DIAMYD MEDICAL

Founded with the Mission to Cure Type 1 Diabetes

April 2025

DISCLAIMER

This Presentation (”Presentation”) has been prepared by Diamyd Medical AB (“Diamyd” or “the Company”).

By accepting this Presentation, the recipient acknowledges and agree to the following:
The information contained herein have been prepared to assist interested parties making their own evaluations of the Company and does not purport to be all-inclusive, or to contain all the information that the prospective investor may desire. In all cases the interested parties should conduct their own investigations and analyses of the Company, and the data set forth in this Presentation. Diamyd does not make any representation or warranty as to the accuracy or completeness of the information contained in this Presentation. Diamyd expressly disclaim any and all liability based on, or relating to, any representations or warranties contained in, or errors or omissions from, this Presentation or any other written or oral communications transmitted to the recipient, or any of its affiliates, or representatives, in the course of its investment evaluation of the Company.

Precision medicine to prevent and cure Type 1 Diabetes

Clinically validated and de-risked immunology platform

- **Antigen-specific immunotherapy** targeting genetic subgroups
- **Durable effect and favorable safety profile** based on 16 trials and more than 1,000 treated patients
- Potential to **extend health** and **life span** by **lowering risk for cardiovascular disease** and other long-term complications

Precision medicine pipeline spanning prevention and intervention

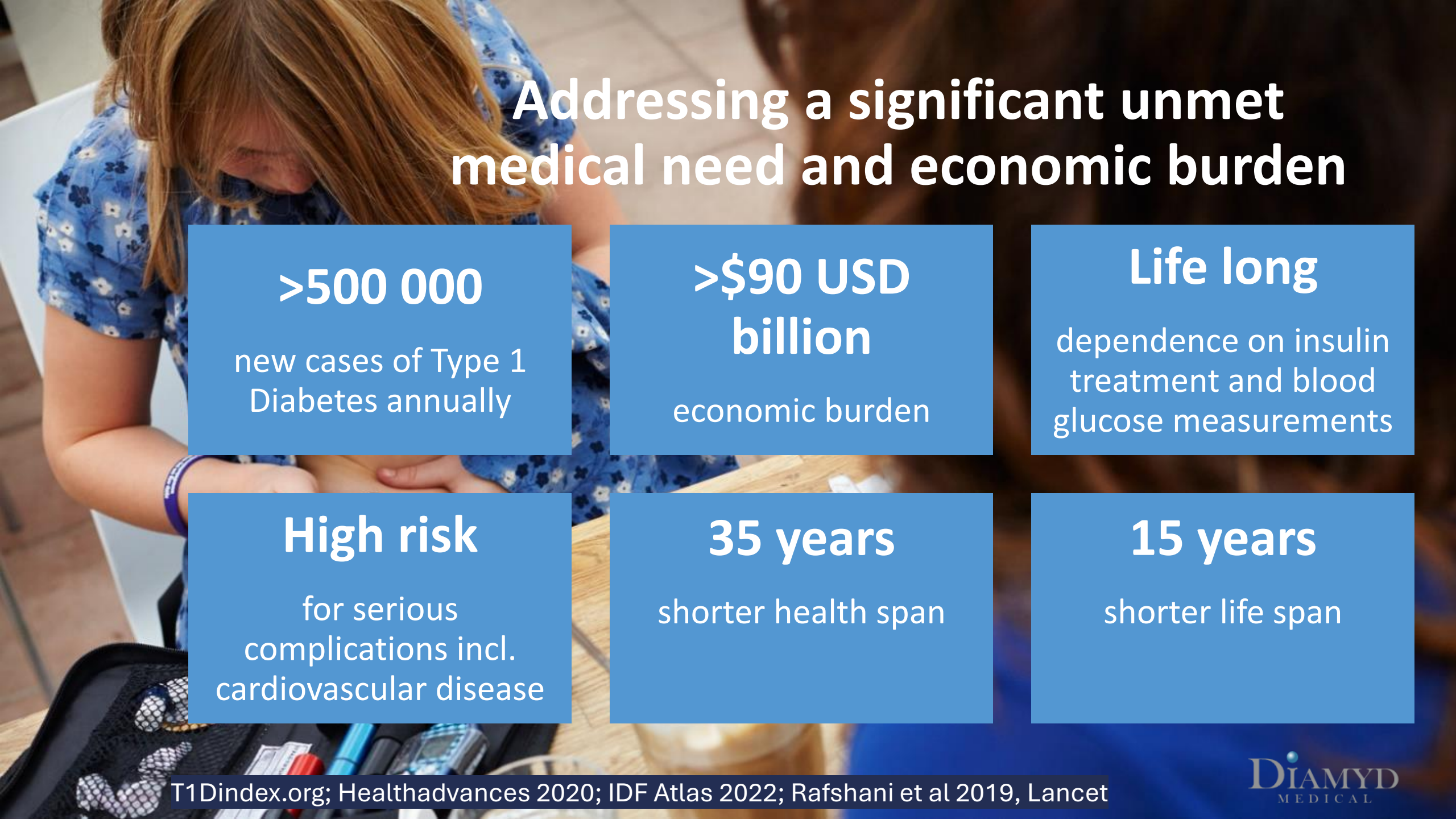
- **Clinical development program, Diamyd® (**targeting 40 % of Type 1 Diabetes**)**
  - **Phase 3 program**: Stage 3 Type 1 Diabetes
  - **Phase 2 program:** Stage 1 & 2 Type 1 Diabetes
- **Discovery program (**targeting 50 % of Type 1 Diabetes**)**
- **Precision medicine ecosystem**: AI driven risk prediction, disease screening, and in-house biologics manufacturing

Significant commercial potential, strong regulatory alignment, near-term milestones

- **>$2 billion sales potential** in the US for Diamyd® launch indication
- **Significant upsides**: RoW, adult-onset Type 1 Diabetes, Stage 1 and 2 Type 1 Diabetes
- FDA **Fast Track** and **Orphan designation**, alignment for an **accelerated approval** pathway
- Phase 3 readout March 2026 to support potential **accelerated BLA**

