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# With the Mission to Cure Type 1 Diabetes

July 2025

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# Precision medicine to prevent and treat Type 1 Diabetes

Therapeutic preservation of pancreatic function

**Clinically validated and de-risked immunology platform**

- **Antigen-specific immunotherapy** targeting genetic subgroups
- **Durable disease-modifying 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 platform -** targeting additional 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 alone for Diamyd® launch indication
- **Significant upsides**: Rest of world, adult-onset Type 1 Diabetes (LADA), Stage 1 and 2 Type 1 Diabetes
- FDA **Fast Track** and **Orphan designation**, alignment for an **accelerated approval** pathway
- Phase 3 readout H1 2026 to support potential **accelerated BLA**

30+ years of Scientific and Clinical development

NASDAQ First North Growth Market, ticker: DMYD B

Market Cap July 14, 2025 ~ MSEK 1 350; Cash May 31, 2025, MSEK 319

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# Addressing a significant unmet medical need and economic burden

**>500 000**

new cases of Type 1 Diabetes annually

**>$90 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

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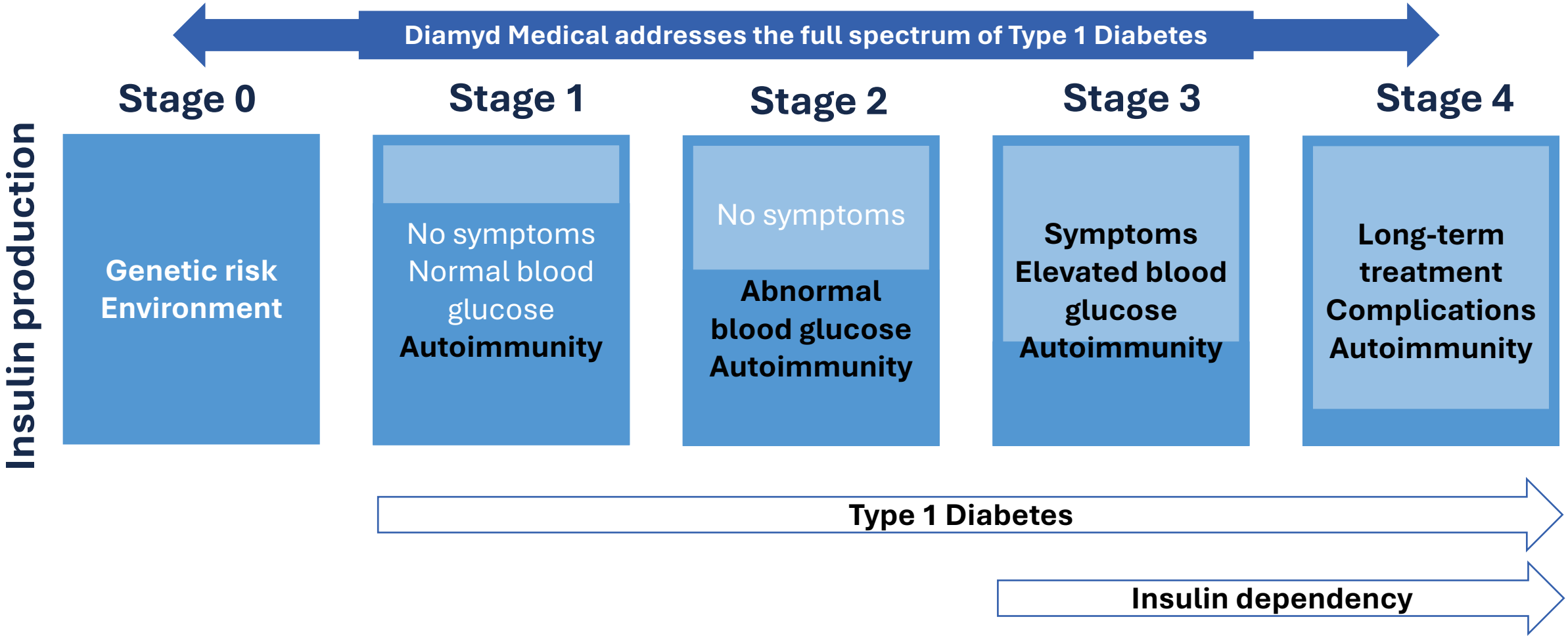
# Type 1 Diabetes – Progressive and irreversible autoimmune destruction of insulin-producing cells in the pancreas

