





Transformational Precision Medicine for Autoimmune Diabetes

Stockholm NASDAQ First North Growth Market - DMYD B



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TARGETING AUTOIMMUNE AND INSULIN DEFICIENT DIABETES



Leading clinical stage pipeline

- First-in-class disease modifying therapies Diamyd® and Remygen®
- R&D partnership with JDRF

De-risked development program



- Responder patients identified for Diamyd®, significantly increasing likelihood for success in pivotal program with a precision medicine approach
- Excellent safety profile and simple procedure support successful commercialization

Strong growth opportunity



- Multibillion dollar market and label expansion opportunities
- **Pivotal program** in Type 1 Diabetes (Diamyd®), **Prevention program** Type 1 Diabetes (Diamyd®), establishing **GMP biomanufacturing facility**

Experienced team



- Significant operational experience in clinical development within diabetes
- Access to world leading scientists and clinical experts





AUTOIMMUNE DIABETES

Significant unmet medical need and health economic burden

Type 1 Diabetes

~ 500,000 new cases every year*

184,100 children and adolescents (0-19 years of age) and 329,000 adults are diagnosed with type 1 diabetes every year. It is more prevalent in western countries with the highest incidence in the Nordic countries.

The disease is characterized by life-long dependence on exogenous insulin therapy and blood glucose monitoring and the disease is associated with severe short and long-term complications that lead to shorter life-expectancy, decreased quality of life and significant health economic costs.

LADA (Latent Autoimmune Diabetes in Adults)

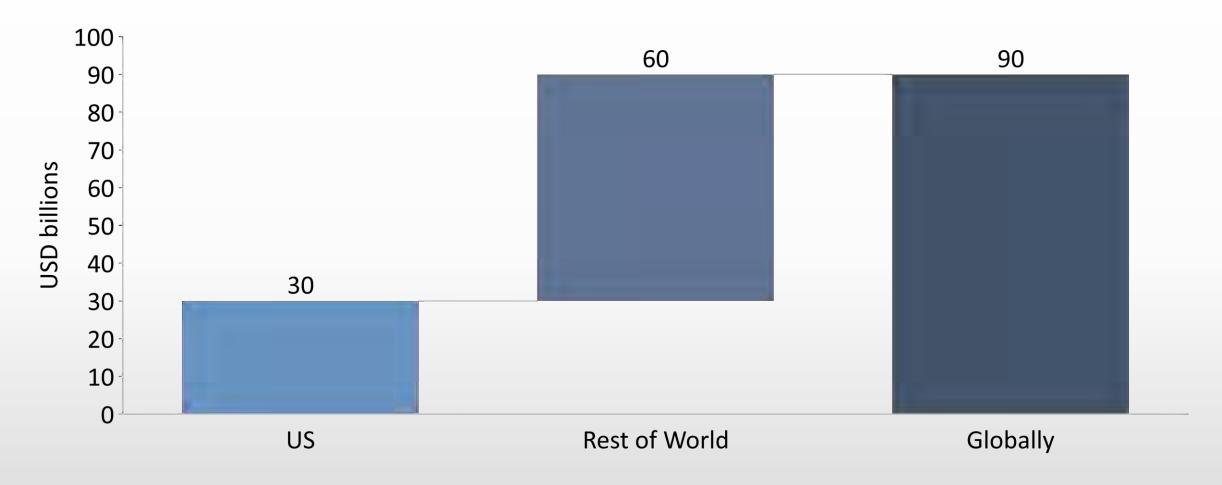
>2 million new cases every year

It is estimated that up to 10% of all type 2 diabetes patients have autoimmune diabetes characterized by autoantibodies against GAD and faster progression to insulin dependence. While type 1 diabetes is rare in many non-western countries, LADA is a prevalent form not only in western countries but also in India, China and Japan.

The disease is today (mis)treated as type 2 diabetes and no disease modifying therapies are available. It is associated with severe short and long-term complications that lead to shorter life-expectancy, decreased quality of life and significant health economic costs.



SIGNIFICANT ANNUAL ECONOMIC BURDEN OF TYPE 1 DIABETES



Disease modifying therapies for T1D are predicted to have a multibillion-dollar economic impact in the US alone

Recent deals emphasize the value of novel innovative therapies for T1D

- \$
- \$2.9 billion acquisition of ProventionBio by Sanofi. FDA-approved immunotherapy "TZIELD" to delay onset of T1D.

\$

Vertex Pharmaceuticals acquisition of ViaCyte (\$320M) and Semma Therapeutics (\$950M) as well as \$100M upfront licensing deal with CRISPR technologies to focus on cell-based treatments for T1D.

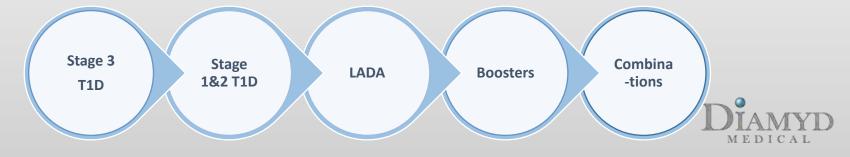
\$

Lilly acquisition of Sigilon Therapeutics developing encapsulated cell therapies for the treatment of T1D with a total deal value of \$309M.

Leading pipeline targeting autoimmune diabetes

PROGRAMME	DEVELOPMENT				STATUS	
Study / Indication	Preclinical	Phase 1	Phase 2	Phase 3	Global Rights	Milestones
DIAGNODE-3 Diamyd®, Recent-onset Stage 3 Type 1 Diabetes (Treatment)					Diamyd	Ongoing in Europe, US start Q3 2023, interim analysis Q4 2024/Q1 2025, topline H2 2026
DiaPrecise Diamyd [®] , Stage 1 & 2 Type 1 Diabetes (Prevention)					Diamyd	Approved, start H2 2023
DIAGNODE-B* Diamyd®, Type 1 Diabetes (*Booster)					Diamyd	Ongoing, topline Q4 2023
GADinLADA Diamyd [®] , LADA					Diamyd	Completed, topline presented at EASD 2022, Publication in preparation
Regenerate-1 Remygen®, Type 1 Diabetes for more than 5 years					DIAMYD	Completed, topline announced Q2 2023

Significant label expansion opportunities for Diamyd®



Diamyd®

Recombinant GAD65 Formulated in Alum (rhGAD65/alum)

Primary Indication

New-onset (stage 3) Type 1 Diabetes with HLA type DR3-DQ2

Label Expansion

Type 1 Diabetes prevention (stage 1 & 2), LADA

Mechanism of Action

Induce immunological tolerance against GAD65

Clinical Effect and Benefit

Preserve the endogenous insulin production, reduce short- and long-term complications