30+ years of Scientific and Clinical development

DIAMYD MEDICAL



Addressing a significant unmet medical need and economic burden

>500 000

new cases of Type 1 Diabetes annually

>$90 USD billion

economic burden

Life long

dependence on insulin treatment and blood glucose measurements

High risk

for serious complications incl. cardiovascular disease

35 years

shorter health span

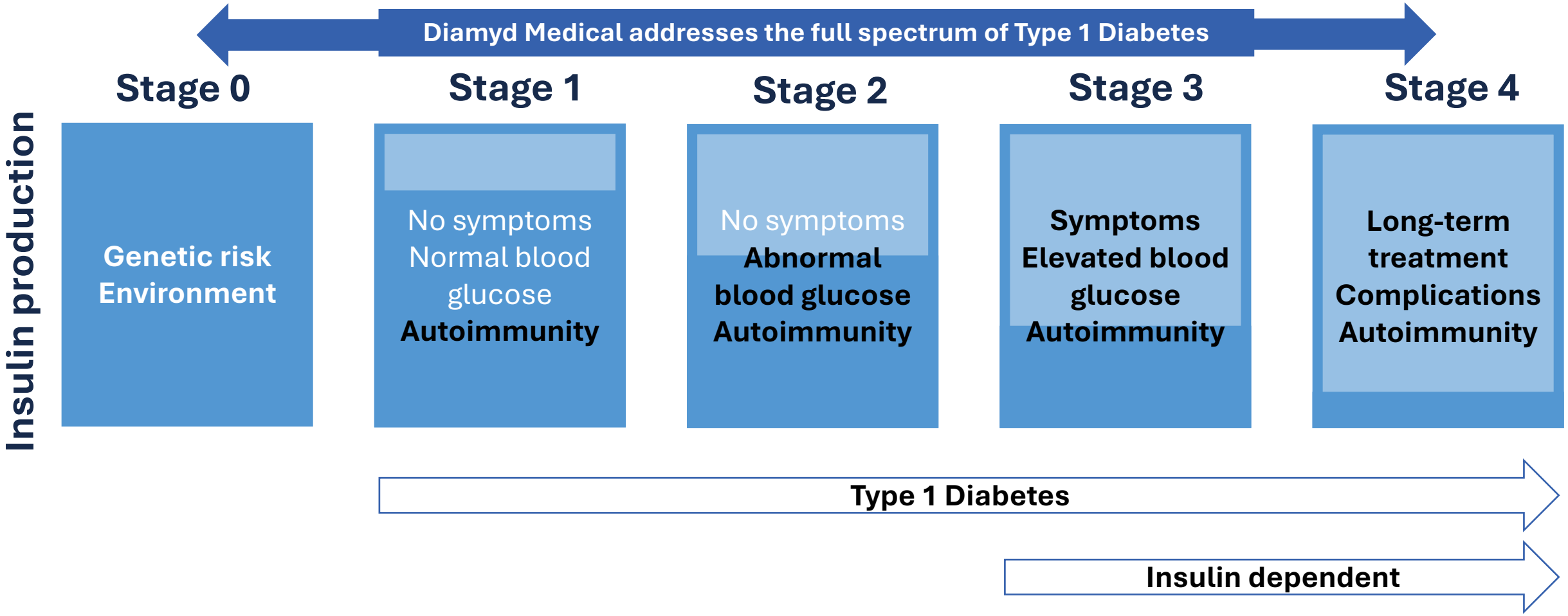
15 years

shorter life span

T1Dindex.org; Healthadvances 2020; IDF Atlas 2022; Rafshani et al 2019, Lancet

DIAMYD MEDICAL

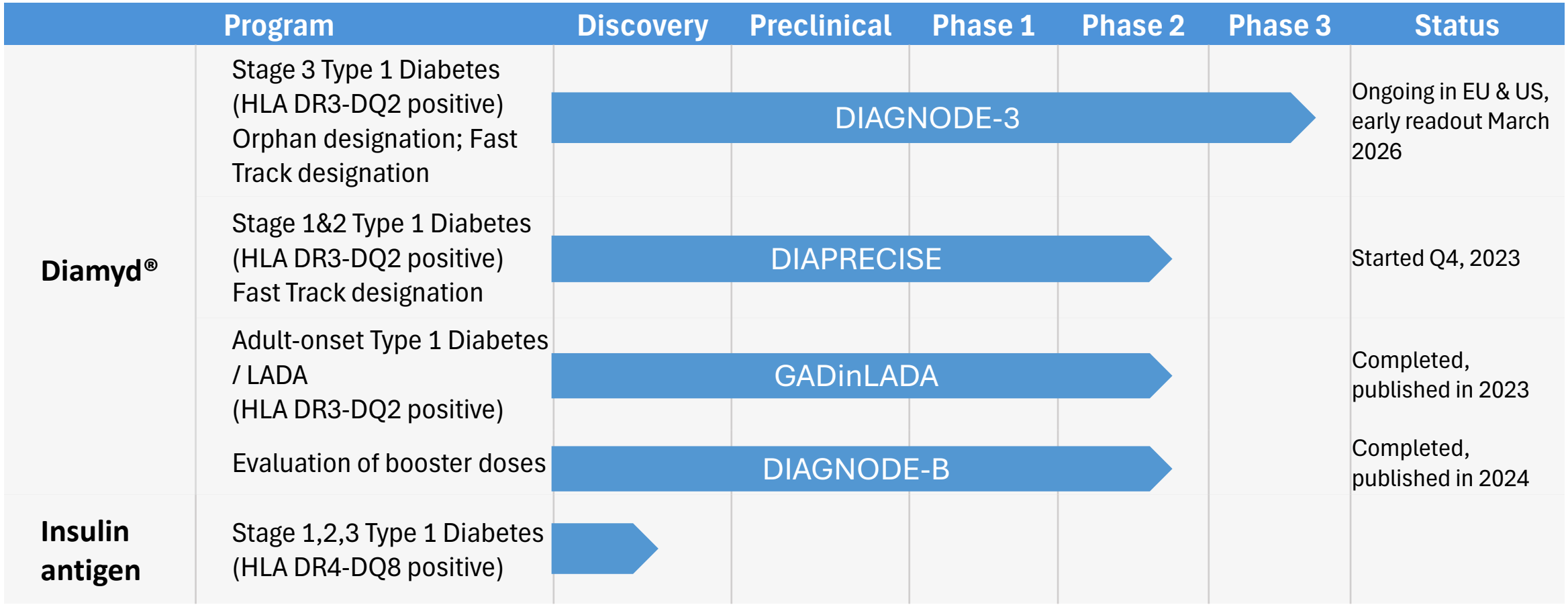
Type 1 Diabetes – Progressive and irreversible autoimmune destruction of insulin-producing cells



DIAMYD MEDICAL

Pipeline Overview

Targeting full spectrum of autoimmune diabetes through HLA-Specific antigen therapies



Global rights available

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
Adult-onset Type 1 Diabetes / LADA

Mechanism of Action
Induce immunological tolerance against GAD65

Clinical Effect and Benefit
Preserve endogenous insulin production, delay or prevent isease progression, reduce or prevent short- and long-term complications

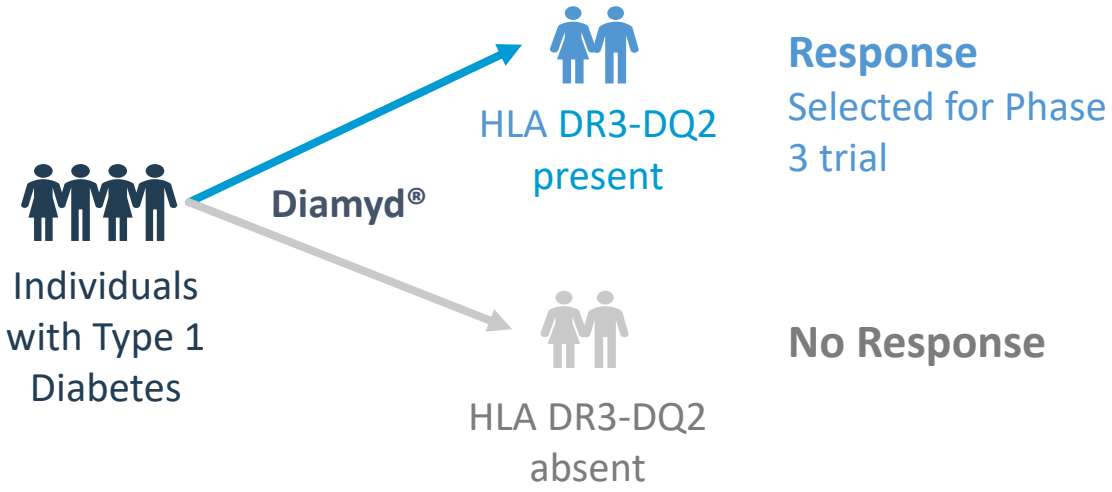
Mode of Administration
Three targeted intranodal injections one month apart, outpatient treatment

Development Status
Phase 3 – Stage 3 Type 1 Diabetes
Phase 2 – Stage 1&2 Type 1 Diabetes
Phase 2 - Adult-onset Type 1 Diabetes / LADA