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# Pipeline overview

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

| | Program | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 | Status |
|---|---|---|---|---|---|---|---|
| **Diamyd®** | Stage 3 Type 1 Diabetes (HLA DR3-DQ2 positive) Orphan designation; Fast Track designation | | | DIAGNODE-3 | | | Ongoing in EU & US, early readout H1 2026 |
| | Stage 1&2 Type 1 Diabetes (HLA DR3-DQ2 positive) Fast Track designation | | | DiaPrecise | | | Started Q4, 2023 |
| | Adult-onset Type 1 Diabetes / LADA (HLA DR3-DQ2 positive) | | | GADinLADA | | | Completed, published in 2023 |
| | Evaluation of booster doses | | | DIAGNODE-B | | | Completed, published in 2024 |
| **Insulin antigen** | Stage 1,2,3 Type 1 Diabetes (HLA DR4-DQ8 positive) | | | | | | |

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# Diamyd®

## Recombinant Glutamic Acid Decarboxylase (GAD) 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 with HLA type DR3-DQ2), Fast Track designation*
*Adult-onset Type 1 Diabetes / LADA*

### Mechanism of Action
*Induce immunological tolerance against GAD65*

### Clinical Effect and Benefit
*Preserve function of the pancreas (endogenous insulin production), delay or prevent disease 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
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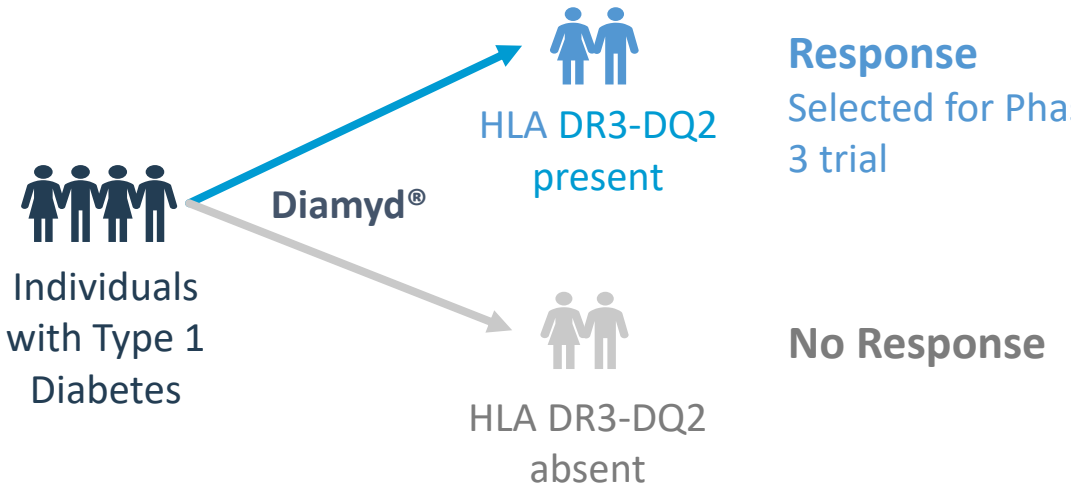
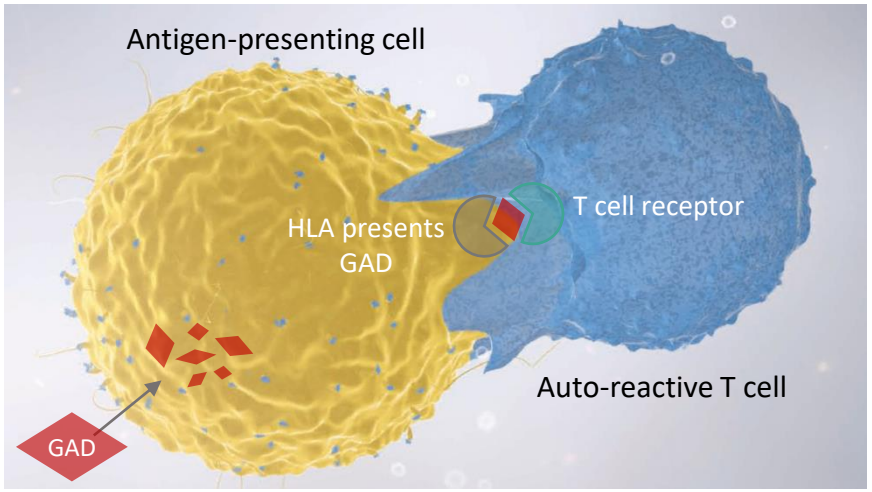
# Diamyd® targets the GADA-first Type 1 Diabetes endotype with HLA DR3-DQ2 positivity




