



DIAMYD
MEDICAL

Diamyd® for the Treatment of Autoimmune Diabetes
Stockholm NASDAQ First North Growth Market – DMYD B

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Diamyd®: Revolutionizing Type 1 Diabetes Treatment with Antigen-Specific Immunotherapy

Diamyd® is an innovative **antigen-specific immunotherapy** targeting a large genetic subgroup of autoimmune diabetes (**Type 1 Diabetes, LADA**).

Currently in **pivotal Phase 3 for Stage 3 T1D** at 60 clinics across Europe and the US, Diamyd® is designed to **preserve beta cell function**.

With **Fast Track** and **Orphan designations**, **biologic exclusivity** as well as support for an **Accelerated Approval pathway by the FDA**, Diamyd® has the potential to command a significant market share.

Base case US peak sales for Stage 3 T1D (lead indication) **>\$2 billion**.

DIAMYD MEDICAL

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

FINANCES

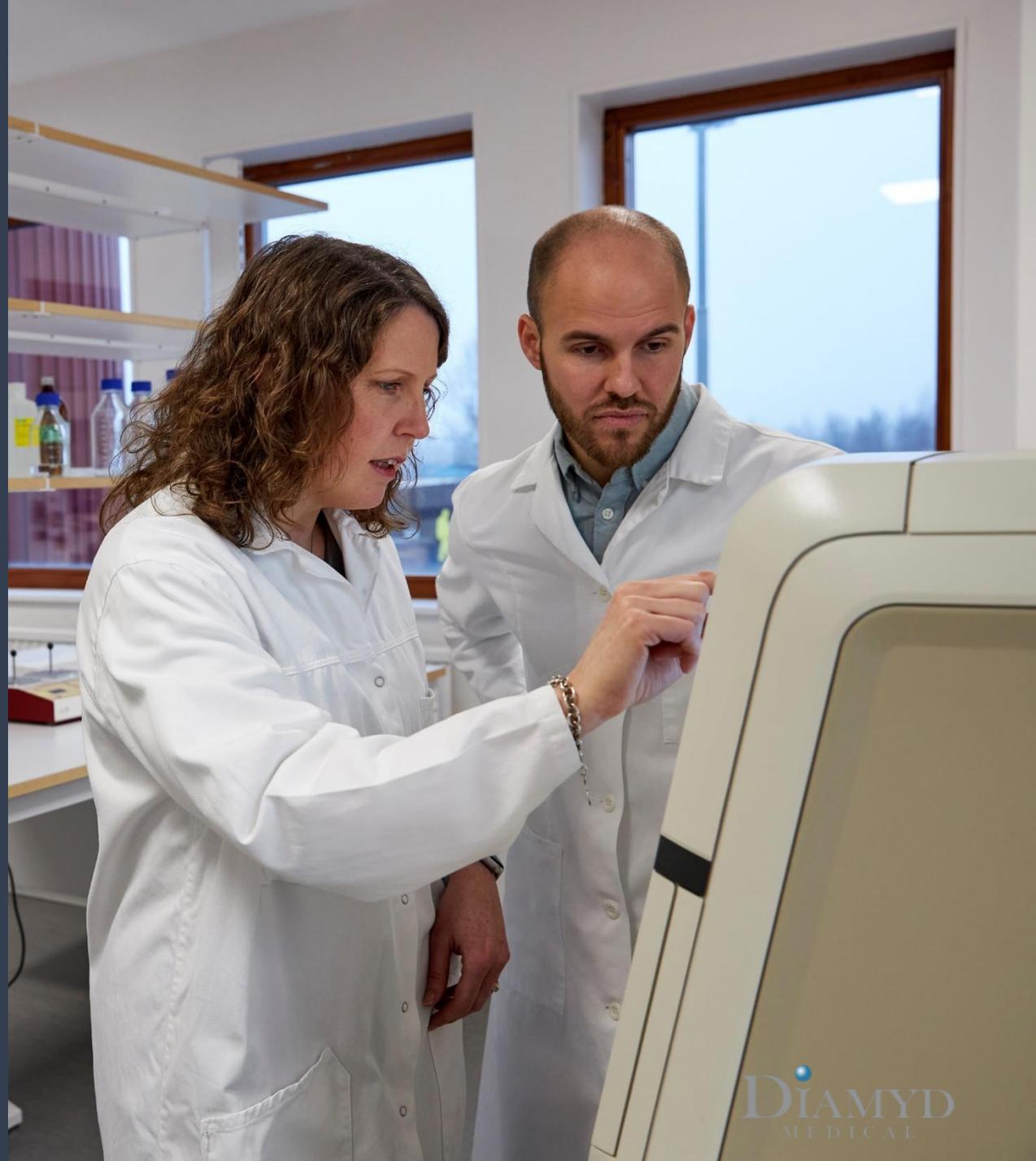
- Market Cap Jan 31, 2025~ MSEK 1,800
- Cash Nov 30, 2024: MSEK 152.9 (warrants of Series TO4 in March 2025 with a potential of MSEK 110)

LEAD PRODUCT

- Diamyd® - Phase 3 development in Stage 3 Type 1 Diabetes

INVESTMENTS

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



Management



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President & Chief Executive Officer



Martina Widman, MSc
Chief Operating Officer



Anna Styrud, BSc
Chief Financial Officer



Anton Lindqvist, MSc
Chief Scientific Officer



Dr. Maja Johansson, PhD
Chief Operating Officer –
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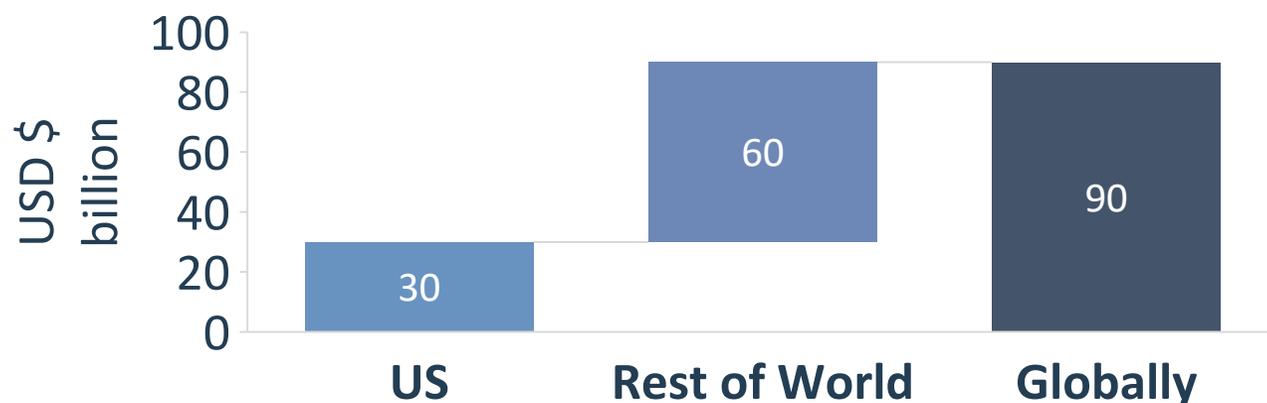
Autoimmune Diabetes: Unmet need & economic burden

Type 1 Diabetes (T1D)

~ 500,000 new cases every year

- More common in Western countries, especially Scandinavia
- Life-long dependence on insulin therapy and blood glucose monitoring

>\$90 BN global annual economic burden*



Latent Autoimmune Diabetes in Adults (LADA)

>2 million new cases every year

- 10% of all Type 2 Diabetes patients may have autoimmune diabetes with GAD autoantibodies and faster progression to insulin dependence
- Common in Western countries, but also in India, China and Japan

*Modelling the total economic value of novel T1D therapeutic concepts, January 2020, Health Advances.



High risk of serious complications, shorter life-expectancy, decreased quality of life and significant health economic costs

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

Accelerating interest for autoimmune diabetes from pharma & regulators

Mar 2023 **\$2.9 billion** acquisition of **Provention Bio** by **Sanofi**. **FDA-approved** immunotherapy **TZIELD** to delay onset of T1D. Sanofi leading concerted effort to raise T1D awareness and build the screening and treatment infrastructure for disease-modifying therapies.

2019-2023 **Vertex Pharmaceuticals** acquired **Semma Therapeutics** in 2019 (\$950M) and **ViaCyte** in 2022 (\$320M); **CRISPR Therapeutics** \$100M upfront licensing deal in 2023

Apr 2023 **Novo Nordisk** partnership with **Aspect Biosystems** (\$75M upfront and milestones up to \$650M) to produce 3D printed cells

Jun 2023 **FDA** approved **cell therapy Lantidra** for treatment of difficult-to-control adult T1D

Jun 2023 Eli Lilly acquired cell therapy company **Sigilon** in 2023 (deal worth up to \$500M)

Clinical Pipeline

Diamyd® is the only disease-modifying therapy in the world for Type 1 Diabetes in Phase 3 development

PROGRAM		DEVELOPMENT				STATUS	
Study / Indication	Asset	Preclinical	Phase 1	Phase 2	Phase 3	Global Rights	Milestones
DIAGNODE-3 Recent-onset Stage 3 T1D with HLA DR3-DQ2 & GADA	Diamyd®	Fast track designation, Orphan designation, R&D partnership with Breakthrough T1D					Ongoing in EU & US, early readout March 2026
DiaPrecise Stage 1 & 2 T1D with HLA DR3-DQ2 & GADA	Diamyd®						Started Q4 2023
DIAGNODE-B T1D with HLA DR3-DQ2 & GADA; 4th or 5th "booster" dose	Diamyd®						Completed, topline results announced Q4 2023
GADinLADA LADA with HLA DR3-DQ2 & GADA	Diamyd®						Completed, topline presented at EASD 2022, published
RegGenerate-1 T1D for more than 5 years	Remygen®						Completed, topline announced Q2 2023
Insulin-based antigen-specific therapy to treat and prevent T1D with HLA DR4-DQ8 and IAA							

Diamyd®

Recombinant GAD65 Formulated in Alum (rhGAD65/alum)

Primary Indication (Fast Track and Orphan designation)