Licensing Status
Global rights available

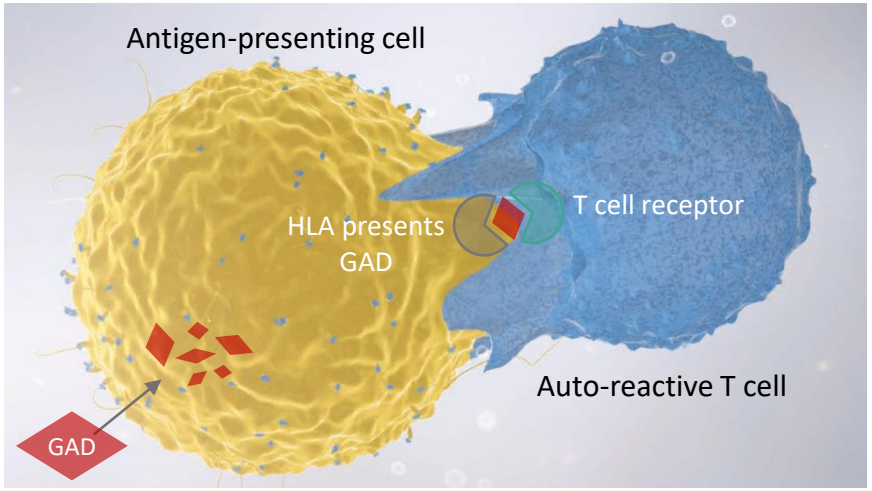
DIAMYD MEDICAL

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



Response
Selected for Phase 3 trial

No Response

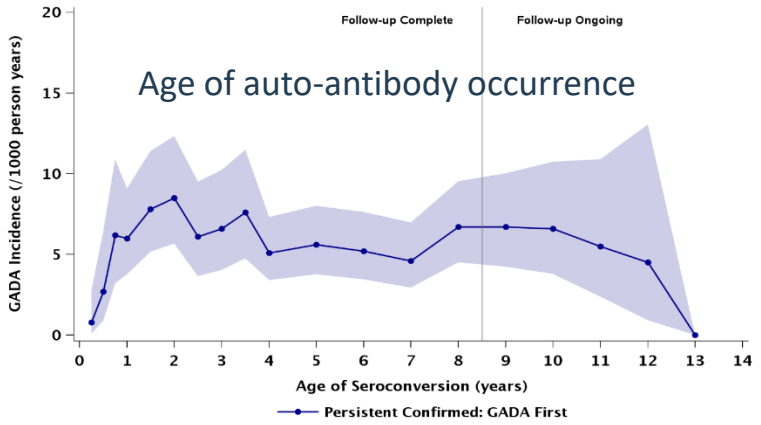


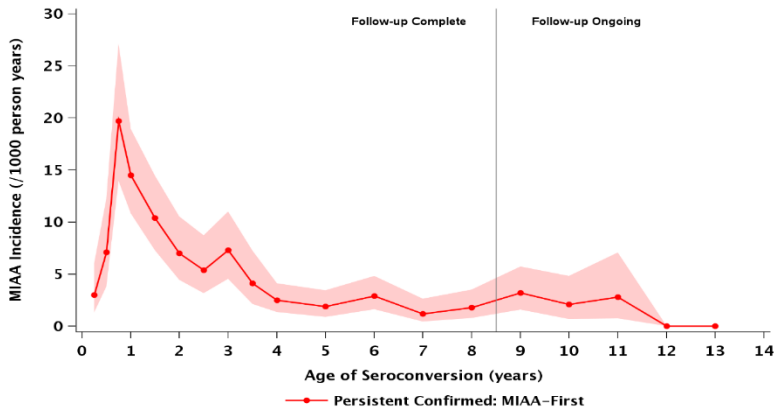
HLA is central to autoimmunity against GAD

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

Courtesy of Prof. Åke Lernmark. Graphs based on data from the TEDDY study.

DIAMYD MEDICAL

Regulatory and Commercial strategy

DIAMYD MEDICAL

Pathway to market for Diamyd®

Single pivotal Phase 3 trial (DIAGNODE-3)

- Aligned with both FDA and EMA

Fast Track designation

- For the treatment of Stage 1, 2 & 3 Type 1 Diabetes with HLA DR3-DQ2

Orphan designation

- For the treatment of Type 1 Diabetes with residual beta cell function

Accelerated approval potential

- Alignment with the FDA
  Interim readout to support accelerated BLA planned for March 2026

DIAMYD MEDICAL

Estimated > $2 Billion Peak Sales in the US Alone

Diamyd® Launch indication

- 60k+ patients (Stage 3 Type 1 Diabetes 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 Type 1 Diabetes insurance coverage and expected high prior authorization)
- At least 30% market penetration

Significant Upsides

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

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

DIAMYD MEDICAL

Strong IP position and regulatory exclusivity

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 **2038**, additional countries pending.
- **Treatment/prevention of HLA DR4-DQ8** with insulin as an antigen approved in South Korea, expiry **2038**, and pending in several territories.

Regulatory exclusivity

- US BLA approval provides **12 years exclusivity**
- US orphan designation provides **7 years exclusivity**
- European approval provides **10 years of exclusivity**

DIAMYD MEDICAL

Significant momentum paves way for potential Accelerated Approval

March 2022
Phase 3 starts

DIAGNODE-3 is initiated in Europe and expands to the US in September 2023

February – June 2024
Fast Track Stage 1,2 & 3 T1D

FDA grants Fast Track designation for Diamyd® across all stages of Type 1 Diabetes

July 2024
Accelerated pathway

FDA acknowledges in Type C meeting C-peptide as surrogate endpoint for accelerated approval for Diamyd®

July 2024
Positive non-futility analysis

DSMB recommendation to continue the trial unmodified

Present
Focus on expedited approval

Potential for accelerated approval. Interim readout, aligned with the FDA, planned **for March 2026.**

BLA

Potential for Priority and Rolling review

Blockbuster potential for launch indication

DIAMYD MEDICAL

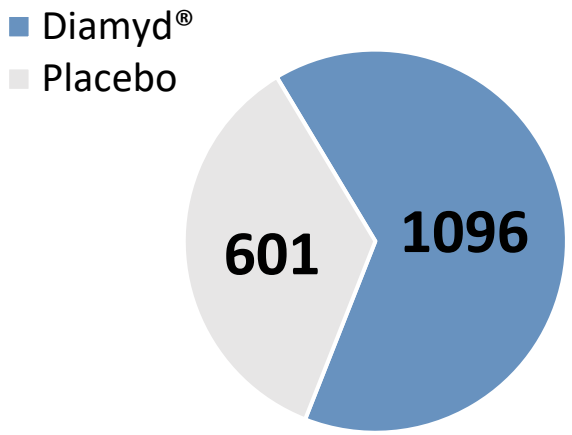
Clinical Data supporting launch indication for Diamyd®

DIAMYD MEDICAL

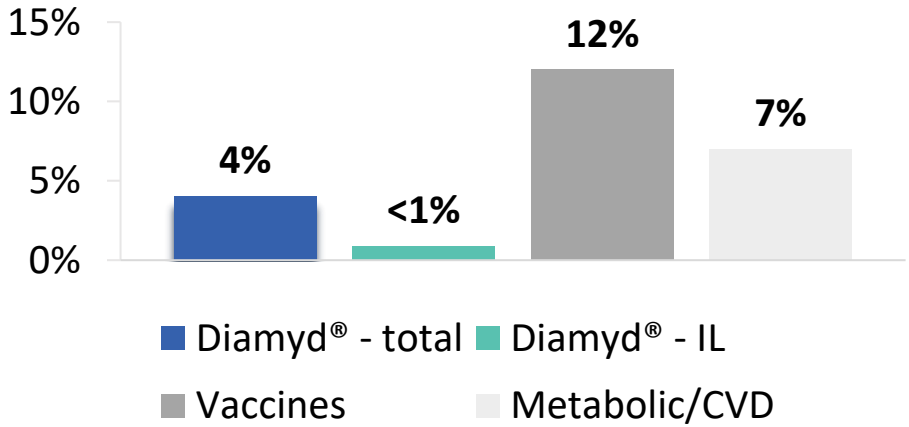
Favorable safety and tolerability profile

No major safety signals in >1,000 patients exposed to Diamyd®. Drop-out rate <1% in trials with targeted administration (intralymphatic, IL) of Diamyd®.

Total patient exposure in 16 trials



Patient drop-out rate in clinical trials



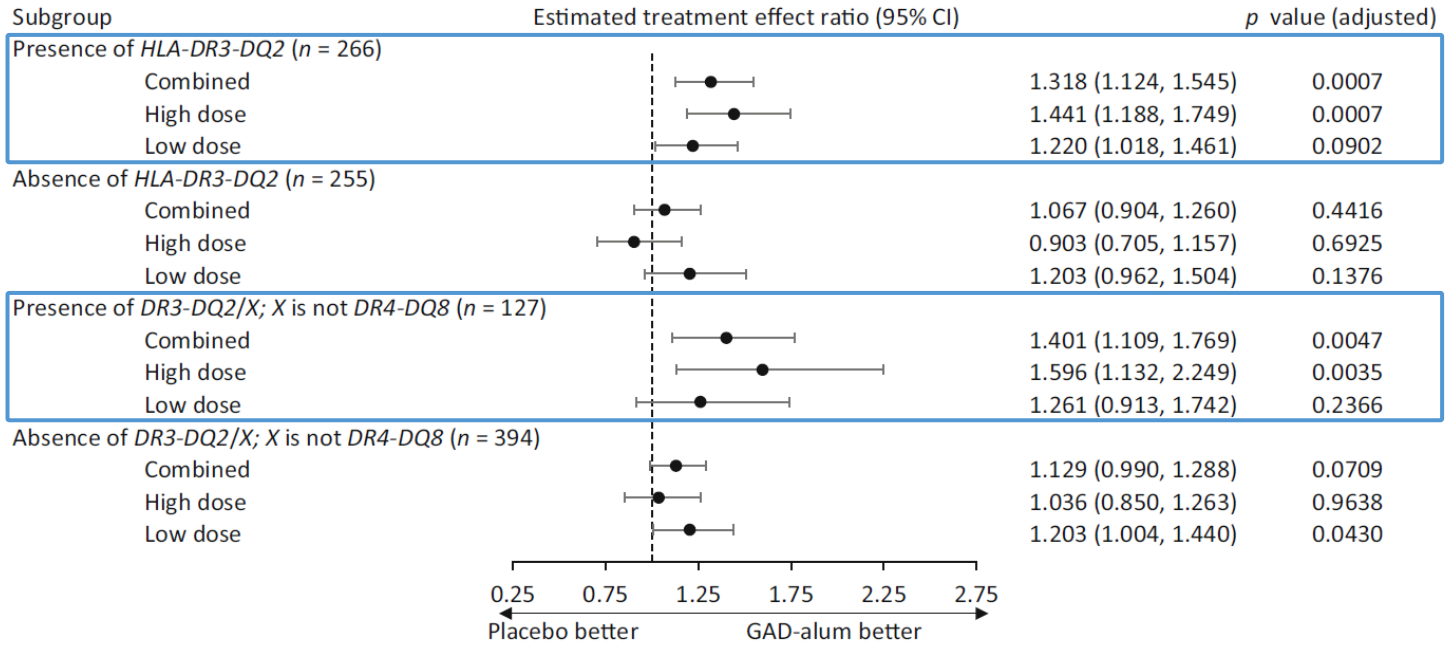
Summary of clinical safety data

- Most **common adverse events**: transient tenderness at injection site, injection site edema, mild injection site pain and injection site reaction (< 7 days)
- **No major safety signals**
- **No drug-related SAEs** in intralymphatic (IL) program (1 in total, LADA population)
- **<1% subject drop-out rate** in IL program
- Safety assessed in persons aged 4 – 70 years, with Stage 1 to Stage 3 Type 1 Diabetes or Adult-onset Type 1 Diabetes / LADA