Mode of Administration

Three intranodal injections one month apart

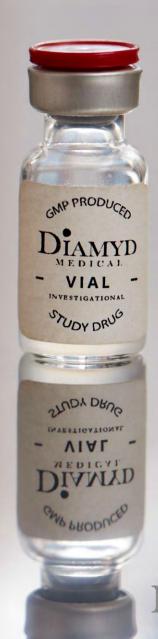
Development Status

Phase III — Stage 3 T1D Phase I/II — Stage 1&2 T1D Phase I/II - LADA

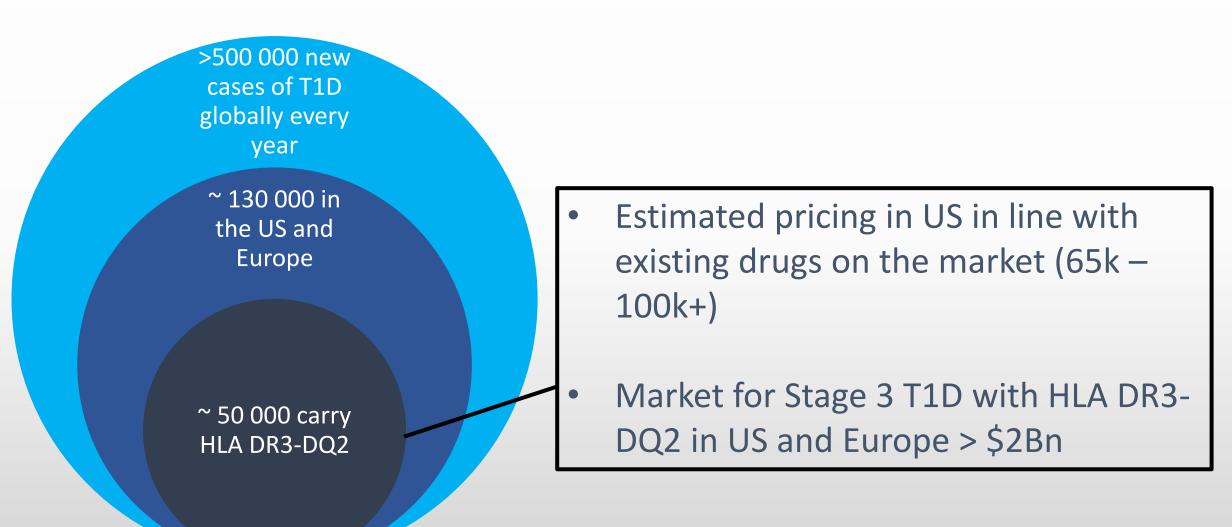
Licensing Status

Global rights available





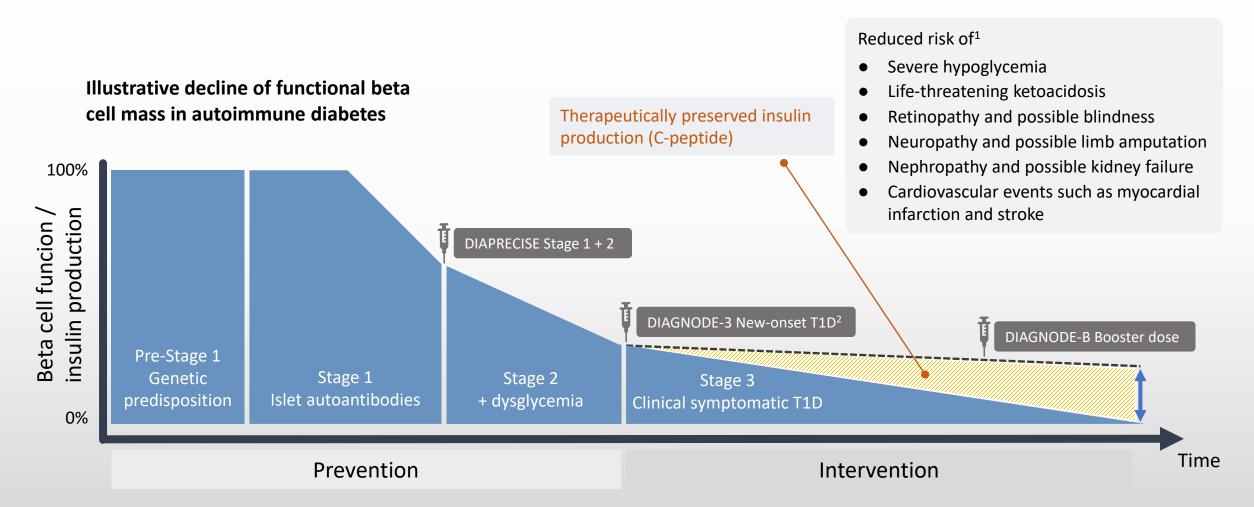
Multibillion total addressable market for Diamyd®

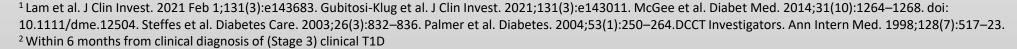




Focus on preemptive medicine

Diamyd[®] is designed to prevent diabetes complications and improve glucose control by stopping the autoimmune destruction of beta cells













Stage 3 T1D Stage 1&2 T1D

LADA

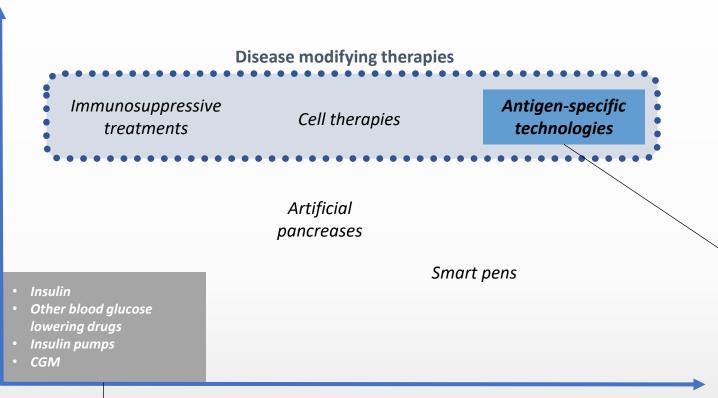
Boosters

Combinations



POSITION DIAMYD® TO MAXIMIZE EFFICACY, SAFETY, CONVENIENCE





Antigen-specific immunotherapy with Diamyd® targets the body's immune system by reprogramming it to stop attacking the insulin-producing cells. This treatment has the potential for long-term efficacy. Compared with other technologies under development often requiring hospitalization, the diabetes vaccine Diamyd® displays an excellent safety profile and is a fast and easy treatment.