Type 1 Diabetes (stage 3) with residual beta cell function and HLA type DR3-DQ2

Label Expansion

*Type 1 Diabetes prevention (stage 1 & 2), Fast Track designation
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

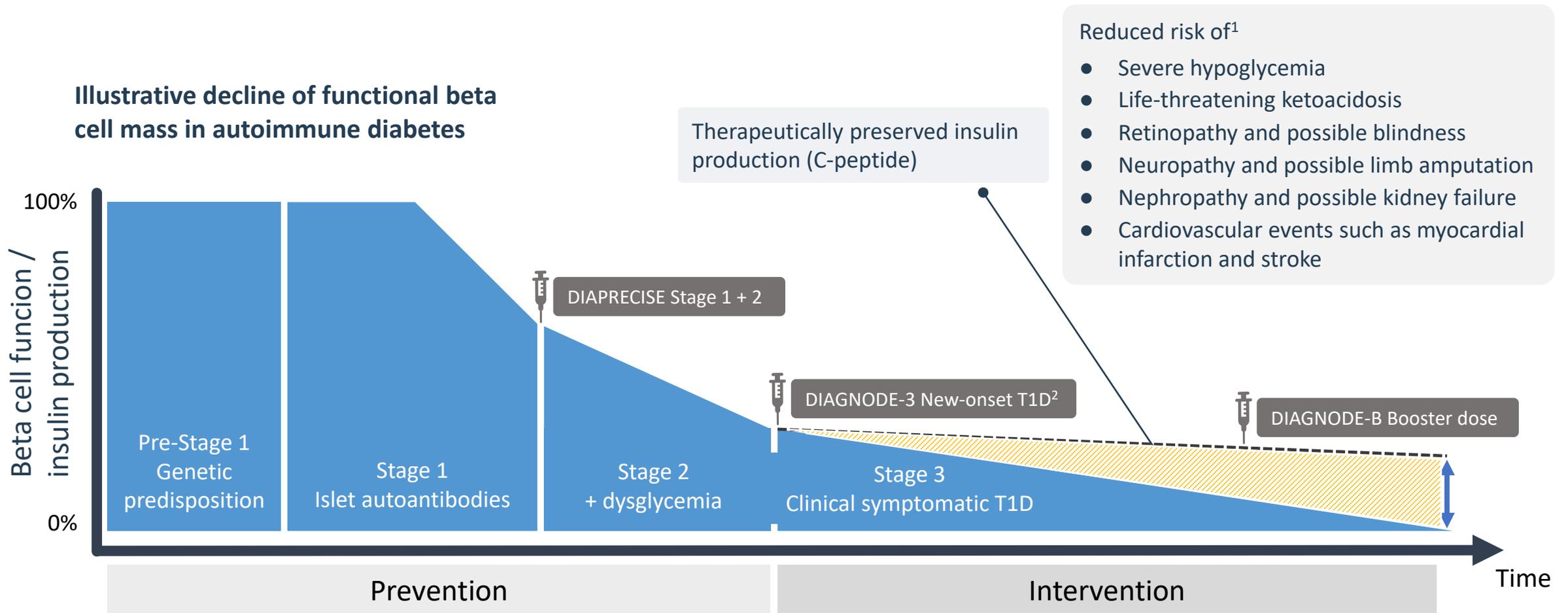
Licensing Status

Global rights available



Focus on preemptive medicine

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

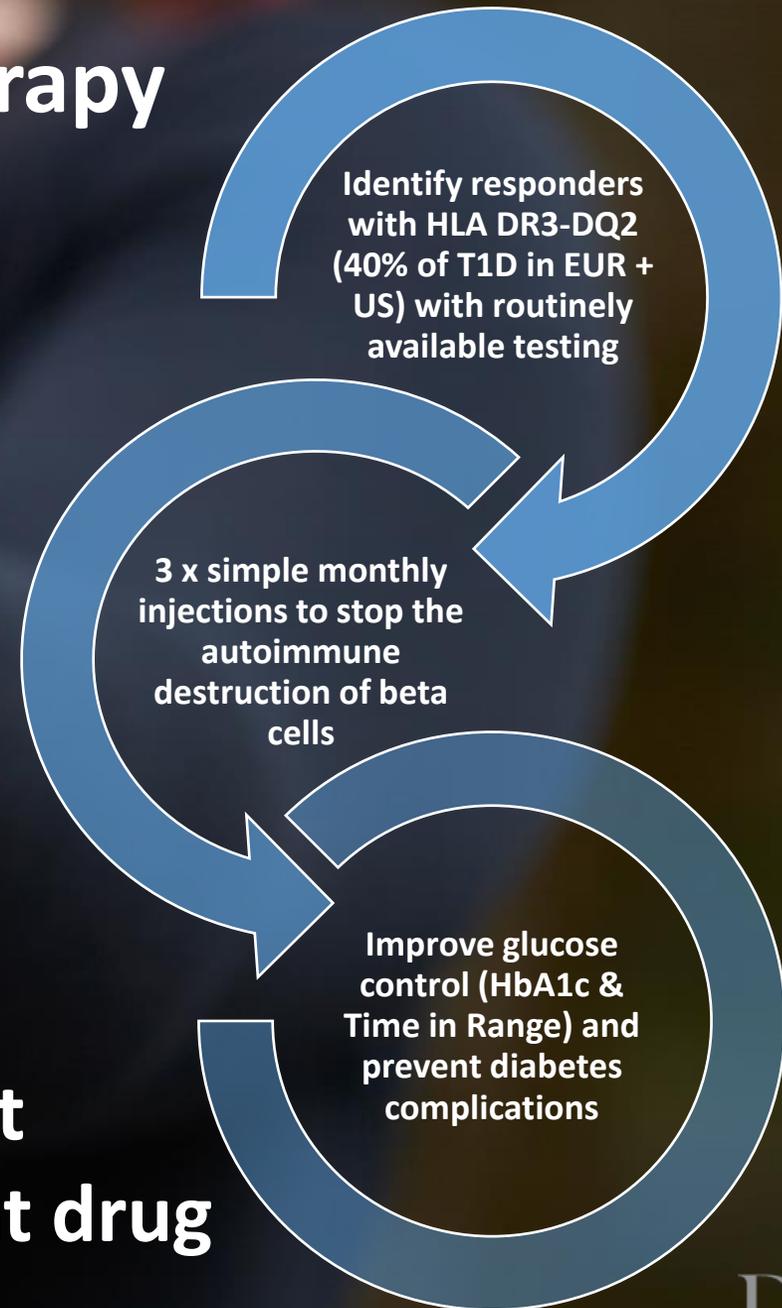


¹ Lam et al. J Clin Invest. 2021 Feb 1;131(3):e143683. Gubitosi-Klug et al. J Clin Invest. 2021;131(3):e143011. McGee et al. Diabet Med. 2014;31(10):1264–1268. doi: 10.1111/dme.12504. Steffes et al. Diabetes Care. 2003;26(3):832–836. Palmer et al. Diabetes. 2004;53(1):250–264. DCCT Investigators. Ann Intern Med. 1998;128(7):517–23.

² Within 6 months from clinical diagnosis of (Stage 3) clinical T1D

The antigen-specific immunotherapy Diamyd® (rhGAD65 in alum)

**Precision Medicine - Treating the right
patient at the right time with the right drug**



Diamyd® (rhGAD65/alum)

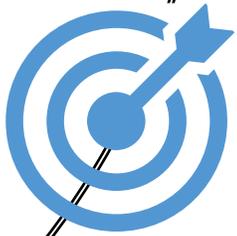
Targeting the Root Cause of Autoimmune Diabetes



Three convenient out-patient administrations only, renders **long-term effect on beta cell preservation.**



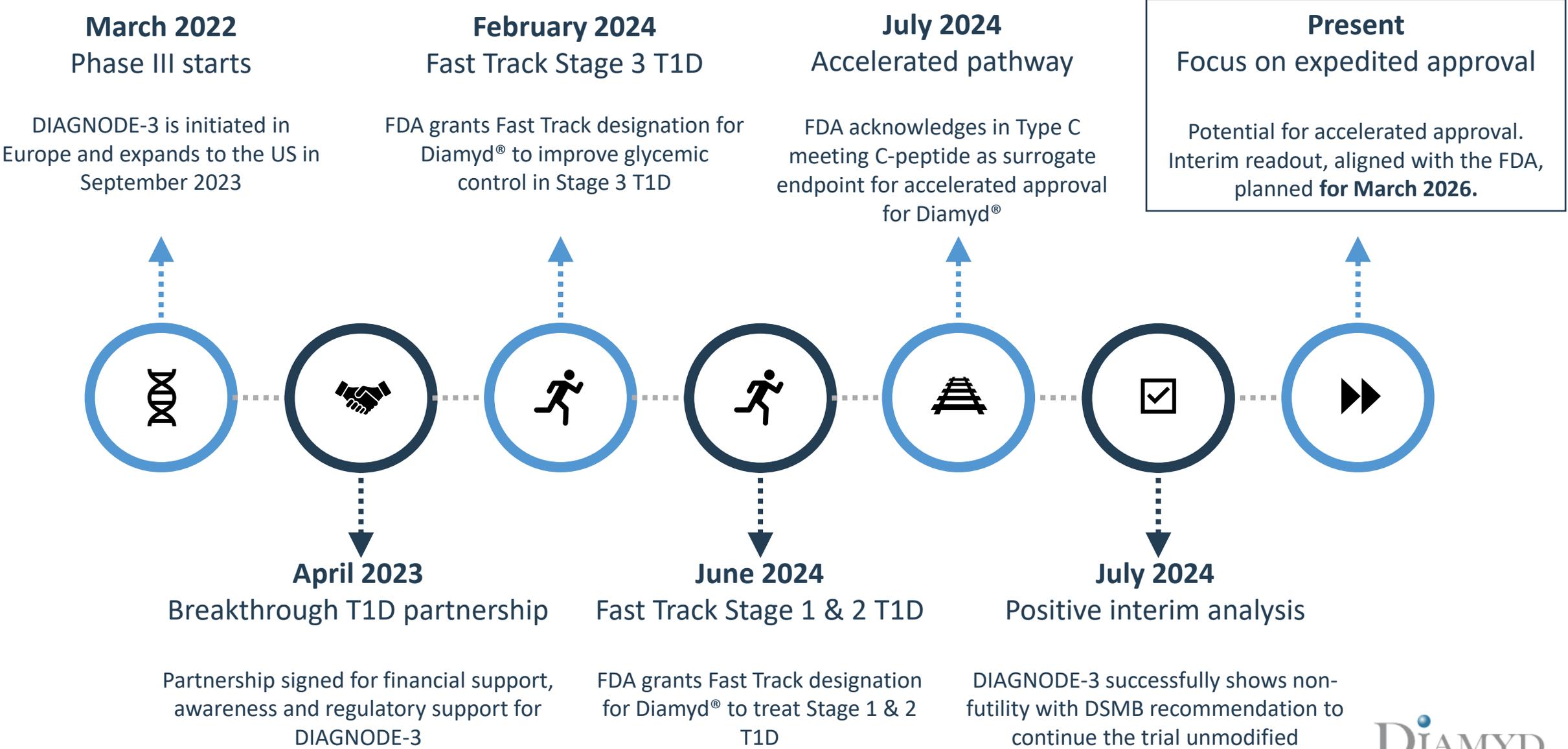
Strong safety profile, **no immunosuppression.** Evaluated in around 1,000 persons with Stage 1, 2 & 3 Type 1 Diabetes as well as in LADA