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

Mixed meal tolerance test (MMTT) stimulated C-peptide



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

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®

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

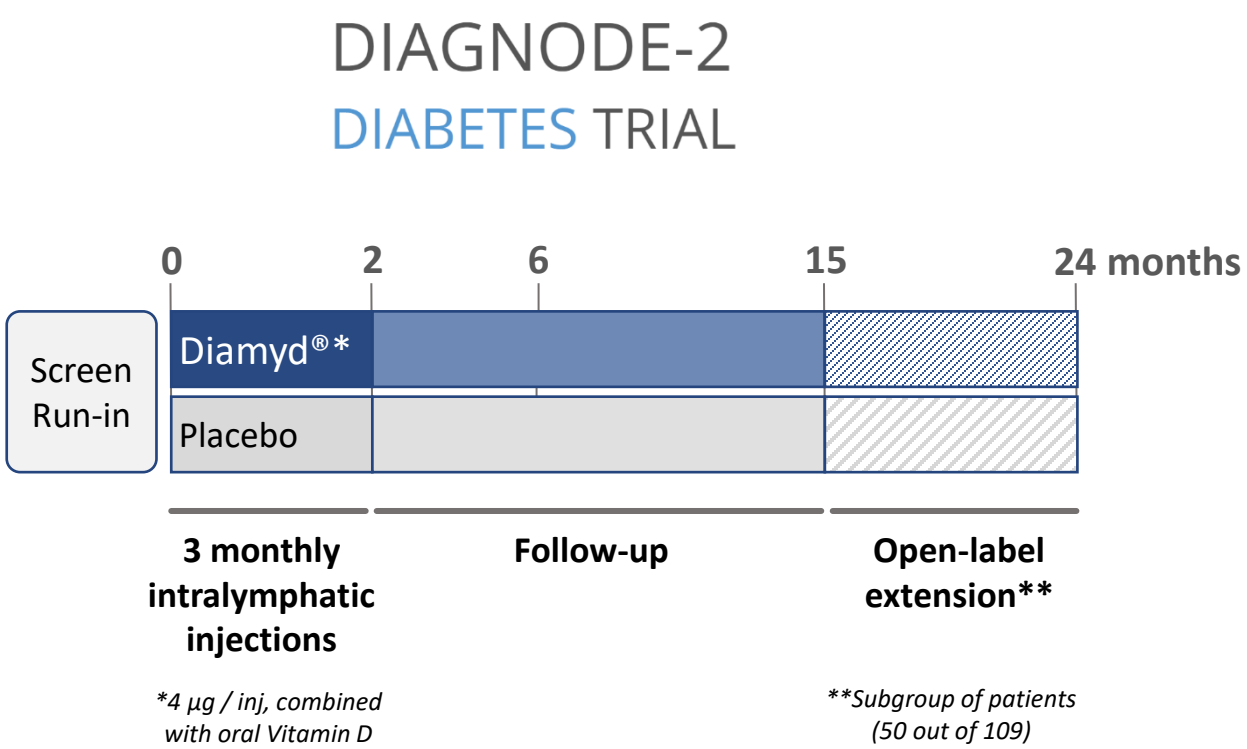
2 **Even larger treatment effect in ca. 50% of responder patients with HLA DR3-DQ2 who lack the HLA DR4-DQ8 gene (super responder patients)**

Hannelius et al. Diabetologia 2020

DIAMYD MEDICAL

DIAGNODE-2 Phase 2b Trial Confirmed Responder Patients

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



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

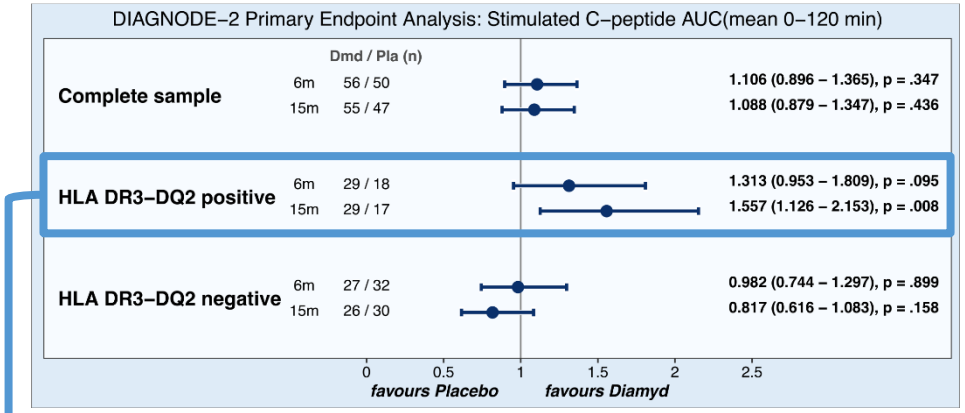
- Persons diagnosed with Type 1 Diabetes less than 6 months ago aged 12-24 years and positive for GAD antibodies
- Residual beta cell function: fasting C-peptide ≥ 0.12 nmol/L
- Pre-specified subgroup added to topline readout before database lock: responder patients with HLA DR3-DQ2 genotype

DIAMYD MEDICAL

DIAGNODE-2 Phase 2b trial confirmed responder patients

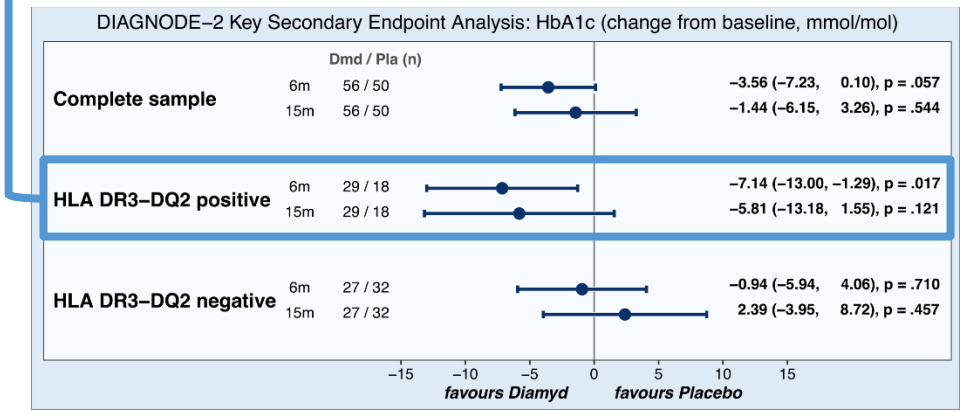
Diamyd® achieved statistically significant preservation of C-peptide secretion, numerical improvement in HbA1c compared to placebo at Month 15 in patients with HLA DR3-DQ2

Mixed meal tolerance test (MMTT) stimulated C-peptide



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

Glycated haemoglobin (HbA1c)