Convenience, Safety

Added value compared to standard of care

The current **standard treatment** for type 1 diabetes is life-sustaining, subcutaneous deliveries of insulin by injection or pump therapy, combined with continuous glucose monitoring (CGM). In addition to non-insulin anti-diabetic drugs and aids, such as artificial pancreases and smart insulin pens to help patients manage their condition, therapies targeting the underlying causes of the disease are also being developed.

Diamyd® (rhGAD65/alum) In Pivotal Phase 3 Program aligned with FDA and EMA



Strong **safety** profile – evaluated in almost 1,000 persons aged 4-70 years

Compelling efficacy for **preserving insulin producing capacity** and improving glucose control based on data from >600 patients

Simple and short treatment - only 3 outpatient injections one month apart

No hospitalization, no known major adverse reactions, no immunosuppression, well tolerated

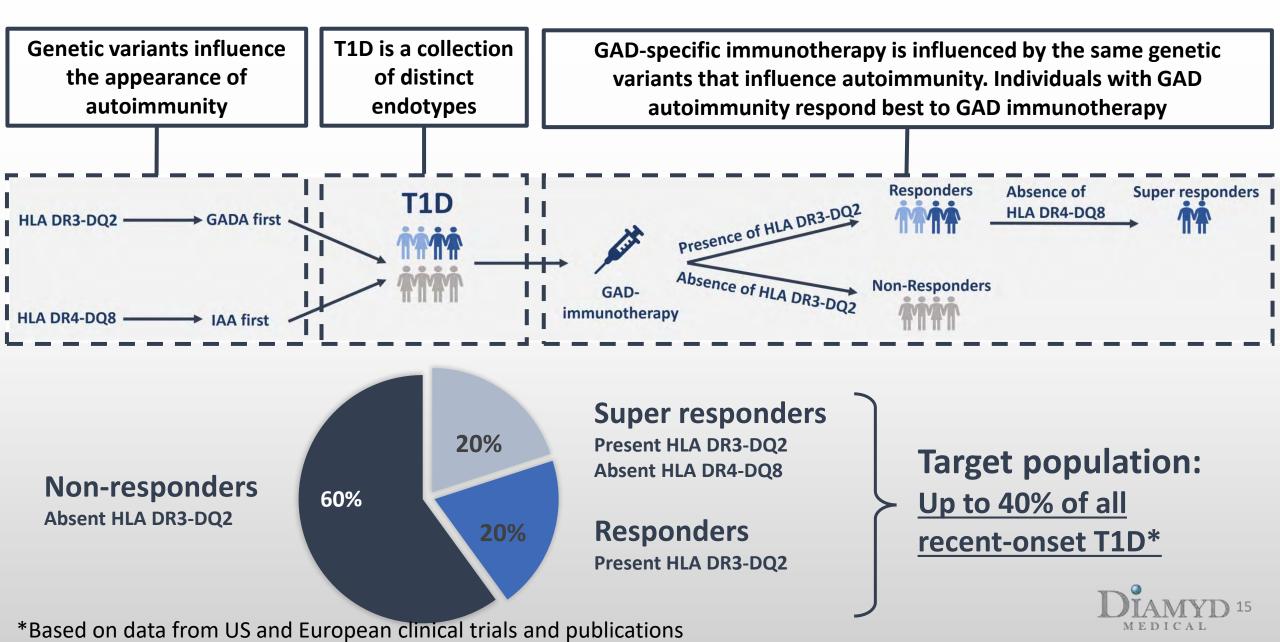
Precision medicine - increased likelihood of clinical & commercial success

 Responder patients easily identified by HLA testing routinely available in US and EU

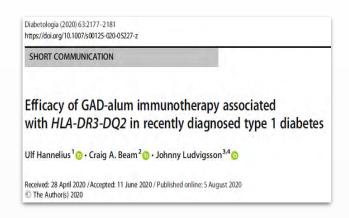


New-onset (Stage 3) Type 1 Diabetes with HLA type DR3-DQ2

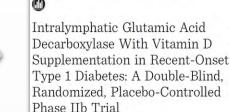
RESPONDERS TO DIAMYD® TREATMENT



CRUCIAL RESEARCH ADVANCES IN PRECISION MEDICINE FOR TYPE 1 DIABETES





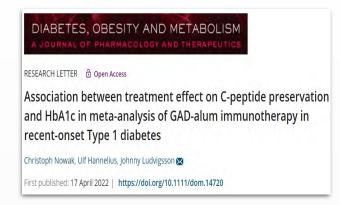


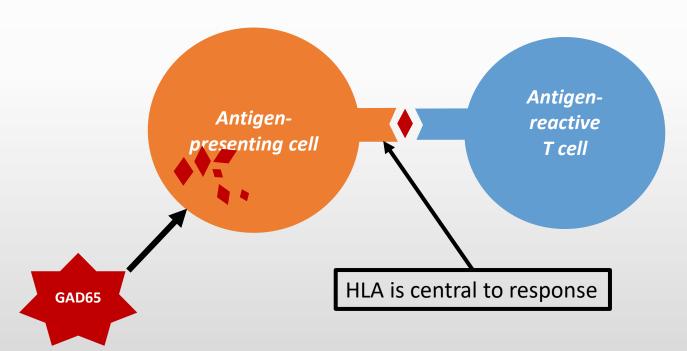
Diabetes Care Volume 44, July 2021

Diabetes Care 2021;44:1-9 | https://doi.org/10.2337/dc21-0318

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Significant treatment effects on:

- 1. Preservation of endogenous insulin production
- 2. Improved HbA1c
- 3. Less glycemic variability
- 4. More time spent in optimal glucose range
- 5. Less time spent in hyperglycemia 💿