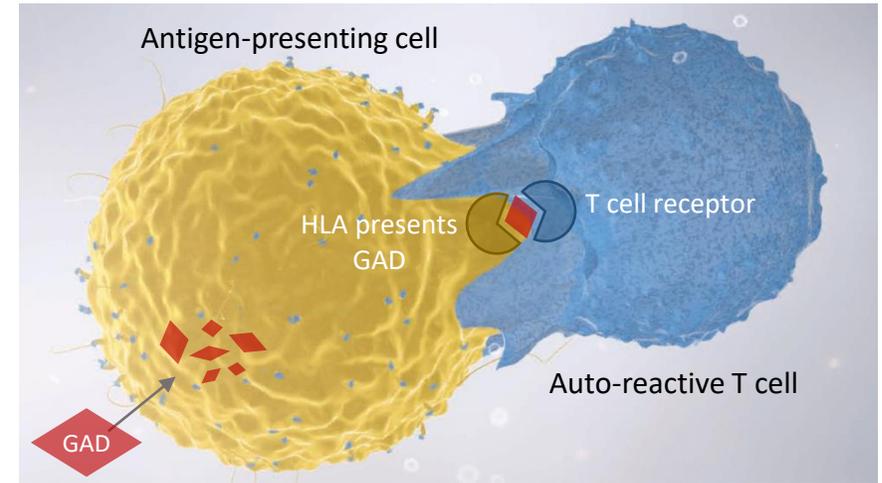
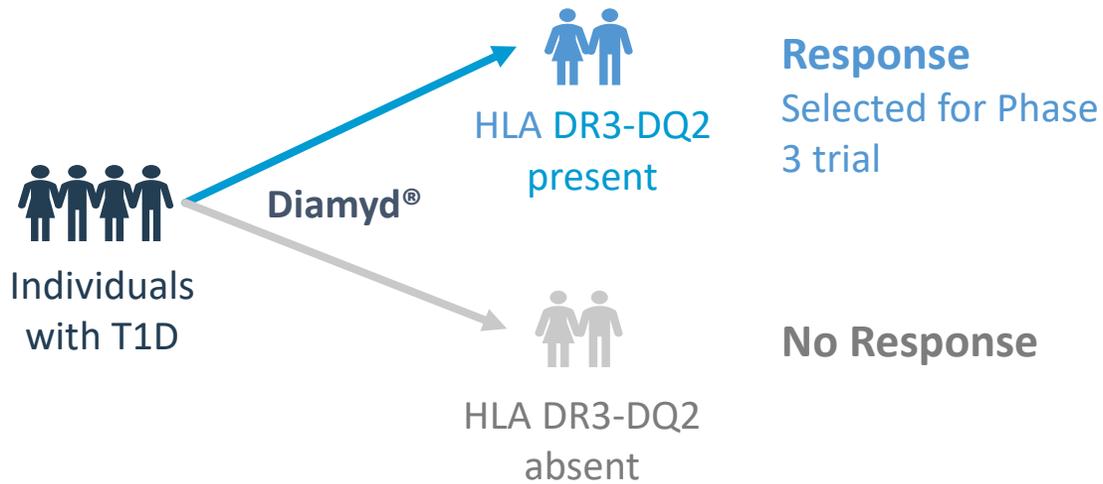
Precision medicine for individuals with specific HLA genetic marker. Approximately 40% of those living with Type 1 Diabetes carry the marker



Significant Momentum Paves Way for Potential Accelerated Approval



Diamyd® targets the GADA-first Type 1 Diabetes endotype with HLA DR3-DQ2 positivity

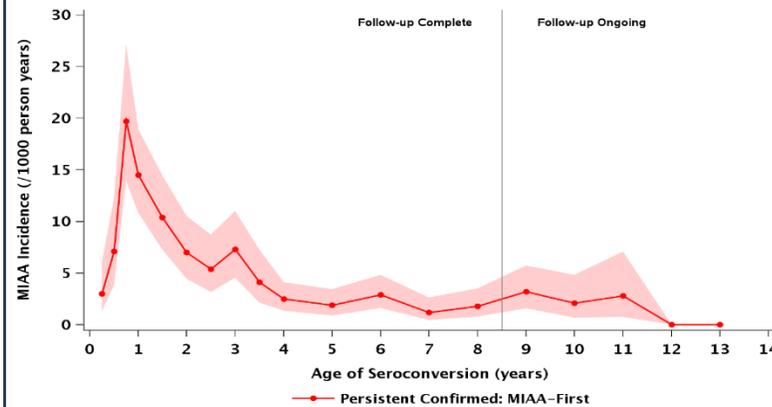
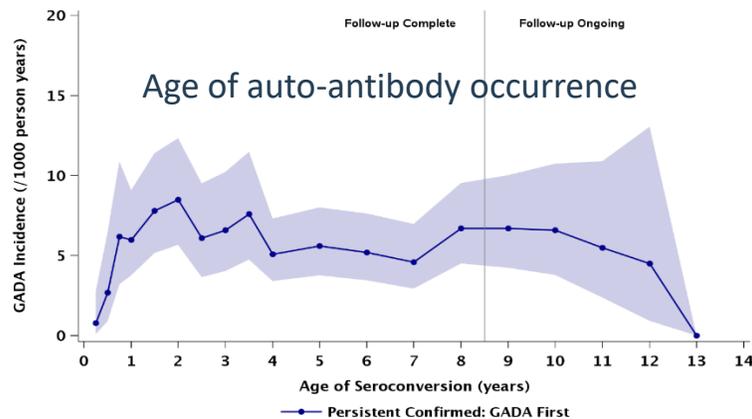


HLA is central to autoimmunity against GAD

Diamyd® responders

GADA-first disease

- HLA DR3-DQ2 (40%)
- Adenovirus F
- *BACH2*
- Likely responders to Diamyd®



IAA-first disease

- HLA DR4-DQ8 (60%)
- Enterovirus B
- *INS*, *PTPN22*, *UBASH3A*
- Likely responders to an insulin-based antigen-specific therapy

Acknowledged Precision Medicine approach

Highlights

- New medical consensus regarding genetically defined groups of T1D
- Strong case for a precision medicine approach targeting likely responders
- Diamyd Medical's approach is to focus on individuals with GAD antibodies and HLA DR3-DQ2 (40% of US + EU T1D) based on
 - Identification of this responder population in previous clinical trials with Diamyd®
 - A biological rationale as HLA DR3-DQ2 is associated with primary autoimmunity against GAD65 (the active component of Diamyd®)

Diabetes Care Volume 43, January 2020

5



Introducing the Endotype Concept to Address the Challenge of Disease Heterogeneity in Type 1 Diabetes

Diabetes Care 2020;43:5–12 | <https://doi.org/10.2337/dc19-0880>

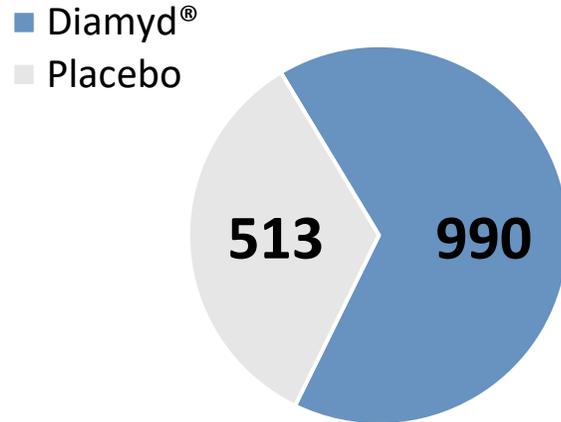
Manuela Battaglia,¹ Simi Ahmed,² Mark S. Anderson,³ Mark A. Atkinson,⁴ Dorothy Becker,⁵ Polly J. Bingley,⁶ Emanuele Bosi,^{1,7} Todd M. Brusko,⁴ Linda A. DiMeglio,⁸ Carmella Evans-Molina,⁹ Stephen E. Gitelman,¹⁰ Carla J. Greenbaum,¹¹ Peter A. Gottlieb,¹² Kevan C. Herold,¹³ Martin J. Hessner,¹⁴ Mikael Knip,¹⁵ Laura Jacobsen,¹⁶ Jeffrey P. Krischer,¹⁷ S. Alice Long,¹¹ Markus Lundgren,¹⁸ Eoin F. McKinney,¹⁹ Noel G. Morgan,^{20,21} Richard A. Oram,^{22,23,24} Tomi Pastinen,²⁵ Michael C. Peters,²⁶ Alessandra Petrelli,¹ Xiaoning Qian,²⁷ Maria J. Redondo,²⁸ Bart O. Roep,^{29,30} Desmond Schatz,¹⁶ David Skibinski,¹¹ and Mark Peakman^{31,32}

Battaglia et al, Introducing the endotype concept to address the challenge of disease heterogeneity in type 1 diabetes, Diabetes Care, 2020

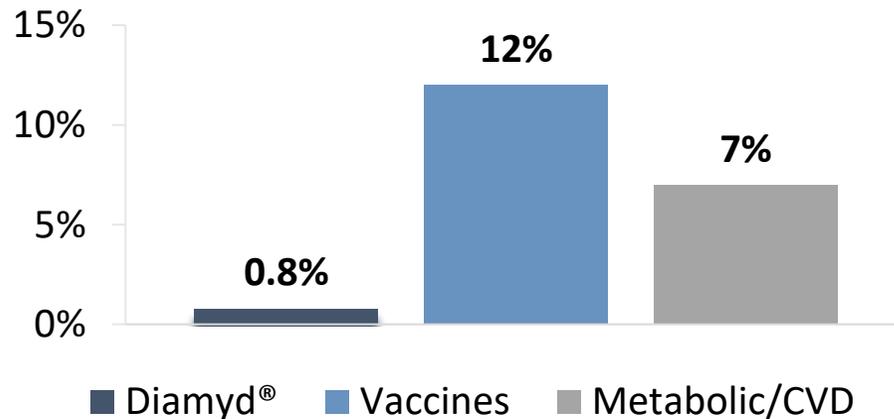
Very Good Safety and Tolerability Profile

No major safety signals in 1000 patients exposed to Diamyd®. Drop-out rate <1% across 15 clinical trials.