56% reduction in C-peptide decline

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

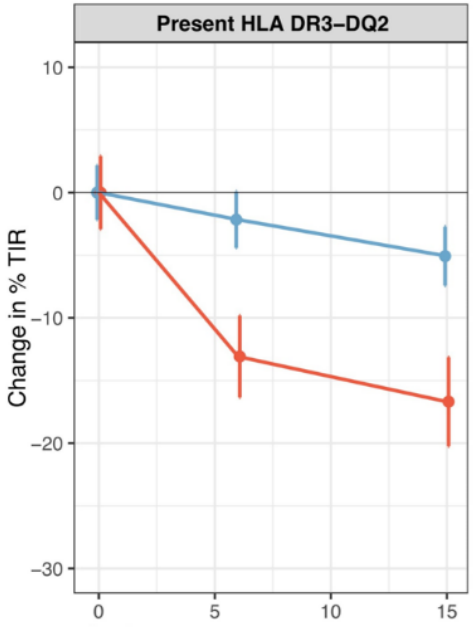
Ludvigsson et al. Diabetes Care 2021

DIAMYD MEDICAL

DIAGNODE-2 Phase 2b Trial confirmed responder patients

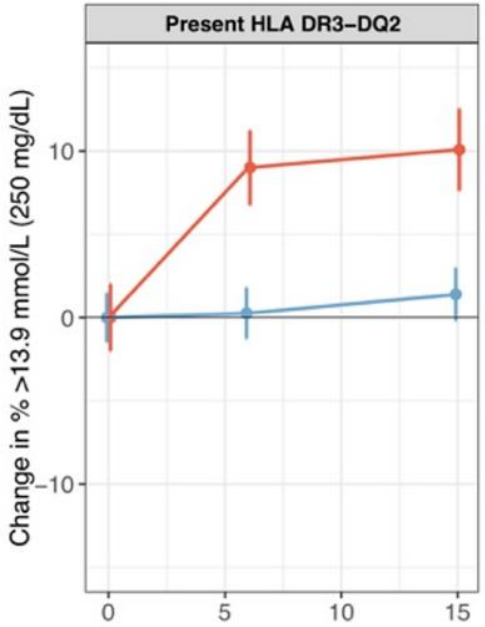
In exploratory analyses, Diamyd® achieved statistically significant benefit on Continuous Glucose Monitoring (CGM) outcomes in patients carrying the HLA DR3-DQ2 responder gene

Time in Range



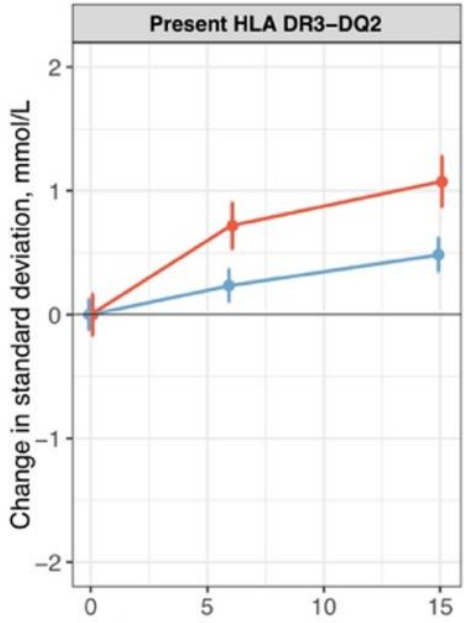
% change from Baseline to Month 15

Time in severe hyperglycaemia

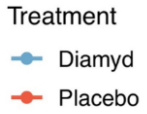


>250 mg/dL (>13.9 mmol/L) % change from Baseline to Month 15

Glycaemic variability



Change in standard deviation from Baseline to Month 15



- Better Time in Range
- Less time in severe hyperglycaemia
- Less glycaemic variability

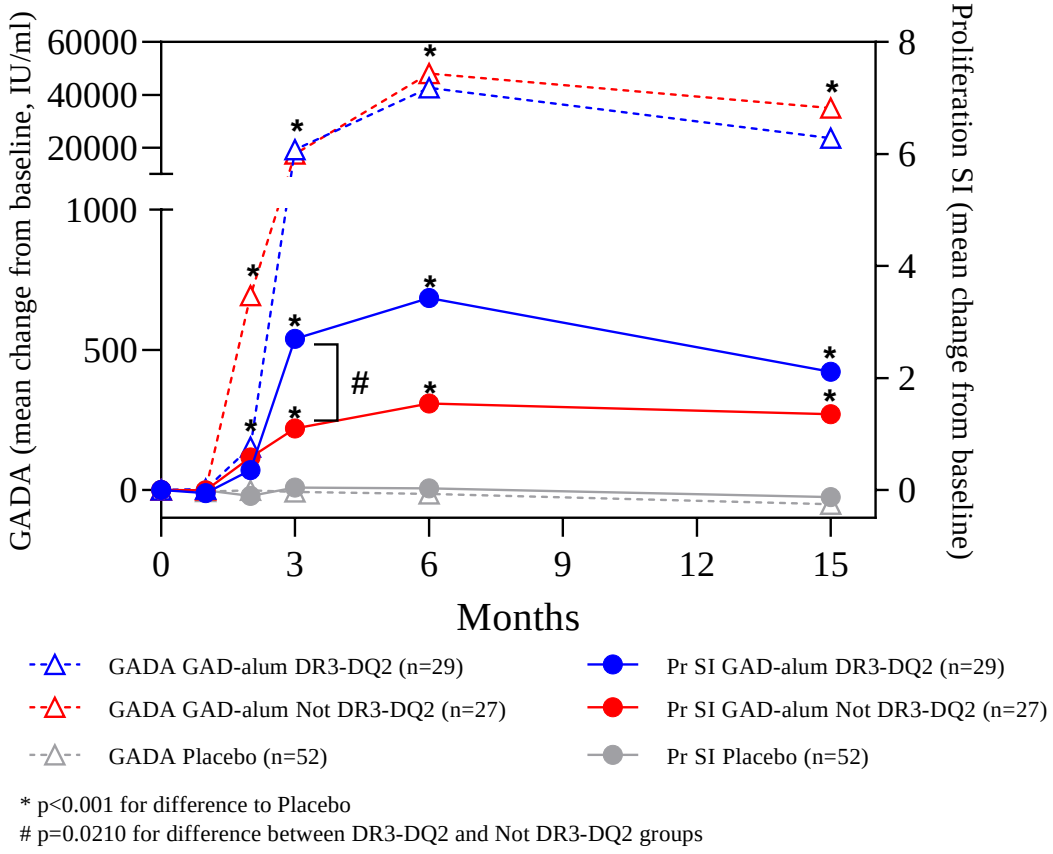
Nowak et al. JCEM 2022

Independent Commentary by Lunati & Fiorina, JCEM 2022

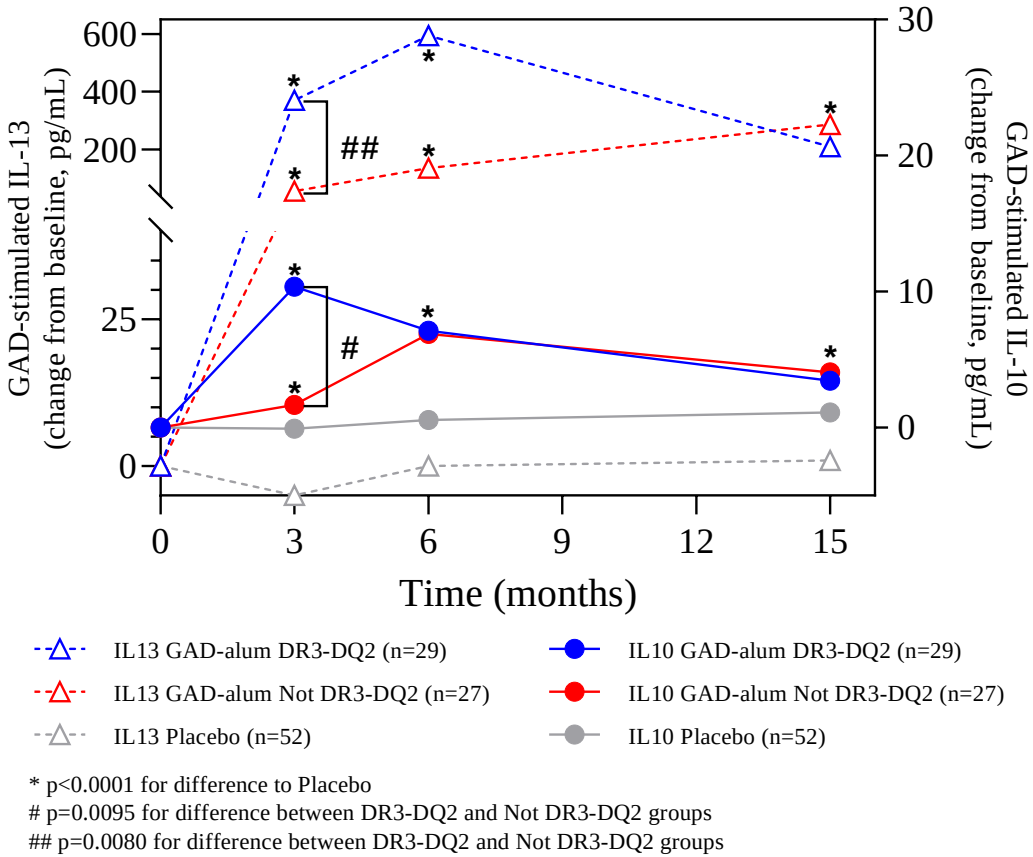
DIAMYD MEDICAL

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

GAD-specific immune response differentiates responders from non-responders



* p<0.001 for difference to Placebo
# p=0.0210 for difference between DR3-DQ2 and Not DR3-DQ2 groups