**Response**
Selected for Phase 3 trial

**No Response**

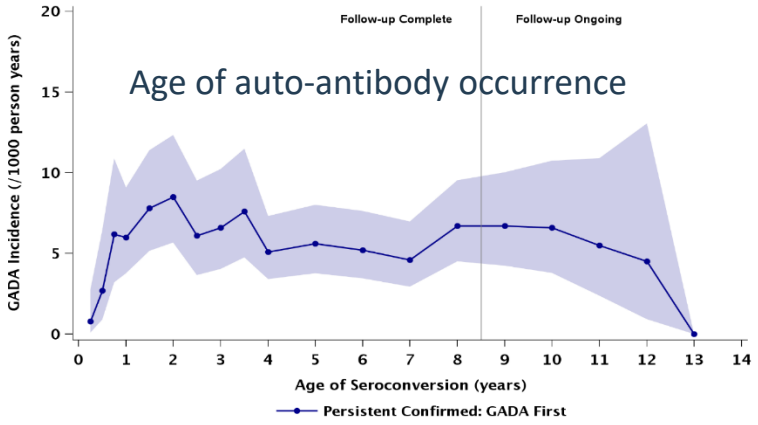


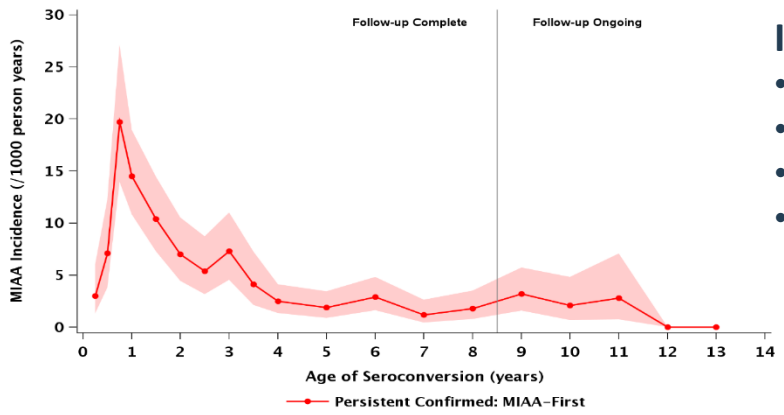

**HLA is central to autoimmunity against GAD**

## 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.*

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# Regulatory and Commercial strategy

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# 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 H1 2026
- C-peptide as the primary endpoint for accelerated BLA

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# 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

- Estimated gross prices ~ $150k – 240k
- Limited Gross-to-Net discounts
- High Type 1 Diabetes insurance coverage and expected high prior authorization
- Untapped market opportunity

## Significant Upsides

- Ex-US sales
- 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** (in addition to launch indication LADA can add an additional $ 2 billion in sales)

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

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# Strong IP position and regulatory exclusivity

## Core Intellectual Property

- **Composition 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 Europe, South Korea, expiry **2038**, and pending in several territories.

## Regulatory exclusivity

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

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# 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 H1 2026.**

BLA

Potential for Priority and Rolling review

Blockbuster potential for launch indication

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# Clinical Data Supporting Launch Indication for Diamyd®

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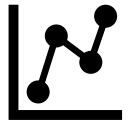
# Summary of clinical development of Diamyd® in Stage 3 T1D

## Discovery

Meta-analysis of clinical trials in the subcutaneous program leads to identification of responder population (individuals with HLA DR3-DQ2)



## Proof-of-concept

DIAGNODE-2 trial showed higher preservation of C-peptide vs placebo in individuals with HLA DR3-DQ2 (pre-specified analysis) using intralymphatic (IL) administration

## Confirmation

DIAGNODE-3 is a pivotal trial to confirm benefit of rhGAD65 vs placebo on C-peptide and HbA1c in individuals with HLA DR3-DQ2, using IL administration

