



Press Release, September 23, 2021

Diamyd Medical and partners are awarded SEK 40 million in VINNOVA funding for the prevention of autoimmune diseases

The Swedish governmental innovation agency VINNOVA provides SEK 40 million in financing for an innovation milieu in sustainable precision health that will be led by Diamyd Medical. The project aims to develop and evaluate new algorithms based on artificial intelligence (AI) for preventive precision medical treatments for type 1 diabetes and other autoimmune diseases. The innovation milieu also includes Mainly AIAB, Lund University, Sahlgrenska University Hospital, the National Diabetes Register and the Leading Healthcare Foundation. Diamyd Medical's part of the five year grant amounts to approximately SEK 18 million.

"This is an incredibly exciting and potentially groundbreaking project in type 1 diabetes and autoimmune diseases," says Ulf Hannelius, CEO of Diamyd Medical. "We know that the autoimmune attack on the body's insulin-producing cells begins years before the patient is diagnosed with type 1 diabetes - and we know that we have a great opportunity to change the course of the disease with, among other things, the diabetes vaccine Diamyd. If we can develop new algorithms that can more accurately predict who is at risk and when in time diagnosis is expected to occur, we have the opportunity to make individualized preventive healthcare a reality."

The innovation milieu ASSET (AI for Sustainable Prevention of Autoimmunity in the Society) will develop and evaluate new algorithms based on AI to be able to assess the individual risk of developing type 1 diabetes. Data to be used come from the cohort study TEDDY (The Environmental Determinants of Diabetes in the Young), from Diamyd Medical's clinical trials with Diamyd® and from the National Diabetes Registry. Other autoimmune diseases that are strongly linked to type 1 diabetes, specifically celiac disease (gluten intolerance) and autoimmune thyroiditis (inflammatory disease of the thyroid gland), will also be investigated. The prediction algorithm will be evaluated in two smaller prevention trials where individuals at high risk for type 1 diabetes will be treated preventively with the diabetes vaccine Diamyd®. In parallel, ASSET will study the health care system implications/effects in terms of organizational, economic, and legal prerequisites and consequences of applying the suggested precision health approach in the Swedish health care system. The goal is to proactively address obstacles that may slow down implementation and spread of the innovations in the healthcare system.

About MainlyAI

MainlyAI is a research and technology-based company offering novel AI and ML methods for predictions, knowledge extraction, key performance indicator monitoring and decision support. The company has been successful in applying state of the art methods of privacy-preserving data and knowledge federation in order to speed up and democratize the introduction of AI technologies in industries. The approach of MainlyAI is centered around a platform as a service with an API providing a knowledge database of data and insights, and services simplifying the data/insight access and adoption of AI technologies for business.

About Lund University

Lund University was founded in 1666 and is repeatedly ranked among the world's top 100 universities. The University has around 44 000 students and more than 8 000 staff base in Lund, Helsingborg and Malmö. The unique disciplinary range encourages boundarycrossing collaborations both within academia and with wider society, creating great conditions for scientific breakthroughs and innovations. The University has a distinct international profile, with partner universities in almost 70 countries. The Lund University CRC in Malmö is a leading center for biomedical research embedded within the Skåne University Hospital. The Centre for Autoimmunity and prevention has research projects tailored to investigator initiated preclinical and clinical studies in type 1 diabetes, celiac disease, autoimmune thyroid disease and narcolepsy.

About Sahlgrenska University Hospital

Sahlgrenska University Hospital (SUH) is one of Sweden's largest university hospitals, in close proximity to all areas of education and research. SUH functions as the county hospital for residents of the Gothenburg region as

well as being an engine for healthcare and medical development in Region Västra Götaland. The Pediatric Diabetes Clinic at SUH is a EU/SWEET Centre of Reference with a documented high standard of care. The number of patients is the second largest in Sweden with more than 550 patients regularly visiting the outpatient clinic. The diabetes research is focused on clinical interventions in treatment of diabetes, especially early in the disease of the child, and on early detection of complications. The clinical Pediatric Diabetes Team is highly involved in regional, national and international development of guidelines and structure for pediatric diabetes care.

About The Swedish National Diabetes Register

The Swedish National Diabetes Register (NDR) was established in 1996 with an overall aim to reduce morbidity and mortality, as well as to maximise the cost-effectiveness of diabetes care. It is the largest diabetes register in the world. NDR is an instrument to facilitate such monitoring and to disseminate findings in an accessible, transparent, comparable and timely manner. The register is both a repository of results and an educational tool for improving local quality assessment efforts. The register enables a focus on national quality indicators while following various process measures that are important at the local level. The NDR also promotes and facilitates the influence and participation of patients in their care and treatment.

About Leading Health Care Foundation

Leading Health Care Foundation (LHC) is an independent academic think-tank working to promote dialogue about how health and social care can be improved. LHC conducts research and disseminates knowledge that is relevant to the organization, governance, management and transformation of health care systems. LHC have a broad academic network and an active partner network which currently consists of about 30 organizations from different parts of the sector. Together with partners, LHC conduct research projects, seminars and workshops about the challenges and opportunities in health and social care. LHC aim to provide an arena where different organizations and interests can come together and exchange views with a common goal in mind: to create value for patients and for society. Since 2009, LHC has been an independent and non-profit foundation. LHC are mainly financed through contract research and annual grants from the partner organizations.

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have been shown in a large genetically predefined patient group in a large-scale meta-analysis as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. Preparations for a confirmatory Phase III trial in the US and Europe are on-going, to start recruiting patients later in 2021. A vaccine manufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. An investigator-initiated Remygen® trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser; phone: +46 8-528 00 399, e-mail: info@fnca.se

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