HLA INFLUENCES EFFECT OF DIAMYD®

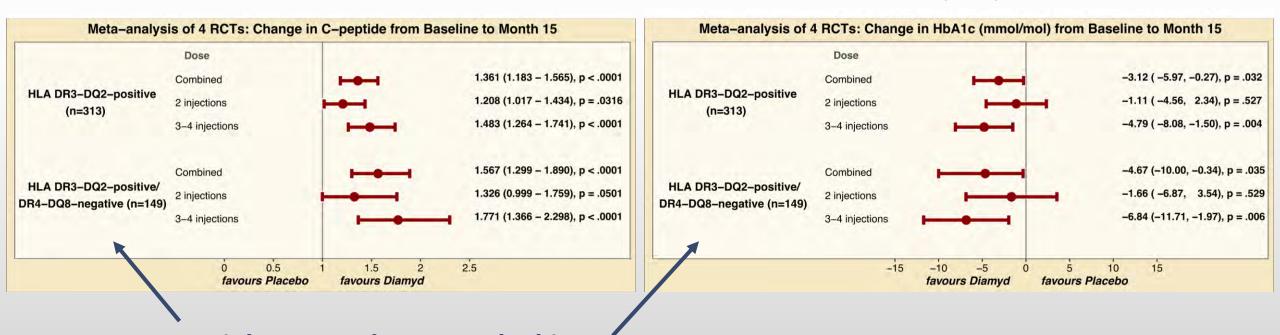
Significant and dose-dependent treatment effect of Diamyd® (GAD-alum) in HLA DR3-DQ2 positive individuals on preservation of own insulin production and HbA1c

Meta-analysis with >600 recent-onset T1D patients

4 RCTs (Phase III EUR, Phase II SWE, Phase II US, Phase IIb EUR)

C-peptide

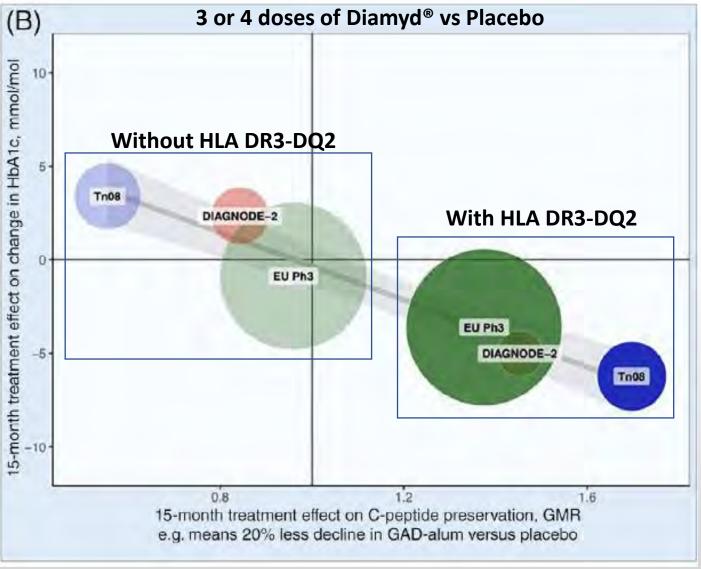
HbA1c



High responder group lacking HLA DR4-DQ8



CORRELATED TREATMENT EFFECTS (CHANGE FROM BASELINE TO MONTH 15 VERSUS PLACEBO) ON C-PEPTIDE AND HBA1C



DIABETES, OBESITY AND METABOLISM

Association between treatment effect on C-peptide preservation and HbA1c in meta-analysis of GAD-alum immunotherapy in recent-onset Type 1 diabetes

Christoph Nowak, Ulf Hannelius, Johnny Ludvigsson

First published: 17 April 2022 | https://doi.org/10.1111/dom.14720

Sensitivity analyses, including adjustment for insulin dose, confirm robust effect



The first ever precision medicine Phase III trial in Type 1 Diabetes

 Diamyd[®] in individuals recently diagnosed with type 1 diabetes and positive for the HLA DR3-DQ2 haplotype



Diagnode-3
study

www.diagnode-3.com

DIAGNODE-3 Pivotal Precision Medicine Phase 3 trial

Ongoing at just over 50 clinical sites in Europe



Approved by FDA to start in US, ca. 10 US sites planned, starting summer of 2023



Diamyd Medical partners with JDRF to advance the DIAGNODE-3 Phase 3 trial in Type 1 Diabetes





April 04, 2023 – Diamyd Medical and JDRF, the leading global type 1 diabetes research and advocacy organization, have entered into a four-year research and development collaboration including a non-dilutive \$5 million award to Diamyd Medical to support its ongoing Phase 3 trial with the precision medicine antigen-specific immunotherapy Diamyd®. The grant will be funded under JDRF's Industry Discovery & Development Partnerships program that focuses on commercialization of therapeutics and devices for the treatment, cure, and prevention of type 1 diabetes and its complications.

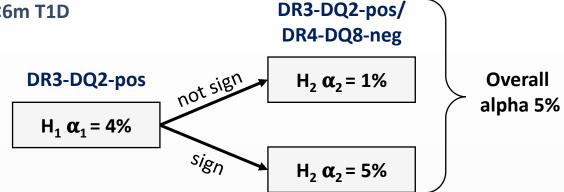
Joint press release, 4 April 2023

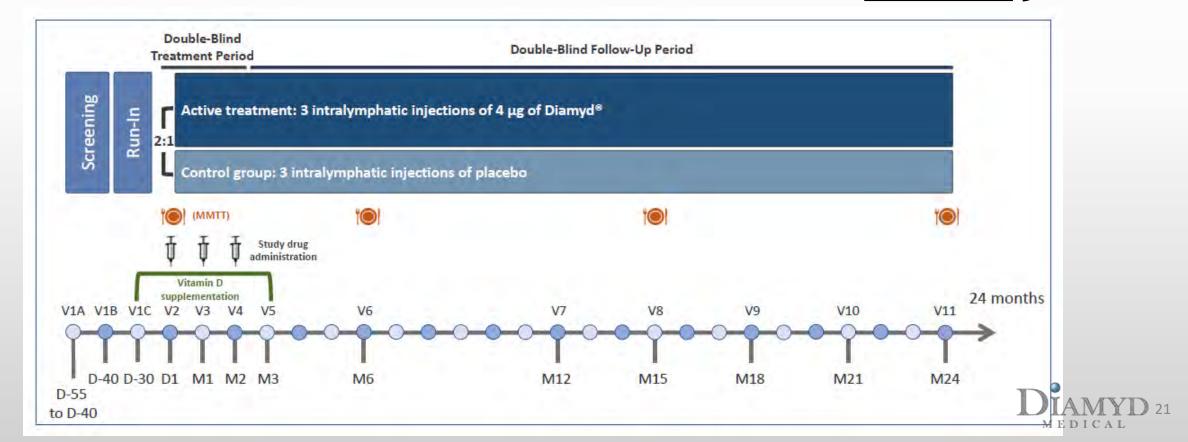
www.diagnode-3.com



RESULTS SUPPORT DESIGN OF PIVOTAL, GLOBAL PHASE III TRIAL DIAGNODE-3

- Responder population HLA DR3-DQ2 (40-50%) with GADA, 12-28 yr, <6m T1D
- Intralympatic injections (superior to subcutaneous injections)
- 3 monthly injections (superior to 2 injections)
- Co-primary endpoints C-peptide and HbA1c (baseline to Month 24)
- Total n = 330