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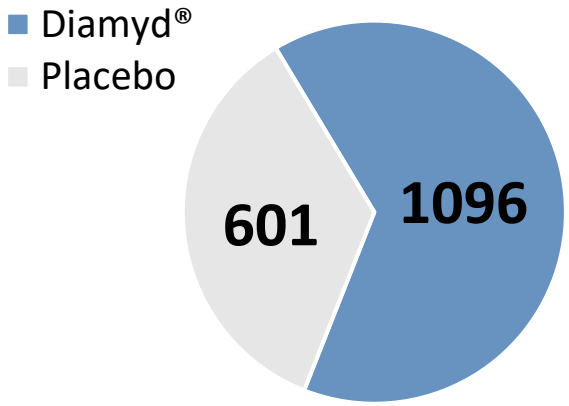
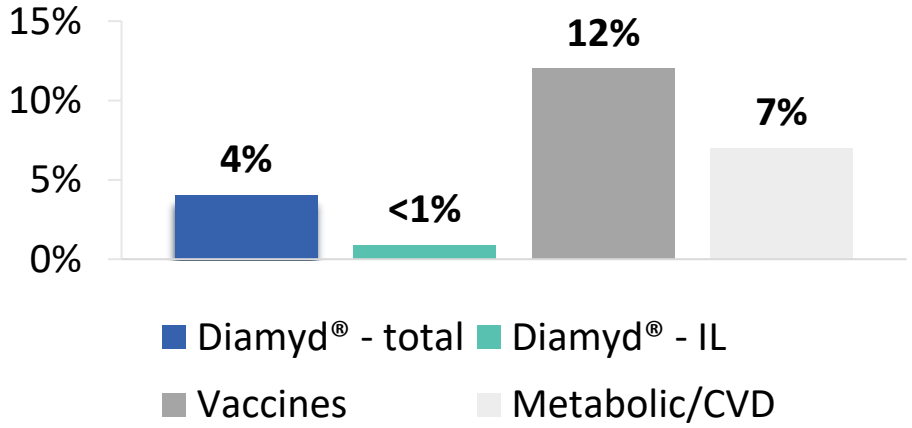
# Favorable safety and tolerability profile

No major safety signals in >1,000 patients exposed to Diamyd® with subcutaneous or targeted intralymphatic administration.

## Total patient exposure in 16 trials




## Patient drop-out rate in clinical trials




## Summary of clinical safety data

- **No major safety signals**
- **No drug-related SAEs** in IL program (1 in total, LADA population)
- Most **common adverse events**: transient tenderness at injection site, injection site edema, mild injection site pain and injection site reaction (< 7 days)
- **<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

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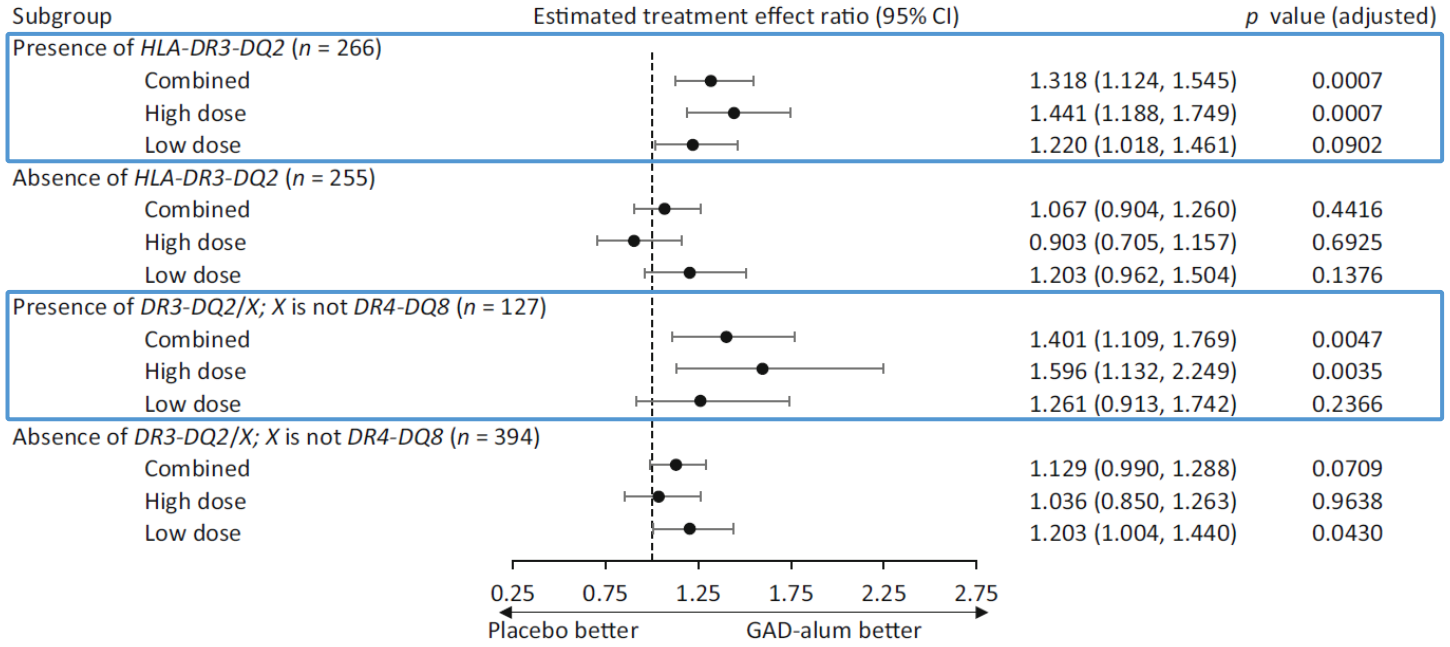
# Meta-analysis of 3 pre-2014 trials identified genetic responder group

