to develop IMMray™ blood-based biomarker signatures for the management of rheumatoid arthritis.

Rheumatoid arthritis (RA) is a devastating chronic autoimmune disease that affects nearly 7 million people yearly in US and Europe, and creates an annual economic burden in the US alone of $19-23 billion, based on direct costs such as hospitalisation, treatment and loss of productivity. Furthermore, rheumatoid arthritis symptoms can progress rapidly and with little advance warning, leading to permanent and debilitating joint damage. It is crucial that physicians stay ahead of the disease, since existing treatments can halt or slow down the disease progression.

However, accurate diagnosis remains a major issue as there are no tests that can detect all RA cases. To begin with, one of the biggest clinical problems is that over 25% of the patients with established RA, unfortunately test negatively for the standard anti-CCP and anti-RF tests, thus making them very difficult to diagnose with current methods. Secondly and even more important, in the early stages of RA, 80% of the patients test negative using the two current standard tests, reinforcing the need for more accurate early diagnostic tools. Overall this leads to estimated 3-4 million test cases in the US and Europe annually because of the shortcomings of current anti-CCP and anti-RF tests.

To address this situation Immunovia has completed three discovery studies to assess IMMray™'s potential in autoimmunity testing. These have all recently shown promising results. The first two studies reported excellent accuracy levels using IMMray™ based signatures for the differential diagnosis of overlapping autoimmune rheumatic diseases such as RA, Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome and Systemic Vasculitis (press release March 7, 2017 and press release January 12, 2017). This initial study data has been discussed with numerous Key Opinion Leaders in autoimmune rheumatic diseases. They all expressed great interest in the differential data, but they highlighted the need for diagnosis of early RA. In the RA field, healthcare recommendations for early diagnosis are already in place[1] and ongoing implementation in the healthcare systems. This strong trend is important for a quick uptake and market penetration of a diagnostic test that would solve the bottlenecks described in the recommendations.

The third recently reported discovery study (press release Aug 22, 2018) showed a major breakthrough: an accuracy higher than 90% for IMMray™ biomarker signatures when diagnosing the CCP negative rheumatoid arthritis patients compared to healthy controls. These exceptionally good results have now triggered Immunovia's strategic decision to focus on RA.

For the next step towards developing a commercial product, Immunovia has started to engage several Key Opinion Leaders in this field to design and run a study aiming to optimize the signature for differentiating the patients with early RA from the controls having other diseases than RA but exhibiting RA-like symptoms.

For SLE, Key Opinion Leaders emphasized that the major clinical unmet need is monitoring SLE flares and treatment. Preliminary studies published in 2016[2] showed that IMMray™ platform could measure SLE high and low activity, but further large discovery studies with many samples per patient would be required to confirm these findings.

"As Immunovia has already shown in cancer applications[3] (press release Aug 15, 2018), IMMray™ blood biomarker signatures offer exciting new opportunities to develop accurate diagnostic tests that could detect the disease in early stages. Our discovery studies have demonstrated the significant power of Immunovia´s IMMray™ technology in autoimmune rheumatic diseases. The overall strategy for Immunovia in the autoimmunity testing that we have now adopted is to solve major clinical unmet needs with the main focus on diagnosis of early RA. Our goal is to provide clinicians with cost-effective multiple testing along the whole patient pathway – from initial diagnosis through treatment selection, monitoring and outcome measurement" says Mats Grahn, Immunovia's CEO.

Telephone conference, October 8, 2018

As announced, a telephone conference today at 3:00 – 4:00 p.m CET will cover Immunovia's autoimmune diseases strategy and be presented by Mats Grahn, CEO, Immunovia and Laura Chirica, CCO, Immunovia. Details in press release dated September 28, 2018.

Reference:

1. *van Steenbergen HW, et al. Ann Rheum Dis 2016;0:1–6*
2. *Delfani P. et al, Deciphering systemic lupus erythematosus-associated serum biomarkers reflecting apoptosis and disease activity, Lupus 26(4) · September 2016*
3. *Mellby L et al, Serum Biomarker Signature-Based Liquid Biopsy for Diagnosis of Early-Stage Pancreatic Cancer,* J Clin Oncol. 2018 Aug 14. doi: 10.1200/JCO.2017.77.6658.

For more information, please contact:
Mats Grahn
Chief Executive Officer, CEO, Immunovia
Tel.: +46-70-5320230
Email: mats.grahn@immunovia.com

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)

This information is information that Immunovia AB 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.

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

About Rheumatoid arthritis (RA)

Rheumatoid arthritis is a long-term condition that causes pain, swelling and stiffness in the joints. The symptoms usually affect the hands, feet and wrists. There may be periods where symptoms become worse, known as flare-ups or flares. A flare can be difficult to predict, but with treatment it's possible to decrease the number of flares and minimise or prevent long-term damage to the joints. Some people with rheumatoid arthritis also experience problems in other parts of the body, or more general symptoms such as tiredness and weight loss.

Recent studies showed that as many as 51% of patients with suspected autoimmune or immune disorders are initially misdiagnosed, in part because of ambiguous laboratory test results. Clinicians warn that misdiagnosis of systemic autoimmune diseases can have serious consequences. Currently the gold standard is to test for anti-cyclic citrullinated peptide (anti-CCP), an auto-antibody present an estimated 70- 75% of rheumatoid arthritis patients.

The global market for RA testing is growing strongly and estimated to reach Euros 2.5 billion by 2024

###