Latent Autoimmune Diabetes in Adults (LADA)*

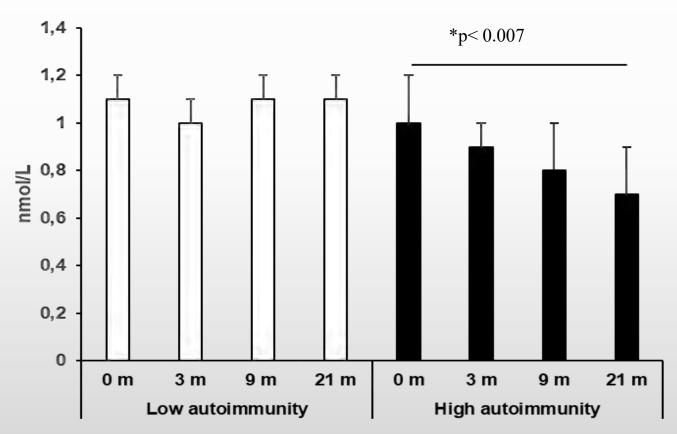


^{*}Also called Slowly progressing Autoimmune Diabetes (SAID) or Slowly progressing insulindependent diabetes mellitus (SPIDDM)

Background

In highly autoimmune LADA individuals: treatment that directly targets autoimmunity is needed

Glucagon-stimulated C-peptide (mean ± SEM)

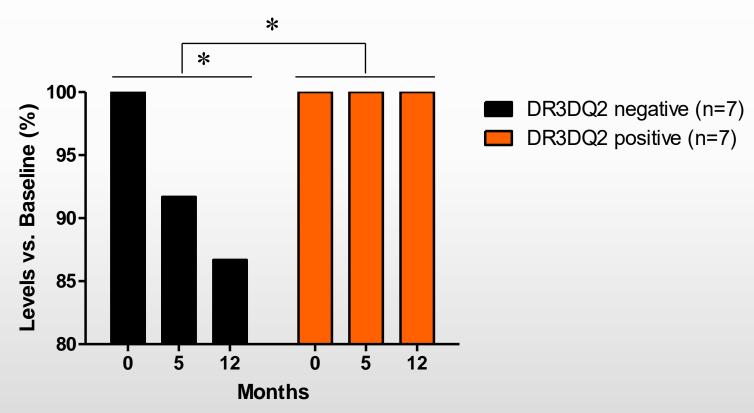


Hals IK, Fiskvik Fleiner H, Reimers N, Astor MC, Filipsson K, Ma Z, Grill V, Björklund A. Investigating optimal β-cell-preserving treatment in latent autoimmune diabetes in adults: Results from a 21-month randomized trial. Diabetes Obes Metab. 2019 Oct

Glucagon-stimulated C-peptide levels unchanged at 12 months vs Baseline (0 months) in the HLA-DR3DQ2 positive subgroup

Phase 2 trial with Diamyd in up to 70 year-old LADA patients

Glucagon-stimulated C-peptide



^{*}p< 0.03 for median 13.3% reduction at 12 months vs. Baseline (0 months) in the DR3DQ2 negative subgroup (n=7).

^{*}p< 0.04 for difference between HLA subgroups in change at 12 months vs. Baseline (0 months).

Conclusions

- Treatment with intralymphatic GAD is well tolerated in LADA individuals no safety concerns
- GAD-induced immune responses appear compatible with those in studies with type 1 diabetes
- Results on C-peptide suggest an HLA-dependent beneficial effect akin to type 1 diabetes

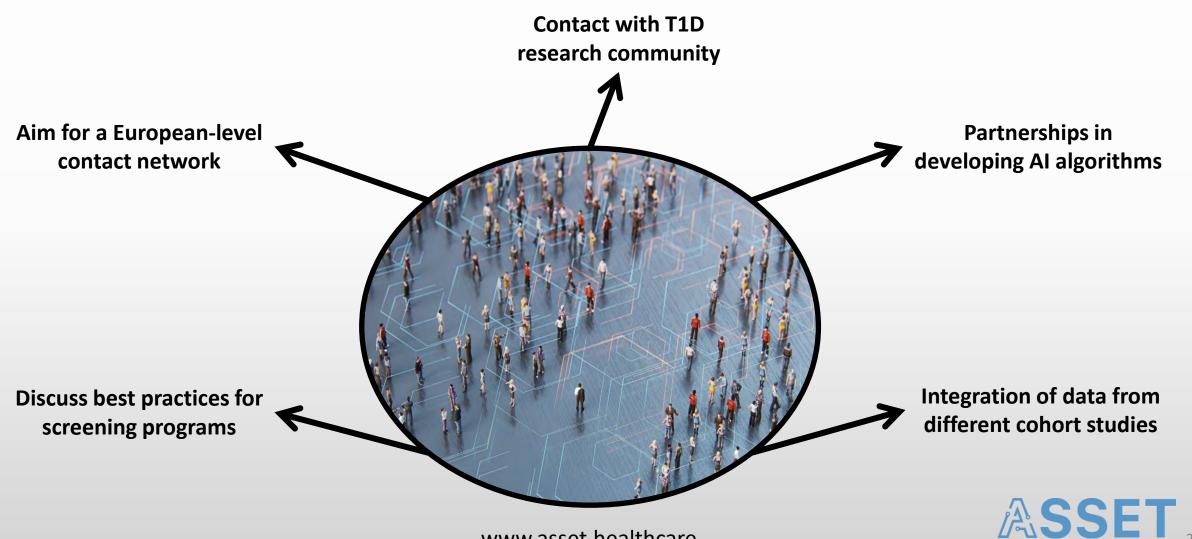
Also see

- Latent Autoimmune Diabetes in Adults: Background, Safety and Feasibility of an Ongoing Pilot Study With Intra-Lymphatic Injections of GAD-Alum and Oral Vitamin D, Björklund et al, Front Endocrinol, 2022
- Press release: Updated results from clinical trial with Diamyd® presented today at diabetes conference

Type 1 Diabetes prevention (Stage 1 & 2)

DIAMYD MEDICAL COORDINATES THE ASSET MILIEU

A T1D Forum to drive precision medicine, prevention and screening



ABOUT ASSET

The innovation milieu ASSET (AI for Sustainable Prevention of Autoimmunity in the Society – www.asset.healthcare) will develop and evaluate new algorithms based on AI to be able to assess the individual risk of developing Type 1 Diabetes (T1D), and the likelihood of responding to different treatments. Data from cohort studies such as TEDDY (The Environmental Determinants of Diabetes in the Young), from Diamyd Medical's clinical trials with Diamyd® and from sources such as the National Diabetes Registry will consitute the initial training dataset for the algorithm. T1D will form the pilot project for the program, but the goal is extend the functionality to other indications including other autoimmune diseases that are strongly linked to T1D such as celiac disease (gluten intolerance) and autoimmune thyroiditis (inflammatory disease of the thyroid gland). The prediction algorithm will be evaluated in clinical 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 organizational, economic, and legal prerequisites and consequences of applying the approach as a tool for precision health in the Swedish health care system. The project has a duration of five years and is financed via the Swedish innovation agency VINNOVA.