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*

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)**

## 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®**

***C-peptide measures endogenous insulin production**

*Hannelius et al. Diabetologia 2020*

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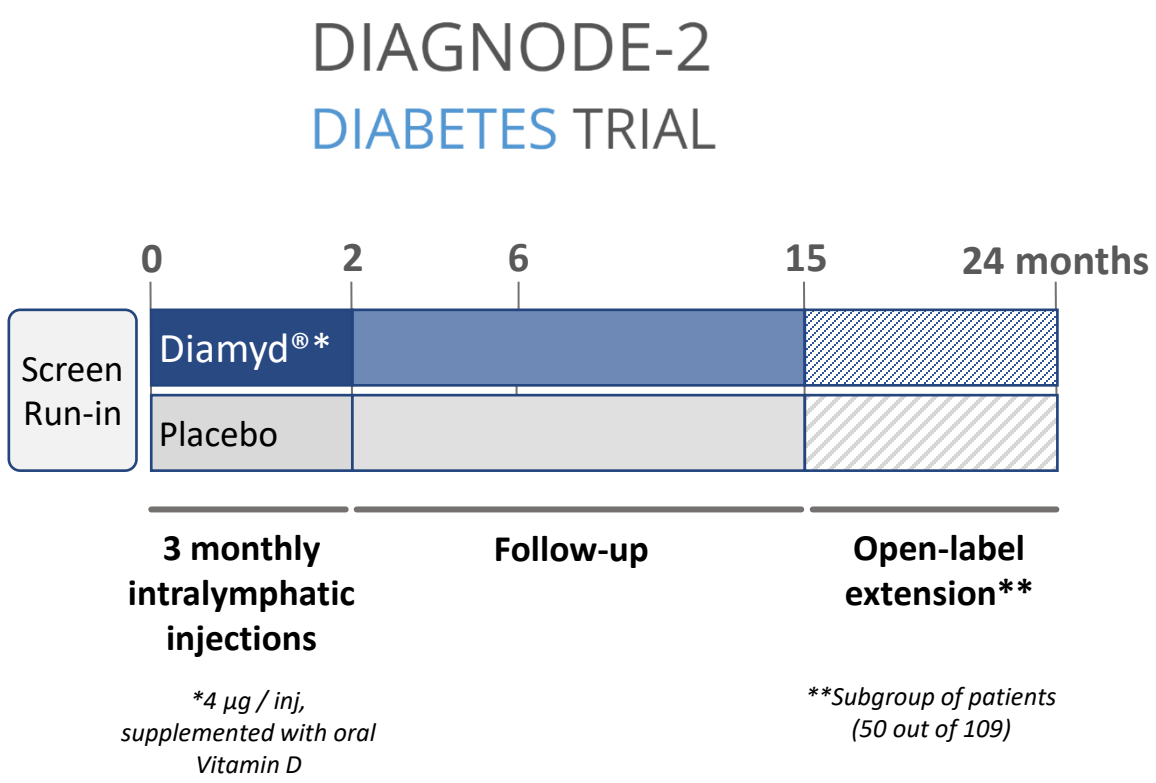
# DIAGNODE-2 Phase 2b trial confirmed responder patients