Total patient exposure in 15 trials



Patient drop-out rate in clinical trials



Summary of clinical safety data

- Most common adverse events: transient tenderness at injection site, injection site edema, mild injection site pain and injection site reaction
- No difference in the rate of occurrence of adverse events between active Diamyd® and placebo treatment
- No major safety signals in 15 clinical trials
- <1% drop-out rate across trials
- Assessed in persons aged 4 – 70 years
- Assessed in persons with Type 1 Diabetes, LADA and healthy persons at-risk of developing Type 1 Diabetes

Meta-analysis of 3 pre-2014 Trials Identified Responder Patients

Meta-analysis of 3 randomized controlled clinical trials with subcutaneous Diamyd® conducted before 2014 with >500 individuals identified patients carrying HLA DR3-DQ2 gene as responders

44% reduction in C-peptide decline

from Baseline to Month 15 compared to placebo in patients carrying the HLA DR3-DQ2 gene who received 3 or 4 injections of Diamyd®

Diabetologia (2020) 63:2177–2181
<https://doi.org/10.1007/s00125-020-05227-z>

SHORT COMMUNICATION

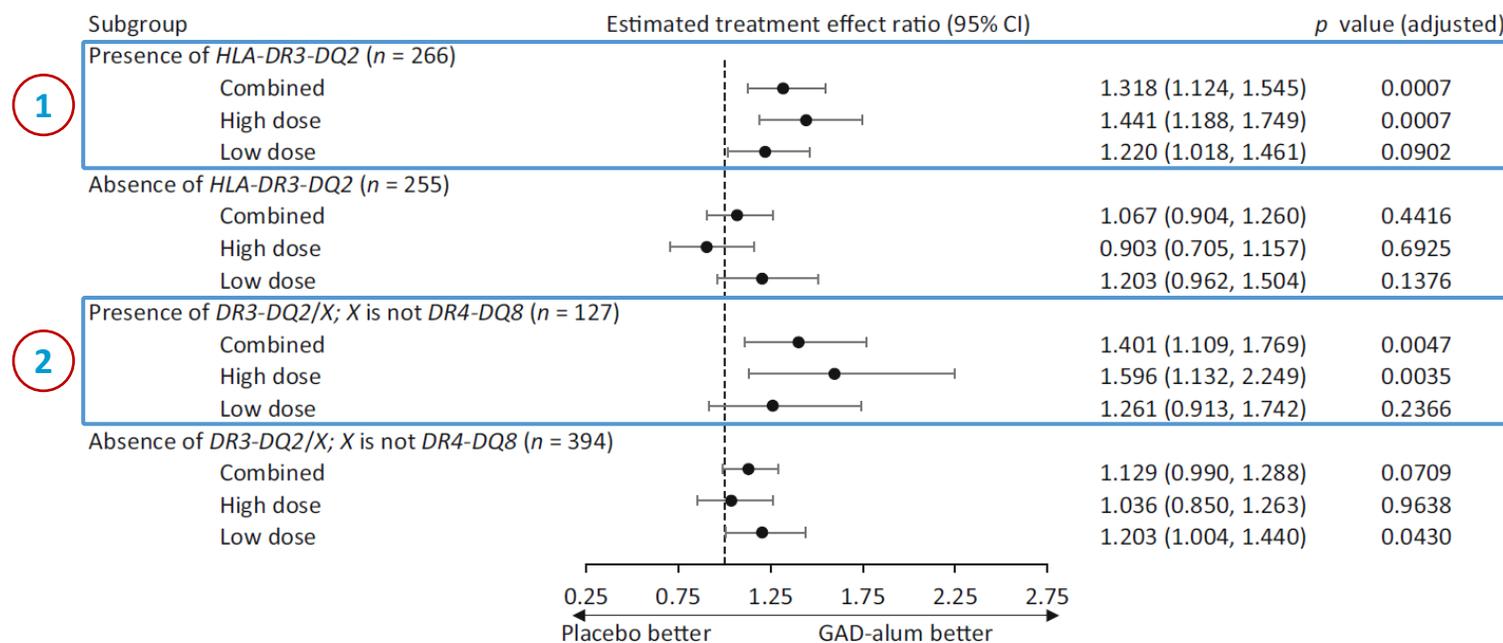
Efficacy of GAD-alum immunotherapy associated with HLA-DR3-DQ2 in recently diagnosed type 1 diabetes

Ulf Hannelius¹ • Craig A. Beam² • Johnny Ludvigsson^{3,4}

Received: 28 April 2020 / Accepted: 11 June 2020 / Published online: 5 August 2020
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Hannelius et al. Diabetologia 2020

Mixed meal tolerance test (MMTT) stimulated C-peptide



High dose = 3 or 4 injections; Low dose = 2 injections; Combined = 2, 3 or 4 injections

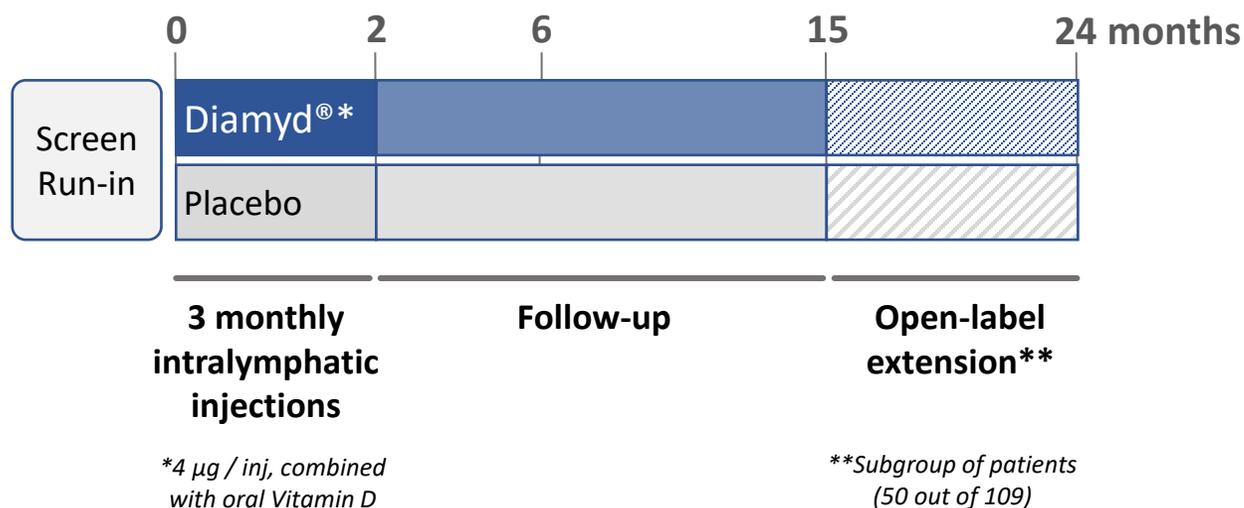
1 Significant treatment effect in subgroup of patients positive for HLA DR3-DQ2 gene (responder patients)

2 Even larger treatment effect in ca. 50% of responder patients with HLA DR3-DQ2 who lack the HLA DR4-DQ8 gene (super responder patients)

DIAGNODE-2 Phase 2b Trial Confirmed Responder Patients

European, multinational, randomized, placebo-controlled, 2-arm trial assessing 3 intralymphatic injections of Diamyd® given on top of standard of care

DIAGNODE-2 DIABETES TRIAL



Primary Endpoint

- Change from Baseline to Month 15 in Mixed Meal Tolerance Test (MMTT) stimulated C-peptide Area under the Curve

Key Secondary Endpoint

- Change in Hemoglobin A1c (HbA1c) between baseline and Month 15
- Change in insulin-dose-adjusted HbA1c (IDAA1c) between Baseline and Month 15
- Change in daily exogenous insulin consumption between Baseline and Month 15

Population

- Persons diagnosed with T1D less than 6 months ago aged 12-24 years and positive for GAD antibodies
- Residual beta cell function: fasting C-peptide ≥ 0.12 nmol/L
- Pre-specified subgroup added to topline readout before database lock: responder patients with HLA DR3-DQ2 genotype

DIAGNODE-2 Phase 2b Trial Confirmed Responder Patients

Diamyd® achieved statistically significant preservation of C-peptide secretion, numerical improvement in HbA1c compared to placebo at Month 15 in patients with HLA DR3-DQ2

56% reduction in C-peptide decline

from Baseline to Month 15 compared to placebo treatment in patients carrying the HLA DR3-DQ2 gene

Intralymphatic Glutamic Acid Decarboxylase With Vitamin D Supplementation in Recent-Onset Type 1 Diabetes: A Double-Blind, Randomized, Placebo-Controlled Phase IIb Trial