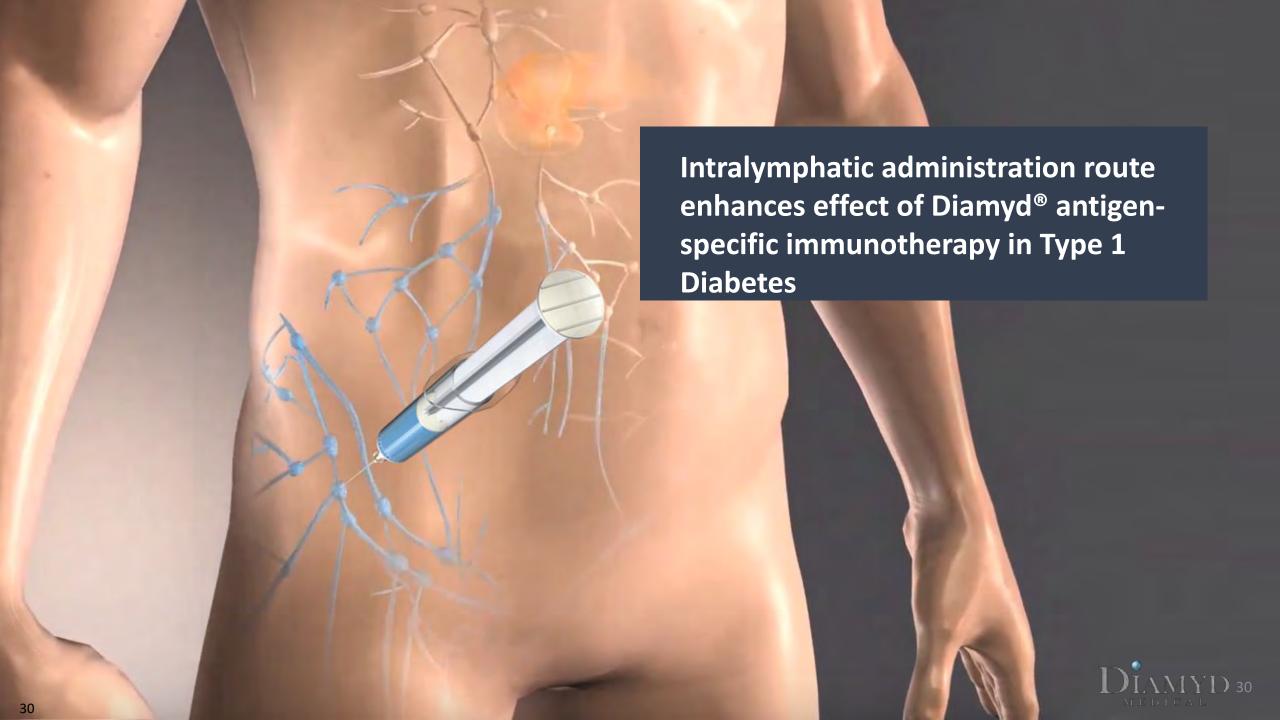






Safety and administration of Diamyd®





MORE EFFICIENT UPTAKE IN AND DRAINAGE TO LYMPH NODES FOLLOWING INTRALYMPHATIC COMPARED TO SUBCUTANEOUS ADMINISTRATION

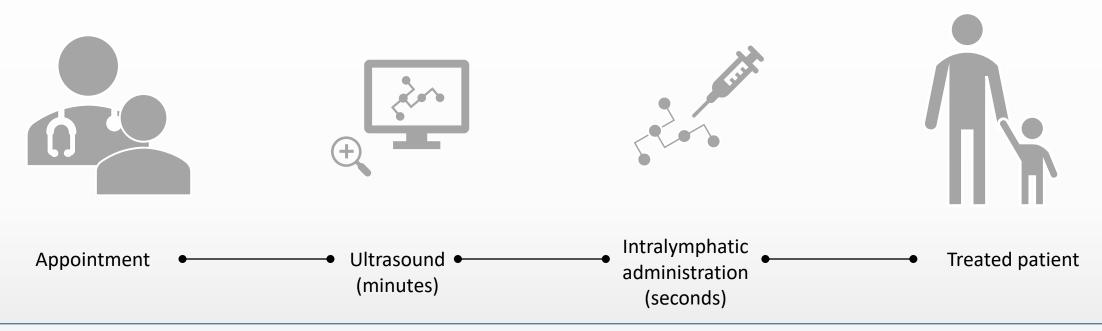
Lessons Learned from Allergy Immunotherapy Trials



Subcutaneously (S.C.) injected large molecules including proteins do not effectively spread to the draining lymphnodes. Intranodal (I.L.) injections lead to immediate spreading to deeper lymphnodes. The image depicts radio tracing of labeled IgG at 20 minutes and 25 hours after subcutaneous and intranodal injection in a healthy human volunteer.

CONVENIENT OUTPATIENT PROCEDURE ENHANCES VALUE PROPOSITION FOR DIAMYD®

Potential to reach patients outside specialized clinics and avoiding costs related to hospitalization

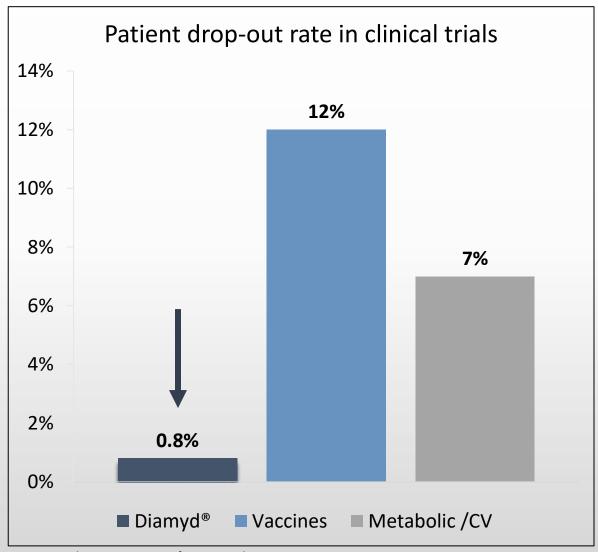


The procedure is performed by a radiologist by way of ultrasound guided injections that are given three times, one month apart. Clinical results and safety support the addition of annual booster injections in the pivotal trial.