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

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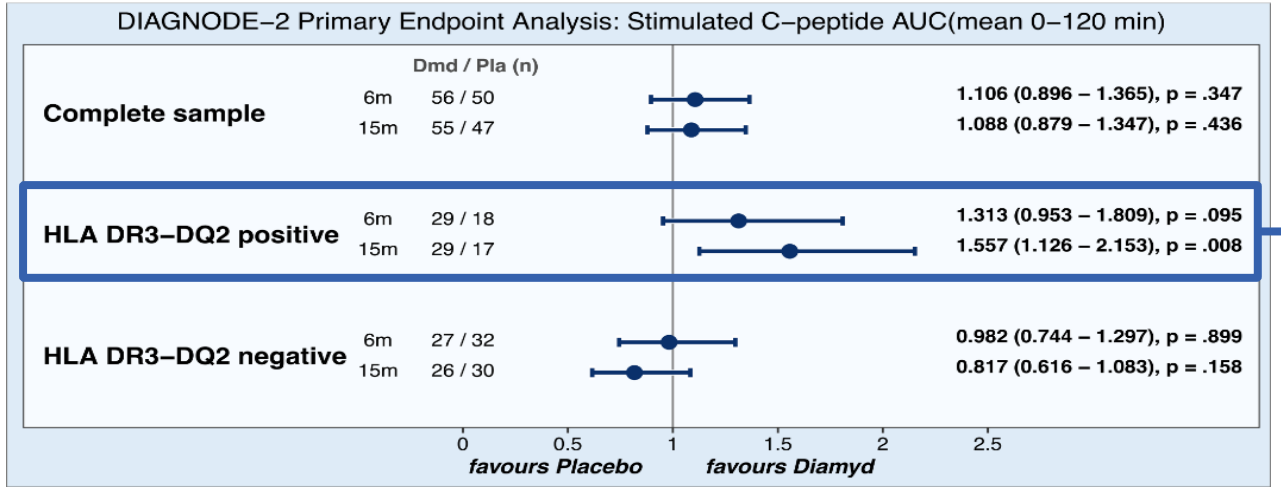
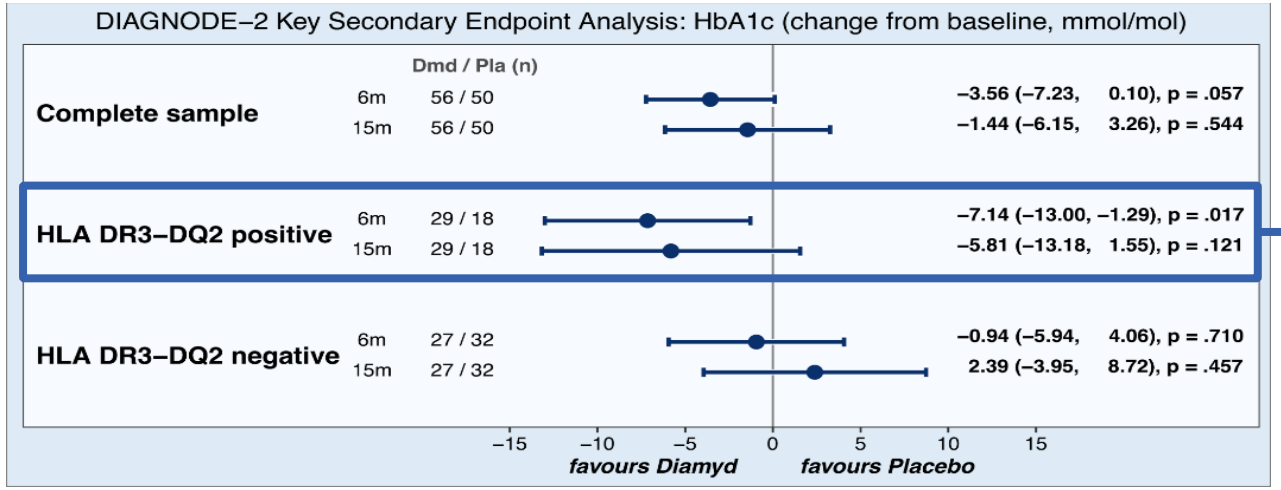
# DIAGNODE-2 Phase 2b trial confirmed responder patients




Diamyd® achieved **statistically significant 56% preservation** of C-peptide secretion, numerical improvement in HbA1c compared to placebo at Month 15 in patients with HLA DR3-DQ2

*Ludvigsson et al. Diabetes Care 2021*

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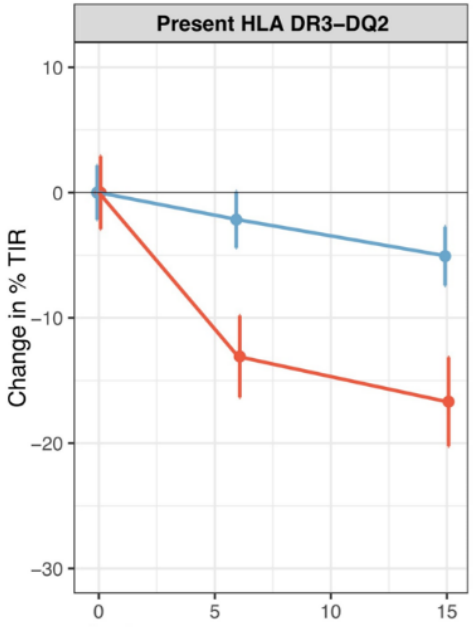
# DIAGNODE-2 Phase 2b trial confirmed responder patients