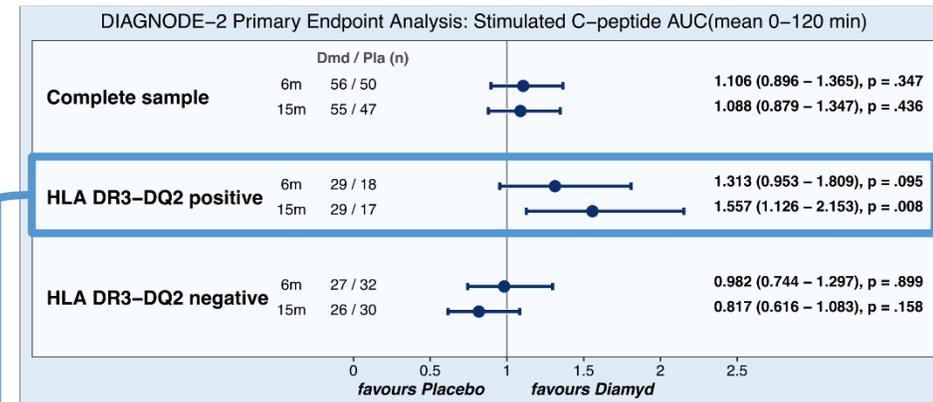
Johanny Ludvigsson,¹ Zdenek Sumnik,² Terezie Pelikanova,³ Lia Nattero Chavez,⁴ Elena Lundberg,⁵ Itxaso Rico,⁶ Maria A. Martinez-Brocca,⁷ MariSol Ruiz de Adana,⁸ Jeanette Wahlberg,⁹ Anastasia Katsarou,¹⁰ Ragnar Hanas,¹¹ Cristina Hernandez,¹² Maria Clemente León,¹³ Ana Gómez-Gil,¹⁴ Marcus Lind,^{15,16} Marta Ferrer Lozano,¹⁷ Theo Sas,¹⁸ Ulf Samuelsson,¹ Stepanka Pruhova,⁷ Fabricia Dietrich,¹⁹ Sara Puente Marin,¹⁹ Anders Nordlund,²⁰ Ulf Hannelius,²¹ and Rosaura Casas¹⁹

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

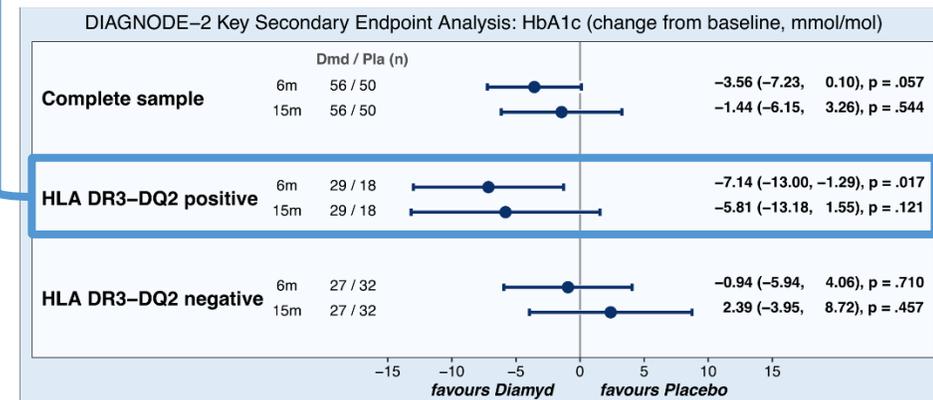
Ludvigsson et al. *Diabetes Care* 2021

Pre-specified subgroup of patients positive for HLA DR3-DQ2 gene

Mixed meal tolerance test (MMTT) stimulated C-peptide



Glycated haemoglobin (HbA1c)



DIAGNODE-2 Phase 2b trial Confirmed Responder Patients

In exploratory analyses, Diamyd® achieved statistically significant benefit on Continuous Glucose Monitoring (CGM) outcomes in patients carrying the HLA DR3-DQ2 responder gene

Better Time in Range, glycaemic variability, time in severe hyperglycaemia



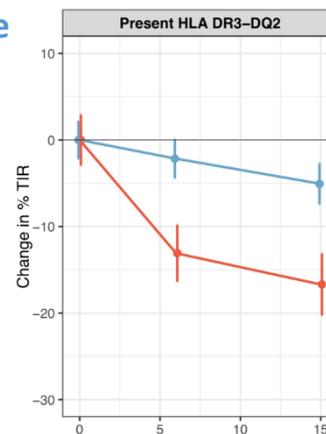
Nowak et al. JCEM 2022



Independent Commentary by Lunati & Fiorina, JCEM 2022

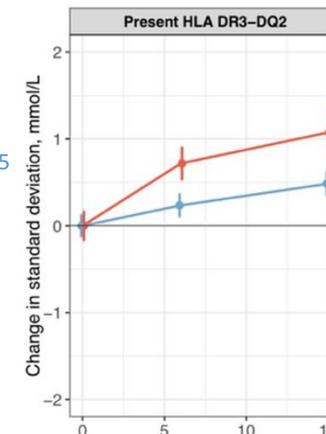
Time in Range

% change from Baseline to Month 15



Glycaemic variability

Change in standard deviation from Baseline to Month 15

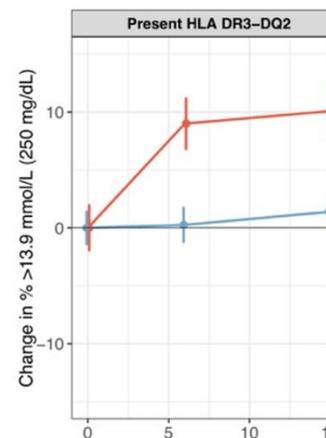


Treatment

- Diamyd
- Placebo

Time in severe hyperglycaemia

>250 mg/dL (>13.9 mmol/L)
% change from Baseline to Month 15

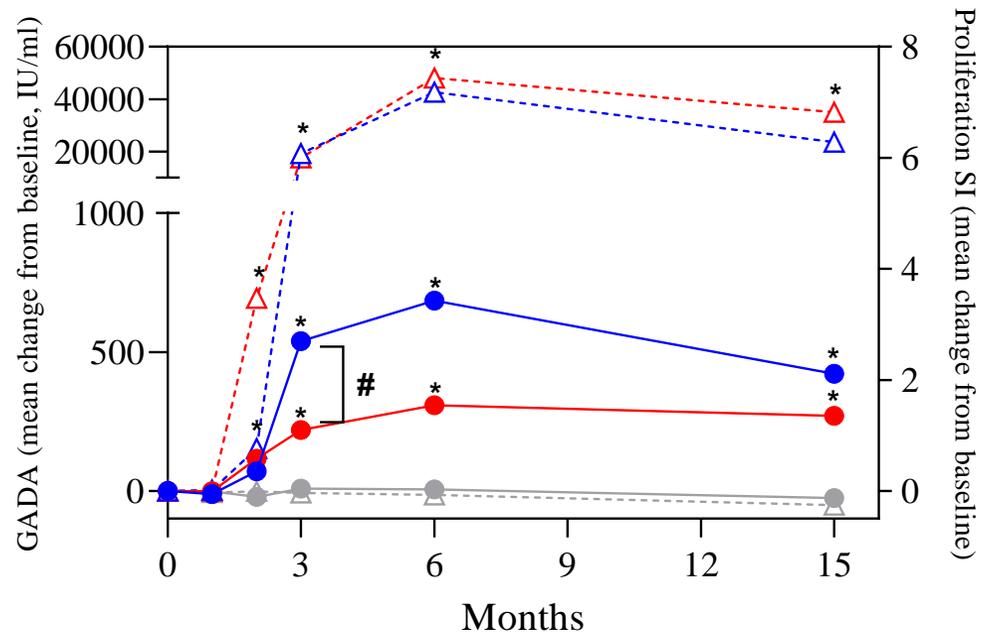


Treatment

- Diamyd
- Placebo

DIAGNODE-2 Phase 2b trial biomarker data support HLA-specific response

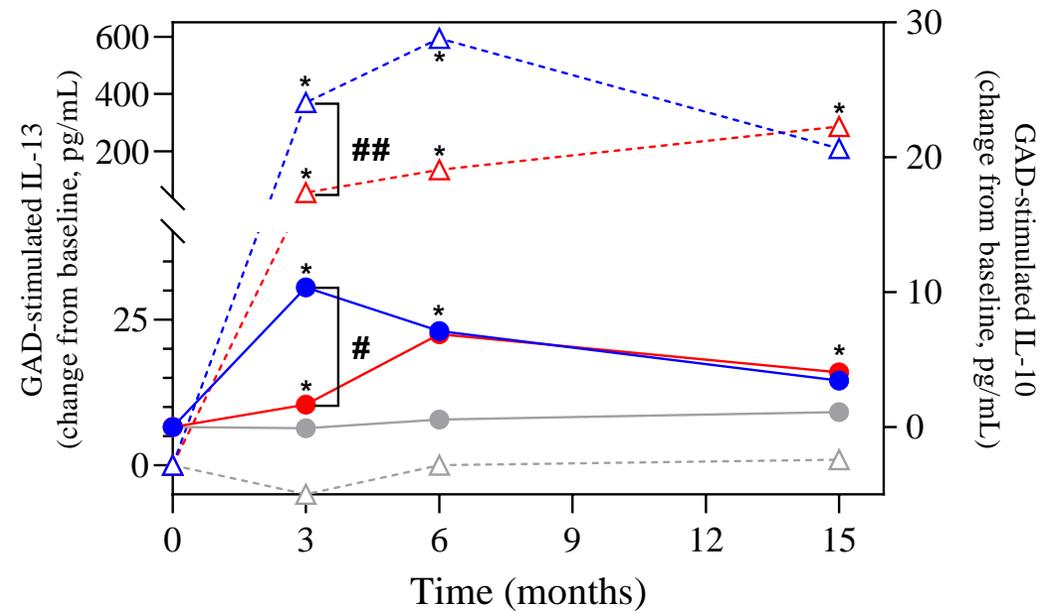
GADA, proliferation and cytokine secretion



- △-△- GADA GAD-alum DR3-DQ2 (n=29)
- △-△- GADA GAD-alum Not DR3-DQ2 (n=27)
- △-△- GADA Placebo (n=52)
- Pr SI GAD-alum DR3-DQ2 (n=29)
- Pr SI GAD-alum Not DR3-DQ2 (n=27)
- Pr SI Placebo (n=52)

* p<0.001 for difference to Placebo

p=0.0210 for difference between DR3-DQ2 and Not DR3-DQ2 groups



- △-△- IL13 GAD-alum DR3-DQ2 (n=29)
- △-△- IL13 GAD-alum Not DR3-DQ2 (n=27)
- △-△- IL13 Placebo (n=52)
- IL10 GAD-alum DR3-DQ2 (n=29)
- IL10 GAD-alum Not DR3-DQ2 (n=27)
- IL10 Placebo (n=52)

* p<0.0001 for difference to Placebo

p=0.0095 for difference between DR3-DQ2 and Not DR3-DQ2 groups

p=0.0080 for difference between DR3-DQ2 and Not DR3-DQ2 groups

Median change from baseline of anti-GAD65 antibodies (GADA) and Proliferation of PMBC (Stimulation Index, SI) (A), and GAD-stimulated secretion by PMBC of IL-10 and IL-13 levels (B) for GAD-alum treated subjects with and without the DR3-DQ2 haplotype Placebo treatment subjects.