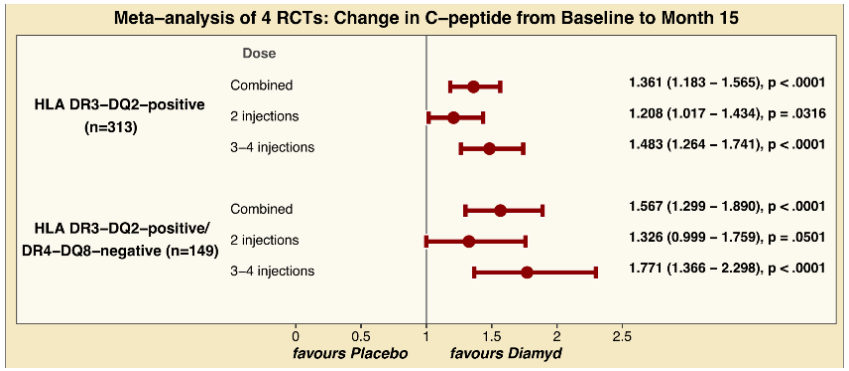
* p<0.0001 for difference to Placebo
# p=0.0095 for difference between DR3-DQ2 and Not DR3-DQ2 groups
p=0.0080 for difference between DR3-DQ2 and Not DR3-DQ2 groups

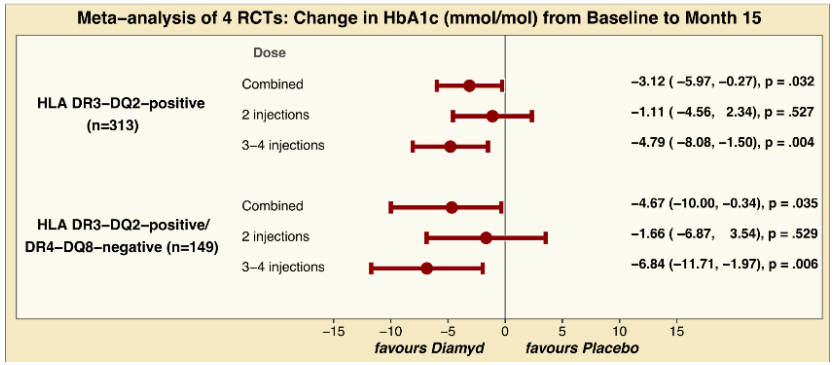
Median change from baseline of anti-GAD65 antibodies (GADA) and Proliferation of PMBC (Stimulation Index, SI) *(A)*, and GAD-stimulated secretion by PBMC of IL-10 and IL-13 levels *(B)* for GAD-alum treated subjects with and without the DR3-DQ2 haplotype Placebo treatment subjects.
P values, Wilcoxon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

DIAMYD MEDICAL

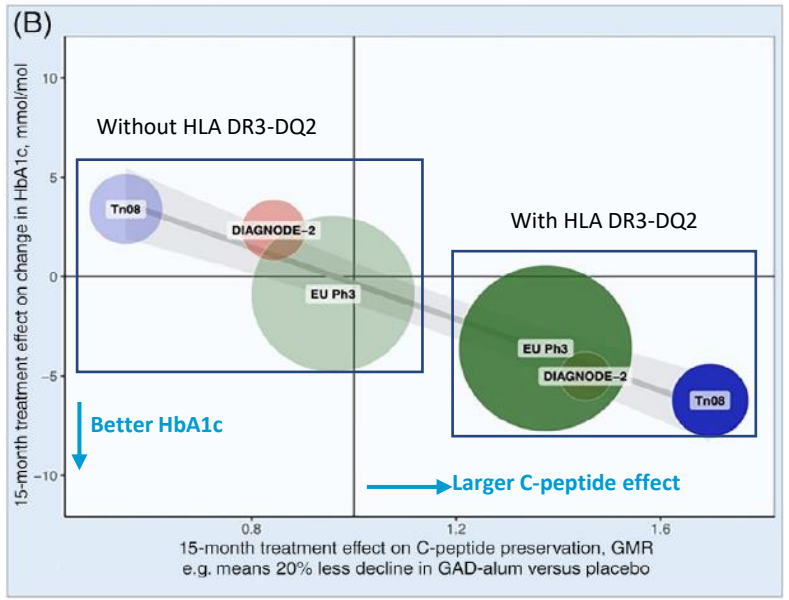
Correlated Diamyd® treatment effects on C-peptide and HbA1c

Updated meta-analysis including the Phase 2b trial shows correlated treatment effects on C-peptide and HbA1c – the two co-primary endpoints of the Phase 3 trial





3 or 4 doses of Diamyd® vs placebo



48% reduction in C-peptide decline, 4.8 mmol/mol (0.5% DCCT units) lower HbA1c

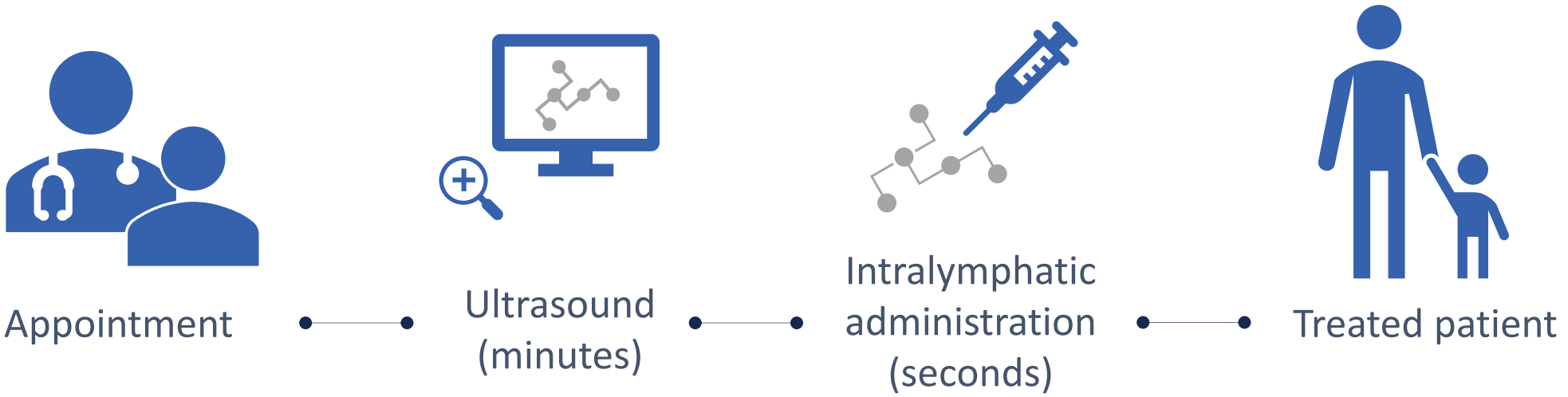
from Baseline to Month 15 compared to placebo in patients carrying the HLA DR3-DQ2 gene who received 3 or 4 injections of Diamyd®

Nowak et al. Diabetes Obesity and Metabolism 2022

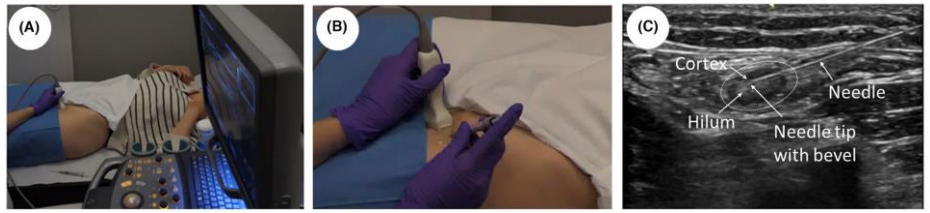
DIAMYD MEDICAL

Ultrasound-guided targeted injection

Quick, low-key outpatient procedure with discomfort comparable to venepuncture. Targets superficial lymphnode to enhance immunological response.