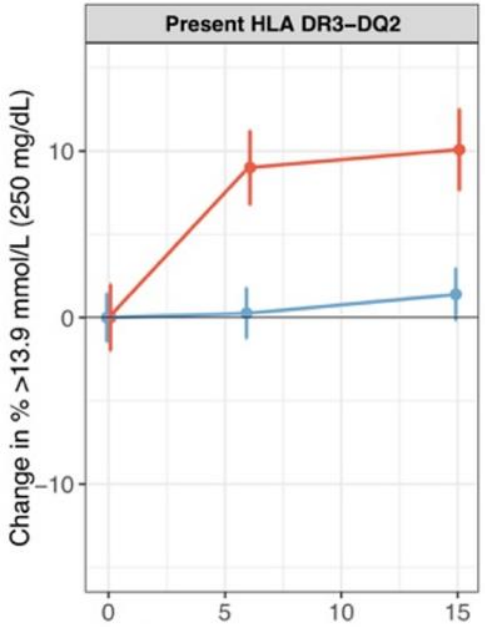
In exploratory analyses, Diamyd® achieved statistically significant benefit on Continuous Glucose Monitoring (CGM) outcomes in patients carrying the HLA DR3-DQ2 responder gene

## Time in Range



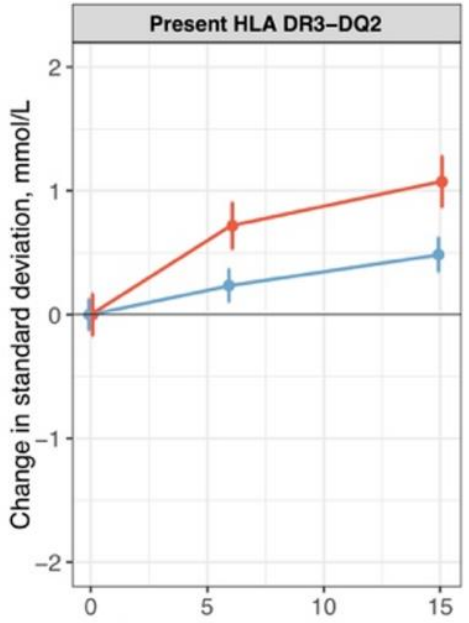

% change from Baseline to Month 15

## Time in severe hyperglycaemia



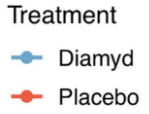

