PRESS RELEASE

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A breakthrough in autoimmune testing – an IMMray™ based novel promising biomarker signature identifies patients with anti-CCP negative rheumatoid arthritis

LUND, Sweden — Immunovia today announced that a new study confirms that the IMMray™ blood test successfully addresses one of the major challenges in autoimmune testing. The present study, performed in collaboration with Linköping University, showed that IMMray™ technology can identify patients with rheumatoid arthritis (RA), despite testing negative with antibodies against cyclic citrullinated peptides (CCP). Currently, this important group of patients – representing 25-30% of all RA cases – is missed using the present gold standard assay to analyze IgG-class anti-CCP.

The present study comprised 122 cases testing sero-negative for rheumatoid factor (RF) and anti-CCP, and 94 healthy controls. In addition, 367 RA patients that were anti-CCP or RF-negative, or positive to both, were tested. The 583 samples were collected according to the same blood sample collection procedure. Importantly, the accuracy was higher than 90% for all RA patients, demonstrating the significant power of Immunovia´s IMMray™ technology.

PI Professor emeritus Thomas Skogh, Department of Clinical and Experimental Medicine (IKE) at Linköping University said: "IMMray™ biomarker signatures provides an ideal platform to differentiate various forms of autoimmune diseases with overlapping clinical symptoms. For example, it has already demonstrated an ability to differentiate patients with systemic lupus erythematosus (SLE) from those with RA or Sjögren's syndrome. This novel study is particularly interesting since, until now, we have been unable to detect the significant number of RA patients not identified by anti-CCP testing. Exceeding 90% accuracy already in this preliminary study clearly indicates that IMMray™ signatures have a great potential to diagnose and help managing autoimmune diseases by the aid of a simple blood test. We now look forward to verifying and validating these first results in larger independent cohorts."

Immunovia´s CEO, Mats Grahn commented: "The capability of IMMray™ biomarker signatures to diagnose CCP negative patients with an accuracy over 90% is in fact a remarkable breakthrough. These very convincing results give us the confidence to also focus on autoimmunity and CCP negative RA. We will immediately start to design studies in collaboration with our Key Opinion Leader network to further verify the results and commence development of a commercial assay.

In US and Europe, 5-7 Million is the estimated number of patients living with RA and more than 250.000 new cases are diagnosed every year. Many more than these who actually have RA need to be tested since overlapping symptoms to early stage RA due to other causes are common. Due to its large patient population, RA leads to substantial costs for individual patients and healthcare systems as a result of symptoms, loss of productivity, long-term co-morbidities, and hospitalisation. The annual economic burden of RA in the US exceeds $19 billion, based on direct costs such as hospitalisation, treatment, and loss of productivity. The clinical need is clear - there are a number of highly effective new drugs available, but early and accurate differential diagnosis remains the key to successful treatment."

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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

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