- Procedure performed by a **radiologist** or **endocrinologist** with ultrasound training
- Pain level equal to taking a blood sample
- No pre-medication (only local anesthetic)



Intralymphatic (IL)-injection with needle placed in plan with the ultrasound probe

Monitoring of IL injection using ultrasound

Flory, S. et al(2024).Allergy, 79(8), 2222–2234

The first ever precision medicine Phase 3 trial in Type 1 Diabetes

Diamyd® in individuals recently diagnosed with Stage 3 type 1-diabetes and positive for the HLA DR3-DQ2 haplotype

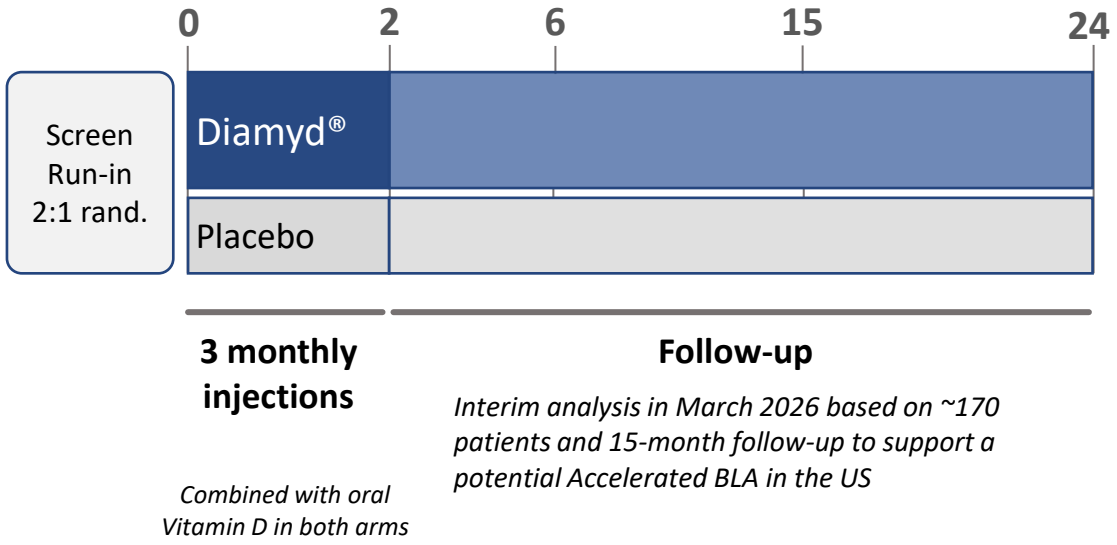
Breakthrough T1D™ Partner since 2023
Formerly JDRF

Diagnode-3 study

www.diagnode-3.com

DIAGNODE-3 Single Pivotal Precision Medicine Phase 3 trial

Aligned with the FDA and EMA. 60 clinics in the United States and Europe.
Randomized, placebo-controlled, 2-arm trial to confirm the effect and safety of 3 targeted injections of Diamyd® given on top of standard of care.



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

Key Secondary Endpoint

- 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

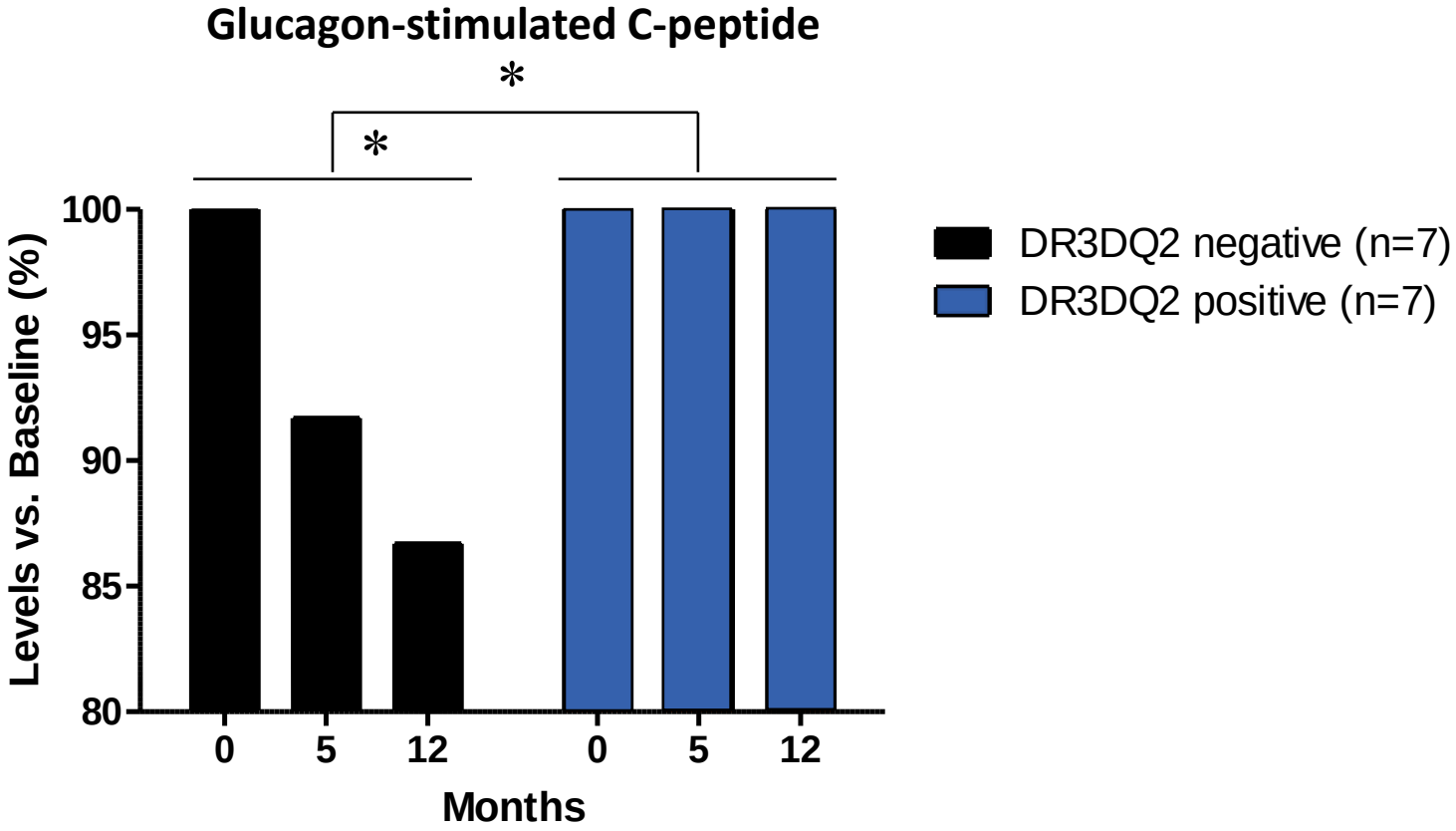
DIAMYD MEDICAL

Supportive clinical data in Stage 1 & 2 Type 1 Diabetes & Adult-onset Type 1 Diabetes (LADA)

DIAMYD MEDICAL

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

1-year pilot study of targeted injections of Diamyd® in individuals with adult-onset Type 1 Diabetes (latent autoimmune diabetes in adults (LADA)) . No safety concerns.



Unchanged glucagon-stimulated C-peptide levels

at 12 months vs Baseline (0 months) in the HLA DR3-DQ2 positive subgroup.

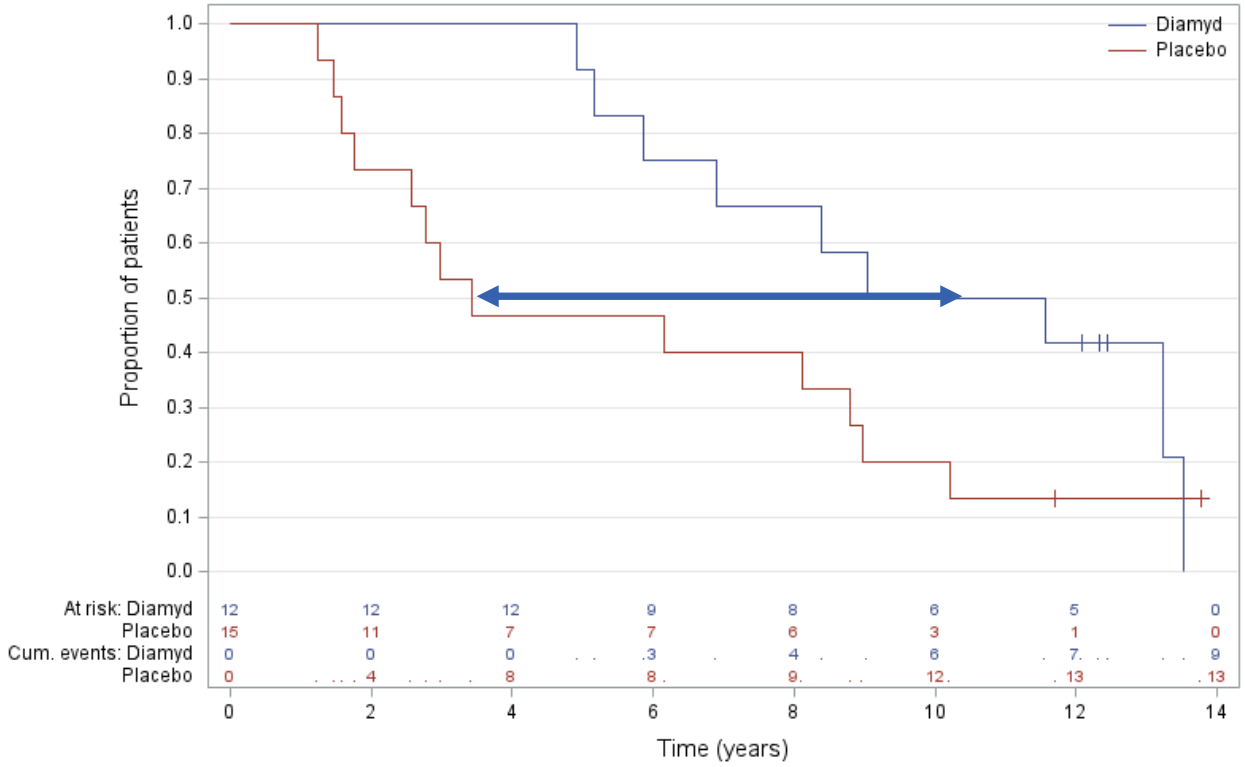
*p< 0.03 for median 13.3% reduction at 12 months vs. Baseline (0 months) in the DR3DQ2 negative subgroup (n=7).
*p< 0.04 for difference between HLA subgroups in change at 12 months vs. Baseline (0 months).