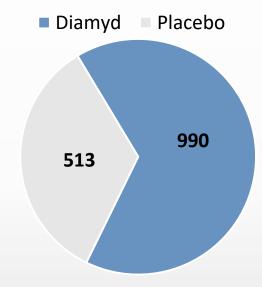
Confirmed* by interviews and questionnaires involving radiologists and study nurses taking part in the ongoing Phase IIb program, the procedure is simple and convenient, and can be performed using hand-held ultrasound devices. Non-radiologists could be educated to perform the procedure.

^{*} Evaluation of the Feasibility of Intralymphatic Injection of Diamyd®, Selam Fessehaye 2019, Master Thesis, Uppsala University

SUPERIOR SAFETY PROFILE



Total patient exposure



Most commonly reported adverse events:

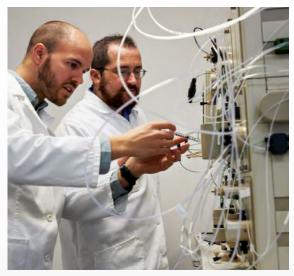
- tenderness, injection site edema, injection site pain and injection site reaction.
- no difference in the rate of occurrence of the adverse events between active Diamyd[®] treatment and placebo

Source: Industry averages, Tufts CSDD, February 2, 2020: https://www.centerwatch.com/articles/24543-recruitment-rates-rising-but-retention-rates-fall-according-to-new-study



Manufacturing and Market Exclusivity of Diamyd®

Full Control and Predictability of the Manufacturing Process









A nascent biomanufacturing plant in Umeå - Northern Sweden's cultural capital

- 20,000 square feet facility comprising clean rooms, laboratory facilities and office space
- Manufacturing facility property fully acquired in 2022. Goal to be be GMP ready in 2023.
- Full control over the manufacturing of recombinant GAD65
 - Independence from CDMOs, third parties
 - In control of costs and resource allocation.
 - Potential beyond GAD manufacturing



DIAMYD® (rhGAD65/ALUM) MANUFACTURING

Upstream process:



Baculovirus expression system & Insect cells



Downstream process:





Clarification
Capture
Polish
Nanofiltration

DP formulation



DIAMYD® IP & MARKET EXCLUSIVITY



Core Intellectual Property

- Substance of matter in the US until 2032
- Intralymphatic administration of Diamyd® in Europe, Japan, China, Australia and Russia, additional countries pending, expiry 2035.
- Intralymphatic administration of additional betacell antigens (proinsulin, preproinsulin etc)
 approved in Australia, Israel, additional countries pending.
- Precision medicine patent based on HLA subgroups approved in Europe and Eurasia, expiry 2035, additional countries pending.



Regulatory exclusivity

- US BLA approval provides 12 years exclusivity
- US orphan designation provides **7 years exclusivity** from approval
- European approval provides 10 years of exclusivity
- Accelerated approval pathways are being evaluated



Modified Release GABA

Primary Indication

Type 1 diabetes

Label expansion

LADA, Insulin-deficient type 2 diabetes

Mechanism of Action

Activate GABA-receptors in the pancreas

Clinical Effect

- Regenerate endogenous insulin production, reduce shortand long-term complications
- Prevention of hypoglycemia

Mode of Administration

Oral

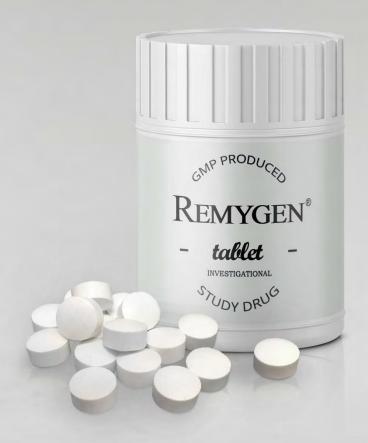
Development status

Phase Ib/IIa

Licensing Status

Global rights available

Remygen®



CLINICAL RESULTS WITH ATTRACTIVE PATH TO MARKET FOR REMYGEN®

- Phase lb/lla first in man trial
 - ReGenerate-1 at the University of Uppsala where Remygen® (proprietary formulation of GABA) alone and in combination with low-dose alprazolam (GABA receptor modulator to enhance effect, see next slide) evaluated in long-standing type 1 diabetes patients
 - Clinical effects (Phase Ib dose-escalation) shown on preventing hypoglycemia by correcting the counter regulatory hormone response and increasing time-in-range in long-term type 1 diabetes (published), potential trend for acute effect of Remygen shown in Phase IIa (further data analyses ongoing).
 - Long-term safety of all doses of GABA as well as combination with low-dose Alprazolam
- Clinical effects of GABA (non-proprietary formulation) shown on decreasing glucagon secretion in recent-onset type 1 diabetes and immunological effects shown on altering Th1 response
- Preclinical effects on insulin secretion, glucagon secretion and beta cell regeneration
- Endogenous substance with very good safety profile







GABA and Combined GABA with GAD65-Alum Treatment Alters Th1 Cytokine Responses of PBMCs from Children with Recent-Onset Type 1 Diabetes

Katie E. Heath 1, Joseph M. Feduska 1, Igne P. Taylor 10, Julie A. Houp 2, Davide Botta 10, Frances E. Lund 10, Gail J. Mick 3, Gerald McGwin, Jr. 4, Kenneth L. McCormick 3 and Hubert M. Tse 5,*

Original research Open access

BMJ Open **Diabetes** Research & Care

GABA induces a hormonal counterregulatory response in subjects with long-standing type 1 diabetes

Daniel Espes , 1,2 Hanna Liljebäck, 3,4 Henrik Hill, Andris Elksnis, 3 José Caballero-Corbalan. 4 Per-Ola Carlsson 3,4

nature communications

Article

A randomized trial of oral gamma aminobutyric acid (GABA) or the combination of GABA with glutamic acid decarboxylase (GAD) on pancreatic islet endocrine function in children with newly diagnosed type 1 diabetes