P values, Wilcoxon test, are indicated.

Correlated Diamyd® Treatment Effects on C-peptide and HbA1c

Updated meta-analysis including the Phase 2b trial strengthens conclusion about patients carrying the HLA DR3-DQ2 gene being Diamyd® treatment responders and shows correlated treatment effects on C-peptide and HbA1c – the two co-primary endpoints of the Phase 3 trial

48% reduction in C-peptide decline, 4.8 mmol/mol (0.5% DCCT units) lower HbA1c from Baseline to Month 15 compared to placebo in patients carrying the HLA DR3-DQ2 gene who received 3 or 4 injections of Diamyd®

DIABETES, OBESITY AND METABOLISM
A JOURNAL OF PHARMACOLOGY AND THERAPEUTICS

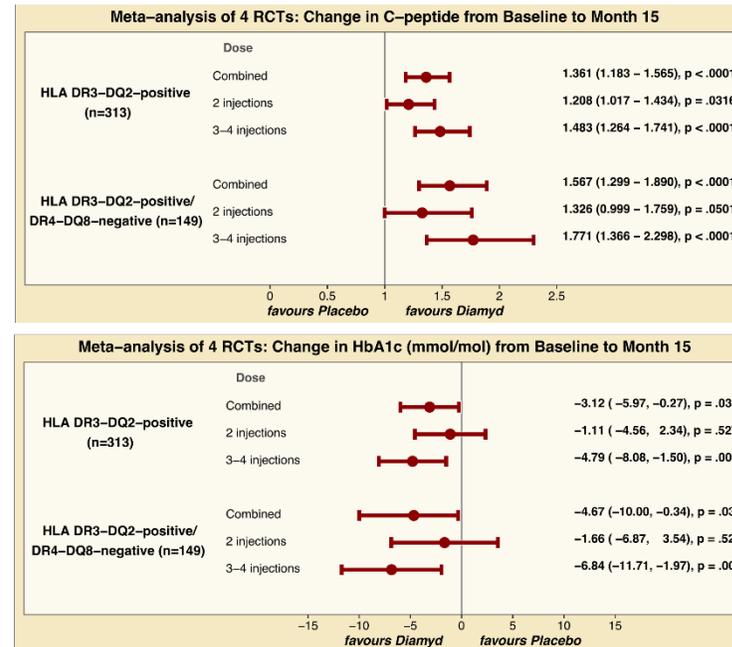
RESEARCH LETTER | Open Access

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

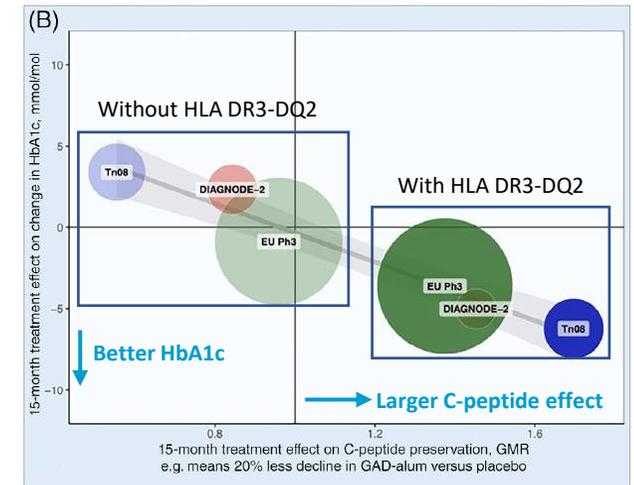
Christoph Nowak, Ulf Hannelius, Johnny Ludvigsson

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

Nowak et al. *Diabetes Obesity and Metabolism* 2022



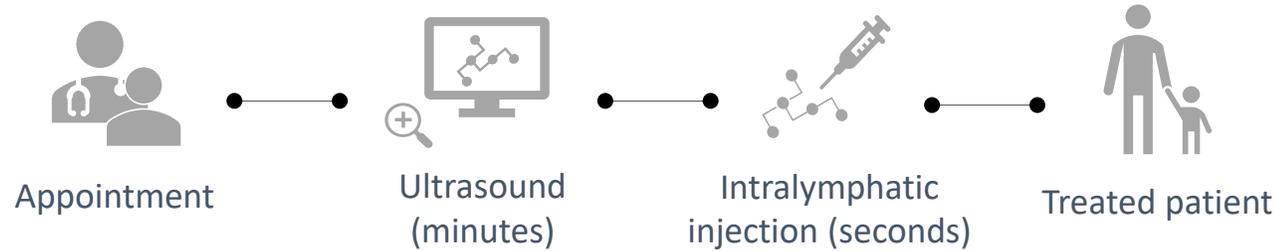
3 or 4 doses of Diamyd® vs placebo



The figure shows individual trial samples of patients with recent-onset T1D divided into present/absent HLA DR3-DQ2 who received 3 or 4 injections of Diamyd® or placebo. It shows a correlation between larger treatment benefit on C-peptide (x-axis; further to the right means larger benefit of Diamyd® over placebo) and lower HbA1c (y-axis, further negative means lower HbA1c and larger benefit of Diamyd® over placebo). All effects refer to change from Baseline to Month 15.

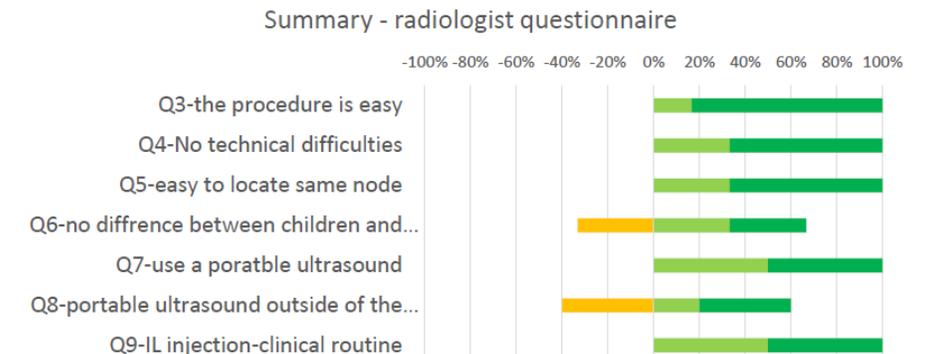
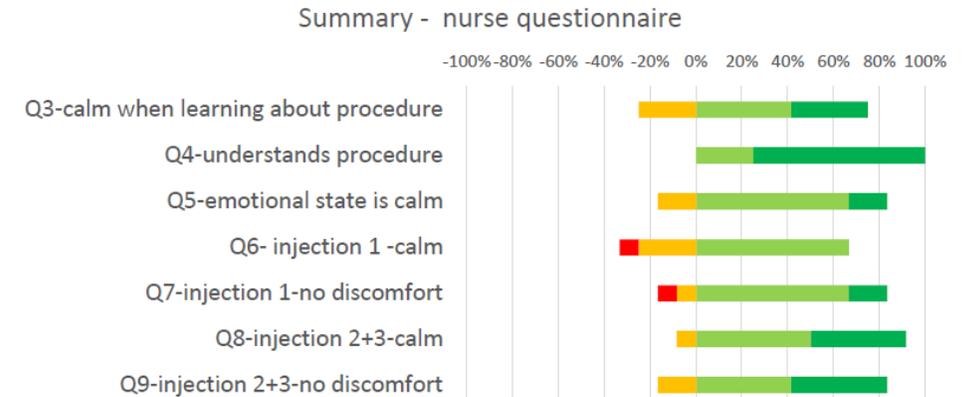
Ultrasound-guided intralymphatic injection

Quick, low-key outpatient procedure with discomfort comparable to venepuncture



- Procedure performed by a **radiologist** or **trained professional**
- **Strong interest from endocrinologists to learn the procedure:** traditionally “underpaid” specialty in US; eager to add ultrasound training to procedural skillset; potential for certification and collaboration with US endocrinology societies
- **Three ultrasound guided injections** in a groin lymph node, one month apart
- **Safe** procedure, assessed in 12-28-year-old (DiaPrecise prevention trial will enrol Stage 1/2 children down to 8 years of age)
- Pain level equal to taking a blood sample