Hals *et al.*, Diabetes, Obes Metab. 2023

DIAMYD MEDICAL

Clinical Data in Stage 1/ Stage 2 Type 1 Diabetes

Long-Term follow-up of DiAPREV-IT shows that two subcutaneous injections of Diamyd® may delay Type 1 Diabetes onset by nearly 7 years



KM plot of time to Type 1 Diabetes in HLA DR3-DQ2 (Diamyd ® n=12, Placebo n=15). The arrow highlights the difference in median time to stage 3 Type 1 Diabetes.

Performed in 2024 based on data from the Swedish National Diabetes Registry combined with phone interviews. The study was performed by Prof. Helena Elding Larsson, Lund University.

Analysis shows that 2 subcutaneous injections of Diamyd® **may delay Type 1 Diabetes onset by nearly 7 years** in children with the HLA DR3-DQ2 genotype – reinforcing its preventive potential and precision medicine approach.

DiAPREV-IT: 2 subcutaneous injections of Diamyd® in 50 children positive for two or more islet autoantibodies.

Poster presented at ISPAD 2024, unpublished

DIAMYD MEDICAL

DIAMYD MEDICAL COORDINATES THE ASSET MILIEU

A Type 1 Diabetes Forum to drive precision medicine, prevention and screening

Contact with Type 1 Diabetes 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

ASSET

www.asset.healthcare

DIAMYD MEDICAL

Manufacturing of Diamyd®

Wholly-owned biomanufacturing plant

Diamyd Medical has established a biomanufacturing plant for GMP commercial scale production of recombinant GAD65

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

- 24,000 square feet facility in Umeå, Northern Sweden, comprising clean rooms, laboratory facilities and office space
- Manufacturing facility property fully acquired in 2021
- 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 MEDICAL

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

Downstream process

Clarification
Capture
Polish
Nanofiltration

Drug Product formulation

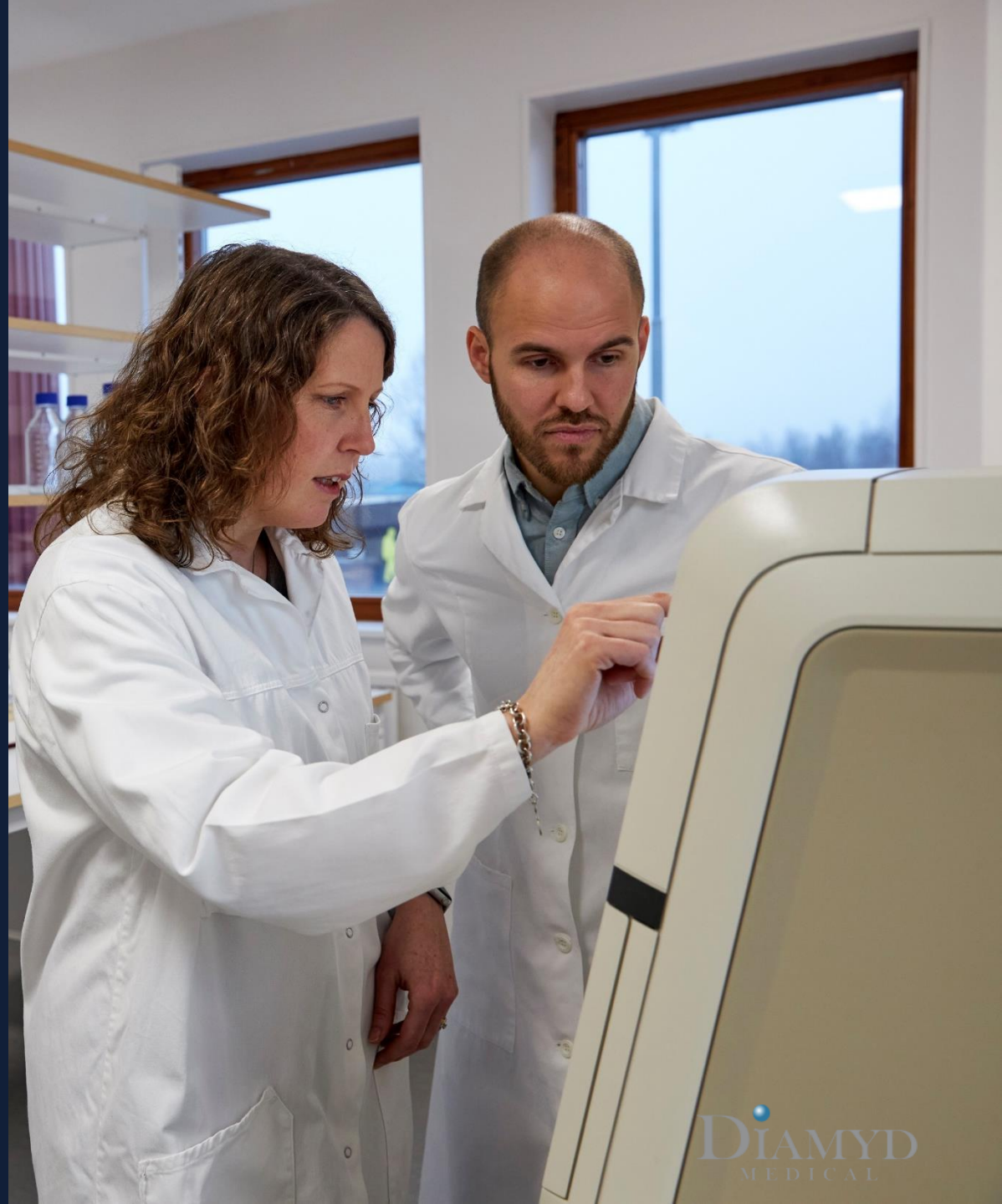
DIAMYD MEDICAL

DIAMYD MEDICAL

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

FINANCES

- Market Cap April 15, 2025 ~ MSEK 810
- Cash Apr 14, 2025: MSEK 93.0
- Preferential rights issue, MSEK 208, incl warrants TO5 exercisable in April 2026. Subscription period April 15-29, 2025.



Management

Dr. Ulf Hannelius, PhD, MBA
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 – Manufacturing Site

Board of Directors

Anders Essen-Möller, MSc
Chairman, Founder

Erik Nerpin, LL.M.
Vice Chairman

Maria-Teresa Essen-Möller, MSc

Dr. Torbjörn Bäckström, MD, PhD

Dr. Mark Atkinson, PhD

Dr. Karin Hehenberger, MD, PhD

Dr. Karin Rosén, MD, PhD

Scientific Advisory Board

Professor Dr. Mark Atkinson, PhD (Chair)
University of Florida

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

Professor Dr. Åke Lernmark, MD, PhD
Lund University

Associate Professor, Dr. Emily Sims, MD
Indiana University School of Medicine

Dr. Alice Long, PhD
Benaroya Research Institute, Seattle

Team with extensive experience from biotech and pharma including Horizon Pharma, GSK, Genentech, Johnsson & Johnsson, Sanofi

DIAMYD MEDICAL

Diamyd Medical

www.diamyd.com

Ulf Hannelius, President & CEO

ulf.hannelius@diamyd.com

DIAMYD MEDICAL