Received: 27 October 2021

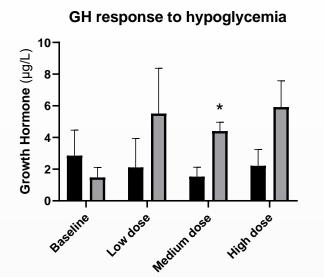
Accepted: 6 December 2022

Published online: 24 December 2022

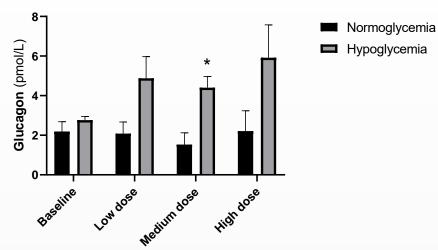
Alexandra Martin^{1,4}, Gail J. Mick ® 1,4 ... Heather M. Choat ® 1. Alison A. Lunsford 1, Hubert M. Tse 2, Gerald G. McGwin Jr. & Kenneth L. McCormick @1



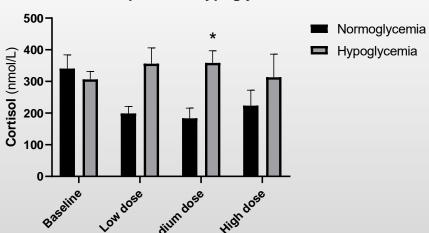
GABA TREATMENT IMPROVES THE HORMONAL RESPONSE TO HYPOGLYCEMIA



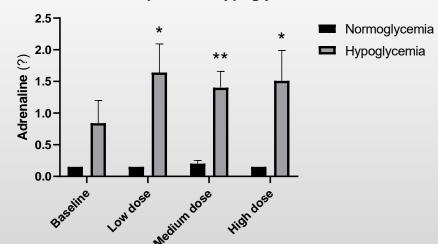
Glucagon response to hypoglycemia



Cortisol response to hypoglycemia



Adrenaline response to hypoglycemia



Comparisions between noro- and hypoglycemia for the respective group using a multiple T-test with p-values corrected for multiple testing using the Holm-Sidak method.

* denotes p<0.05, ** <0.01 Values are given as mean±SEM



Normoglycemia

Hypoglycemia

REMYGEN® MARKET EXCLUSIVITY AND MANUFACTURING



Core Intellectual Property

- Exclusive license from UCLA on treating diabetes and other inflammatory diseases with GABA
- **Formulation patent** application (Remygen®). Application in national phase.
- Exclusive license from UCLA on GABA in combination with GABA receptor modulators to enhance the regenerative and immunomodulatry effect. Application in national phase.



Regulatory exclusivity

• 505(b)(2) regulatory pathway in the US provides potentially faster time to market at reduced cost



Manufacturing

• GMP drug substance (GABA) and drug product (Remygen®) manufacturing in place



Management

Board of Directors

Scientific Advisory Board



Dr. Ulf Hannelius, PhD, MBA President & Chief Executive Officer



Erik Nerpin, LL.M. Chairman of the Board



Professor Dr. Mark Atkinson, PhD (Chair)



Martina Widman, MSc **Chief Operating Officer**



Anders Essen-Möller, MSc Founder



Professor Dr. David Leslie, MB BS, MRCS, MD, FRCP, FAoP



Anna Styrud, BSc **Chief Financial Officer**





Maria-Teresa Essen-Möller, **MSc**



University of London



Anton Lindqvist, MSc Chief Scientific Officer



Dr. Torbjörn Backström, MD, **PhD**



Professor Dr. Daniel Kaufman, PhD **UCLA School of Medicine**



Dr. Maja Johansson, PhD Chief Operating Officer -Manufacturing Site

Eva Karlström, MSc



Dr. Mark Atkinson, PhD



Dr. Karin Hehenberger, MD, **PhD**



Dr. Karin Rosén, MD, PhD



Dr. Christoph Nowak, MD, PhD Chief Medical and Business Officer

Chief Regulatory Affairs Officer



TOP WORLDWIDE EXPERTS

Covering the areas of clinical practice and scientific excellence in Type 1 Diabetes and



Prof. Johnny Ludvigsson

Professor of Pediatrics. First in the world to use immune intervention in children and teenagers with newly diagnosed T1D, and in collaboration with others

64kD was found. An alumformulation of GAD was developed (Diamyd®), used as a treatment in an effort to deviate the immune system and create tolerance.



Prof. David Leslie

Professor of Diabetes and Autoimmunity. Professor Leslie has been Director of the British Diabetic Twin Study since 1982, the world's largest twin study of its type and Principal Investigator of the European Action LADA consortium. By studying twins, Professor Leslie has been able to show the possibilities for predicting and preventing autoimmune diabetes.



Prof. Åke Lernmark

Professor in Experimental
Diabetes Research, Professor
Lernmark has focused his
research on diabetes and at an
early stage identified the
antigen that later proved to be
GAD. He and his colleagues
were the first to clone GAD65
from human islets using
biochemical methods and was
thus the first to define
autoantibodies against GAD65
in patients with type 1 diabetes.



Prof. Daniel Kaufman

Professor Kaufman's research is focused on studies in the field of autoimmunity, particularly type 1 diabetes (T1D) and understanding the disease mechanisms in order to develop novel therapeutics in mouse models that could potentially be translated to clinical use. Using preclinical models, Dr. Kaufman's lab helped to develop some of the GAD and GABA-based diagnostics and therapeutics for T1D that are in clinical use or are being tested in clinical trials.



Prof. Mark A. Atkinson

Professor of Diabetes Research, Department of Pathology, Immunology and Laboratory Medicine, University of Florida, USA. American Diabetes Association Eminent Scholar for Diabetes Research. Director, UF Diabetes Institute, University of Florida. Independent of the Company and its principal owners.

Diamyd Medical Board member.



DIAMYD MEDICAL

- Swedish clinical phase pharmaceutical company, founded 1994
- NASDAQ First North Growth Market, ticker DMYD B

FINANCES

- Market Cap Jul 17, 2023 ~ MSEK 843
- Cash May 31, 2023: MSEK 77 (+ MSEK ~70 from share issue July 2023)

INDICATIONS

- Diabetes
- Autoimmunity

PRODUCT CANDIDATES

- Diamyd® (Phase III)
- Remygen® (Phase Ib/IIa)

INVESTMENTS

- NextCell Pharma (Stockholm, Sweden)
- MainlyAl (Stockholm, Sweden)



Diamyd Medical

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