HCP feedback in DIAGNODE-2



■ Somewhat agree ■ Strongly agree
■ Somewhat disagree ■ Strongly disagree

DIAGNODE-3 Pivotal Precision Medicine Phase 3 trial

Ongoing at approx. 50 clinical sites in Europe



Germany



Czech Rep



Estonia



Spain



Hungary



Netherlands



Sweden

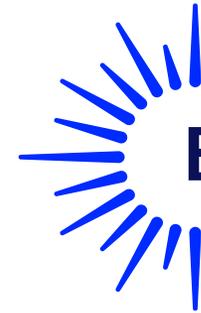


Poland

Ongoing at around a dozen clinical sites in the US



In partnership with



Breakthrough T1D™

Formerly JDRF



**Coordinating Investigator,
DIAGNODE-3**

Prof. Johnny Ludvigsson

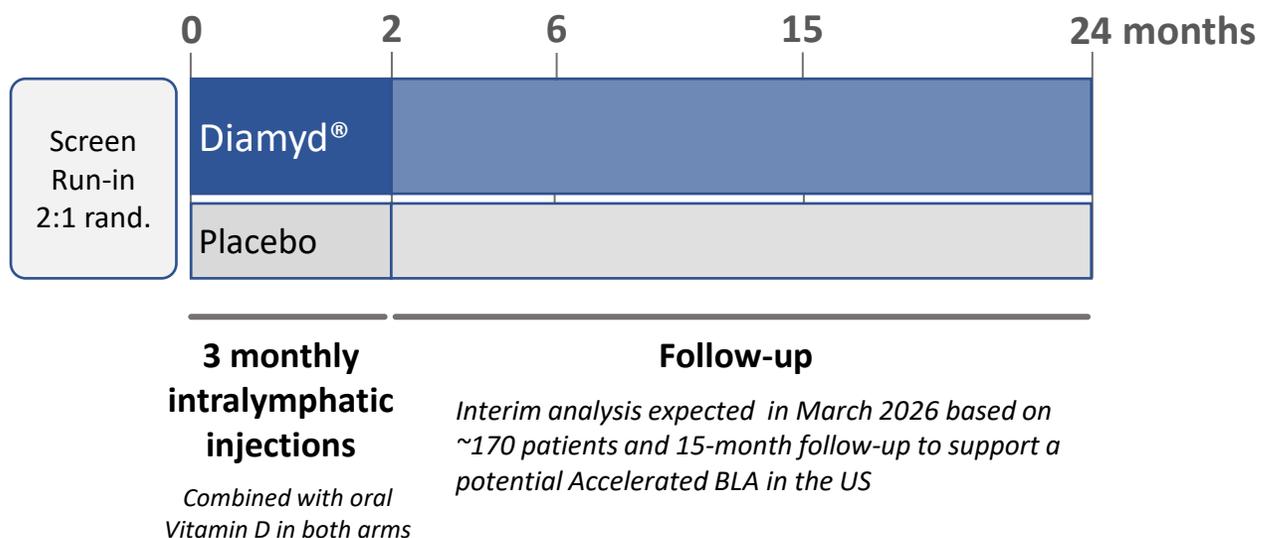
Professor of Pediatrics. First in the world to use immune intervention in children and teenagers with newly diagnosed T1D, and in collaboration with others

www.diagnode-3.com

DIAGNODE-3 Pivotal Precision Medicine Phase 3 Trial

Multinational (EU + US), randomized, placebo-controlled, 2-arm trial assessing 3 intralymphatic injections of Diamyd® given on top of standard of care. Designed based on Phase 2b trial in alignment with FDA and EMA. Enrolling only likely responder patients carrying the HLA DR3-DQ2 gene.

Diagnode-3 study



Co-Primary Endpoints

- Stimulated C-peptide area under the curve, change from Baseline to Month 24 in Mixed Meal Tolerance Test (MMTT)
- HbA1c, change from Baseline to Month 24

Secondary Endpoints

- Time in glycemic target range 3.9-10 mmol/L (70-180 mg/dL) assessed by CGM, change from Baseline to Month 24
- Proportion of patients with insulin dose-adjusted HbA1c (IDAA1c) ≤ 9 (partial remission) at Month 24
- Number of episodes per patient of severe hypoglycemia between Baseline and Month 24
- Number of episodes per patient of diabetic ketoacidosis (DKA) between Baseline and Month 24

Population

- Persons diagnosed with T1D less than 6 months ago aged 12-29 years who are positive for GAD antibodies and positive for HLA DR3-DQ2
- Residual beta cell function: fasting C-peptide ≥ 0.12 nmol/L

Estimated > \$2 Billion Peak Sales in the US Alone

Diamyd® Launch indication

- 60k+ patients (Stage 3 T1D with residual beta cell function, HLA DR3-DQ2 positive, Age >= 12)

US Pricing, formulary status & market share

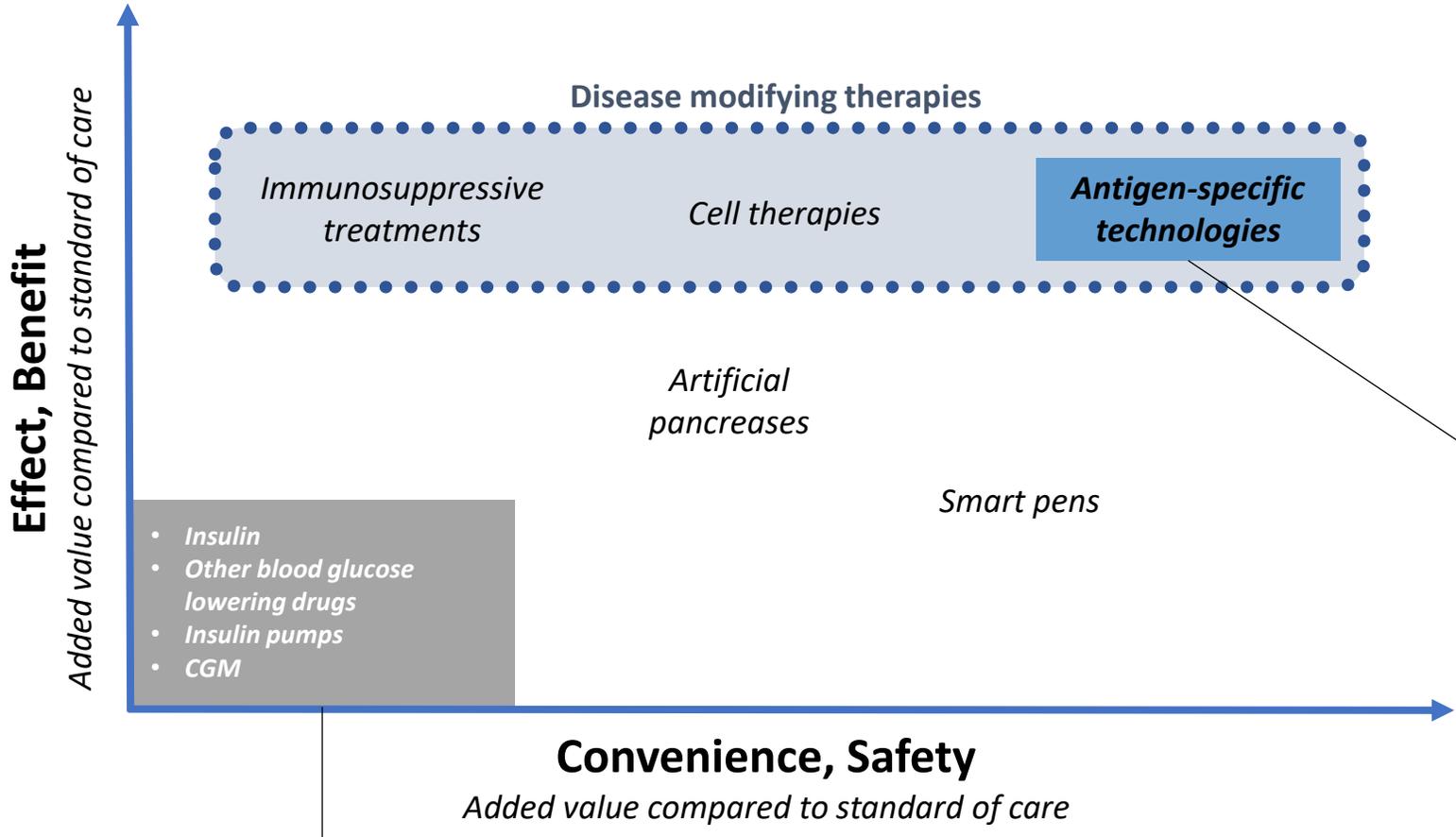
- WAC (gross) price \$157K/course, grown at 2% p.a.
- Limited Gross-to-Net discounts, max 20%.
- > 80% access (high T1D insurance coverage and expected high prior authorization)
- At least 30% market penetration

Significant Upsides

- Ex-US sales (40% of global sales based on T2D analogs)
- Life Cycle Management – Stage 1,2 T1D, LADA, booster courses
- LADA base case US peak sales estimated at > **\$2 billion**

Note: Base case assumptions informed by US payer and HCP Research Nov-24

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.

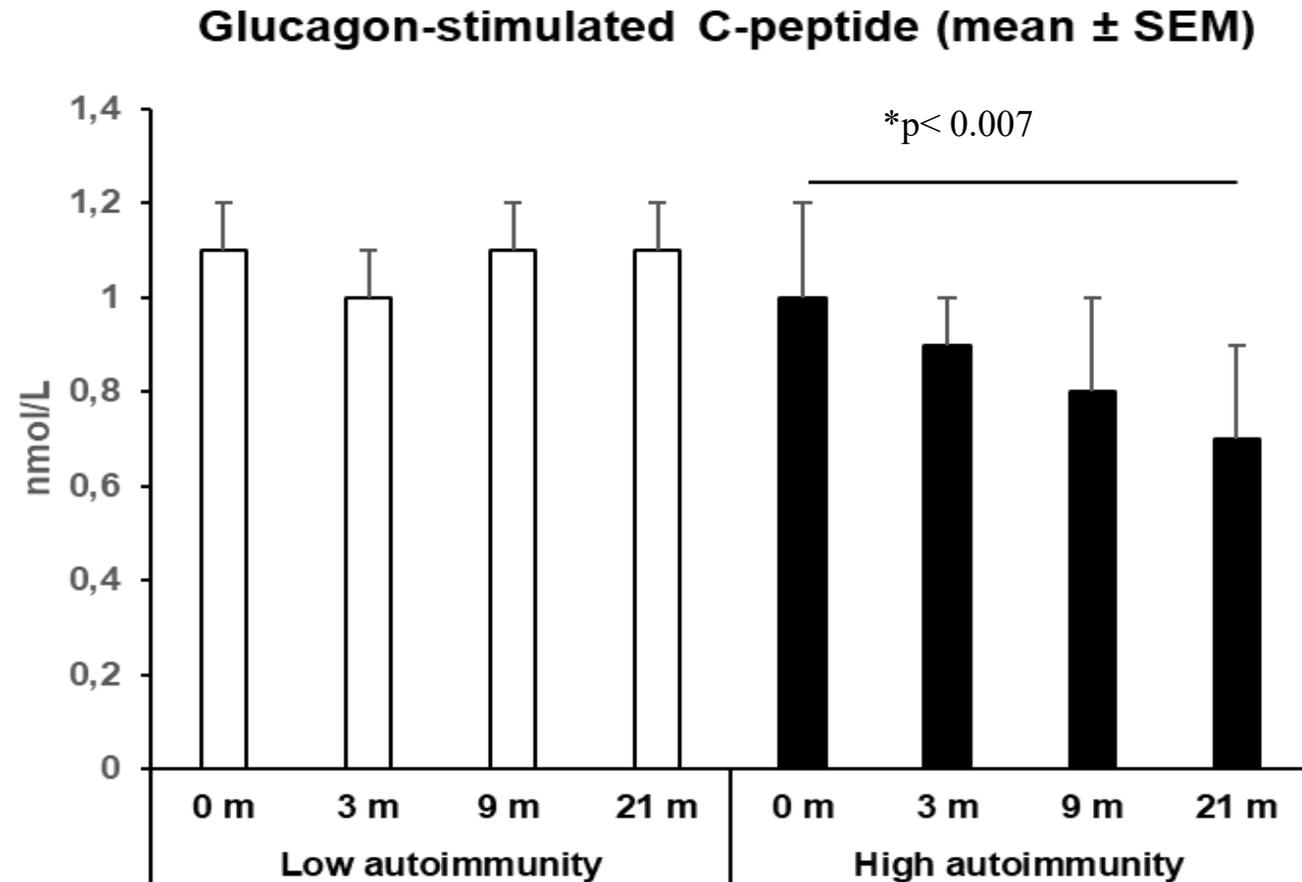
The current **standard treatment** for type 1 diabetes is life-sustaining, subcutaneous deliveries of insulin by injection or pump therapy, combined with continuous glucose monitoring (CGM). In addition to non-insulin anti-diabetic drugs and aids, such as artificial pancreases and smart insulin pens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

Latent Autoimmune Diabetes in Adults (LADA)*

*Also called Slowly progressing Autoimmune Diabetes (SAID) or Slowly progressing insulin-dependent diabetes mellitus (SPIDDM)

Background

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

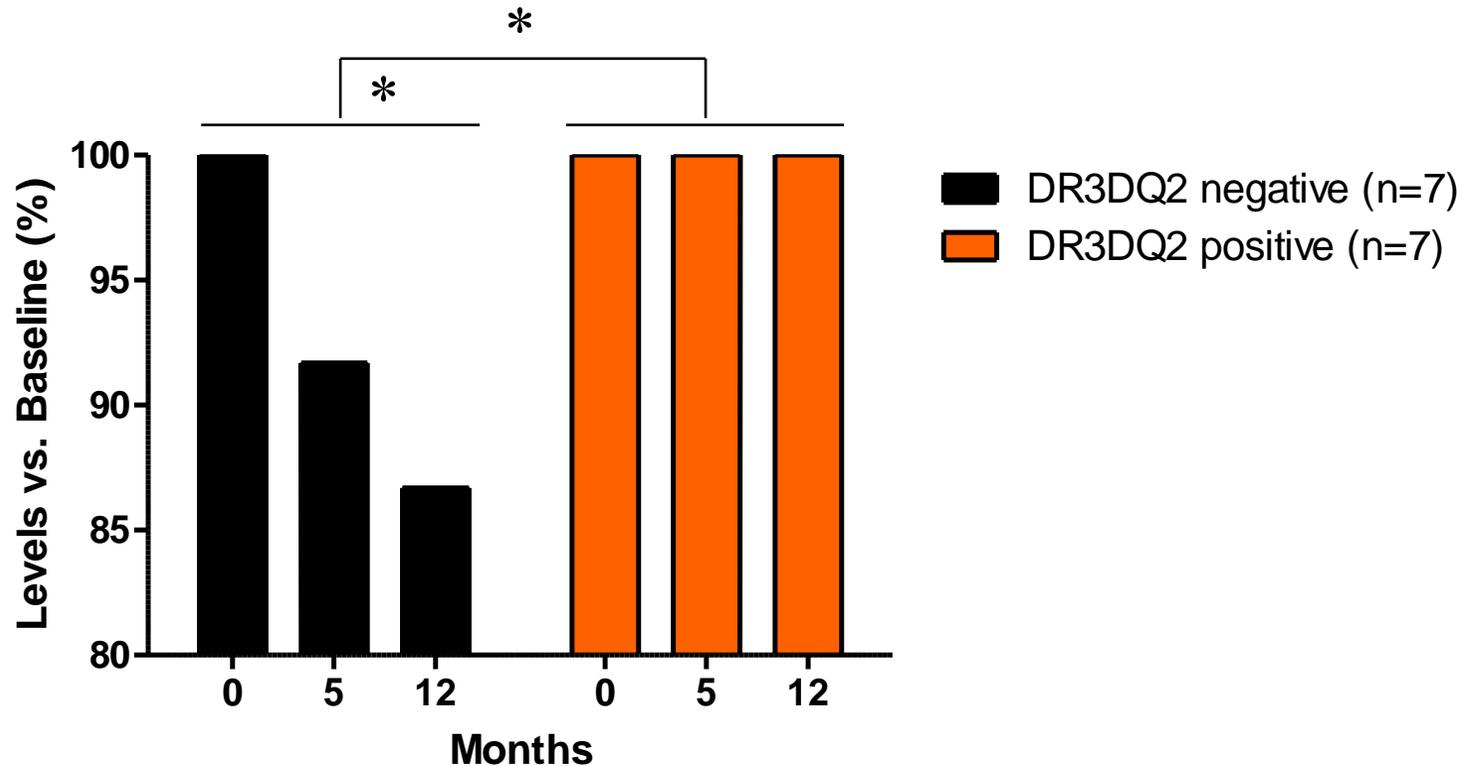


Hals IK, Fiskvik Fleiner H, Reimers N, Astor MC, Filipsson K, Ma Z, Grill V, Björklund A. Investigating optimal β -cell-preserving treatment in latent autoimmune diabetes in adults: Results from a 21-month randomized trial. Diabetes Obes Metab. 2019 Oct

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
- A 1-year pilot study of intralymphatic injections of GAD-alum in individuals with latent autoimmune diabetes in adults (LADA) with signs of high immunity: No safety concerns and resemblance to juvenile type 1 diabetes, Hals et al, Diabetes, Obes Metab. 2023
- [Press release: Updated results from clinical trial with Diamyd® presented today at diabetes conference](#)

Type 1 Diabetes prevention (Stage 1 & 2)



Press Release, November 7, 2023

Diamyd Medical partners with DiaUnion to recruit participants for Type 1 diabetes prevention trial

Diamyd Medical has entered into a collaboration agreement with DiaUnion, a center of excellence in type 1 diabetes, to identify participants for the DiaPrecise trial, an open-label trial evaluating the safety, feasibility and immune response of intralymphatic injections of Diamyd® in children at risk of developing type 1 diabetes who also carry the HLA DR3-DQ2 genotype. The DiaPrecise trial has been initiated and is ongoing at the Department of Clinical Sciences at Lund University, Malmö, with Markus Lundgren M.D., PhD, as the Principal Investigator.



DIAMYD MEDICAL COORDINATES THE ASSET MILIEU

A T1D Forum to drive precision medicine, prevention and screening

Contact with T1D
research community

Aim for a European-level
contact network

Partnerships in
developing AI algorithms

Discuss best practices for
screening programs

Integration of data from
different cohort studies



www.asset.healthcare

ASSET

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 constitute 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.



LUNDS UNIVERSITET



Leading Health Care

VINNOVA

ASSET publication on using AI for T1D screening published in Diabetologia and highlighted by EASD e-Learning

EASD e-Learning [In series](#) [Diary dates](#)



Unlocking AI's potential to screen for type 1 diabetes

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Assisting the implementation of screening for type 1 diabetes by using artificial intelligence on publicly available data

For Debate | [Open access](#) | Published: 14 February 2024
Volume 67, pages 985–994, (2024) [Cite this article](#)

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Manufacturing and Market Exclusivity of Diamyd®



Diamyd Medical is building a biomanufacturing plant for GMP commercial scale production of rhGAD65



Commercial-scale production of rhGAD65 planned to be ready for BLA/MAA and market entry

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

Full Control and Predictability of the Manufacturing Process

Diamyd Medical's Umeå facility uses the Baculovirus Expression Vector System (BEVS) in the complex manufacturing process of recombinant human GAD65 protein

Upstream
process



Baculovirus
expression system
& insect cells



Clarification
Capture
Polish
Nanofiltration



Drug Product
formulation



Downstream
process



Strong IP position

Core Intellectual Property

- **Substance of matter** in the US until **2032**
- **Intralymphatic administration** of Diamyd® in Europe, Japan, China, Hong Kong, Australia, South Africa, Eurasia and Canada, additional countries pending, expiry **2035**.
- **Intralymphatic administration** of additional betacell antigens (proinsulin, preproinsulin etc) approved in Australia, Israel, Russia, additional countries pending.
- **Treatment/prevention of HLA DR3-DQ2** subgroup with Diamyd® approved in Europe, Eurasia, Israel, Hong Kong, South Africa, Japan, South Korea, expiry **2035**, additional countries pending.
- **Treatment/prevention of HLA DR4-DQ8** with insulin as an antigen approved in South Korea, expiry **2035**, and pending in several territories.

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**

Multibillion Dollar Potential and Accelerated Approval Pathway

Diamyd® offers a compelling vision, combining strong clinical progress, strategic regulatory advantages and several indications each with USD Multibillion potential

Potential for Accelerated Approval in the US, with interim readout aligned with the FDA and planned for **March 2026**, supported by **Fast Track** and **Orphan designations**

Investors and partners stand to benefit from **early involvement** in a **first-in-class therapy** that addresses a **critical unmet need in T1D** management, with substantial upside potential

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