>250 mg/dL (>13.9 mmol/L) % change from Baseline to Month 15

## 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*

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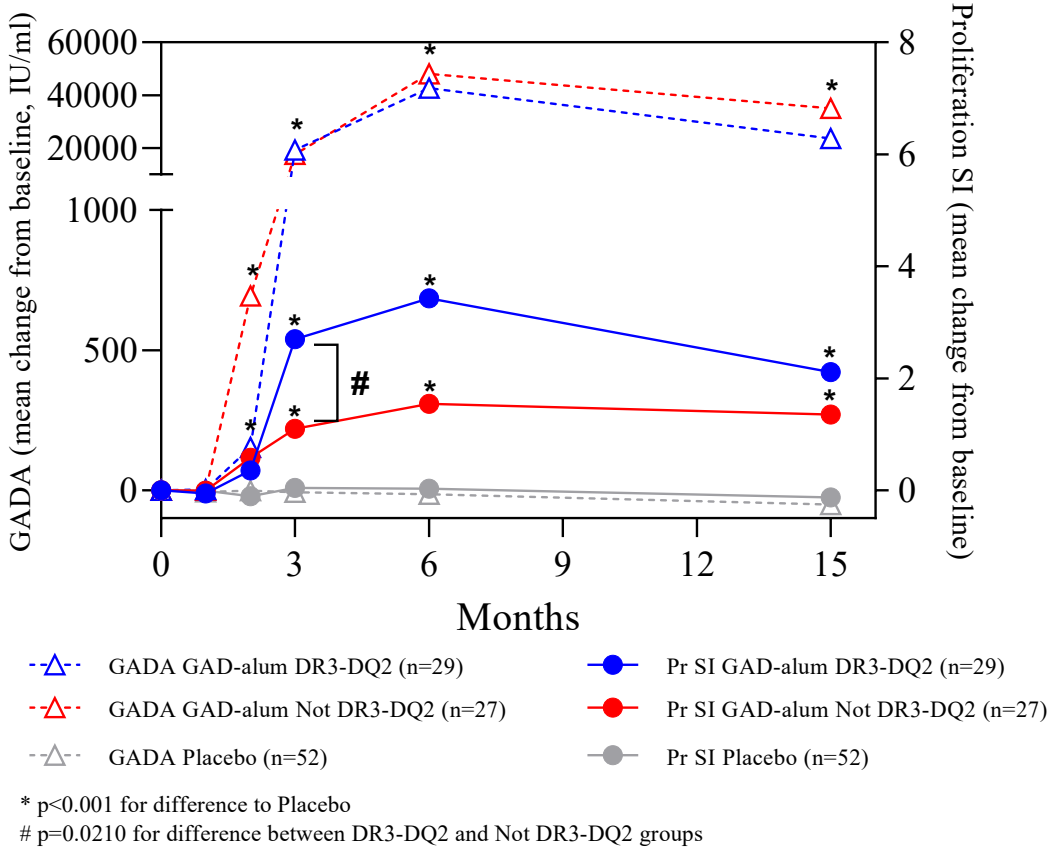
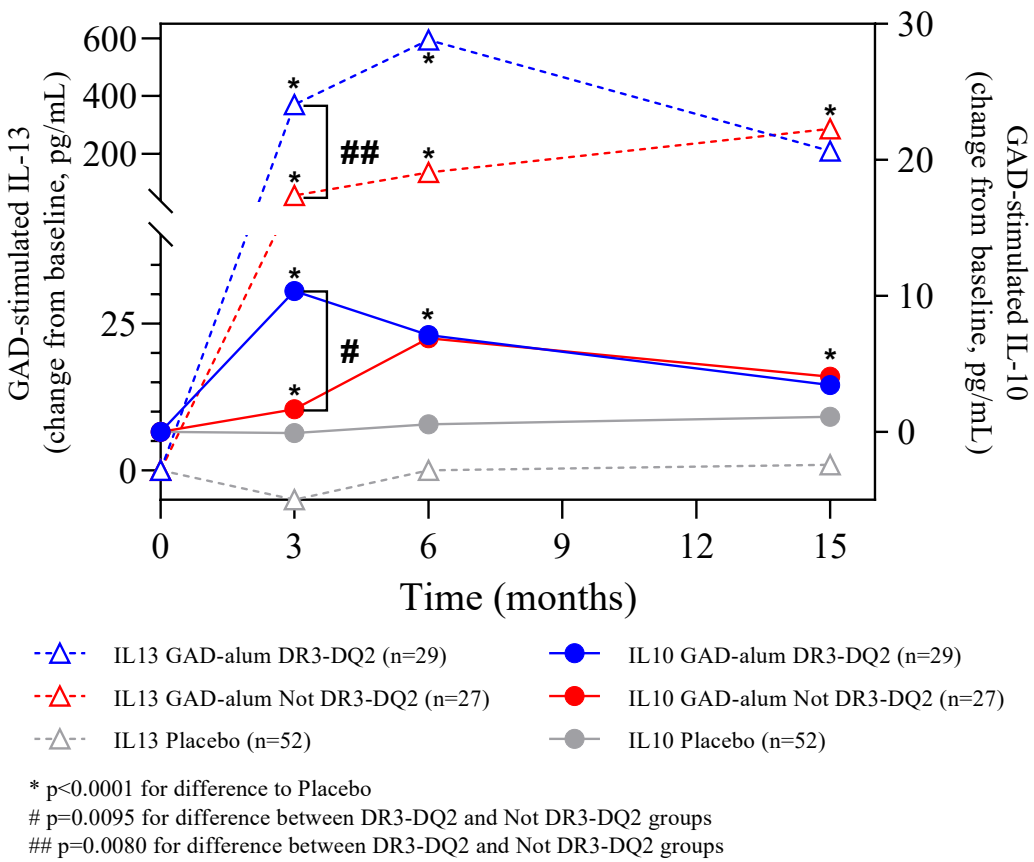
# DIAGNODE-2 Phase 2b trial biomarker data support HLA-specific response

## 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.

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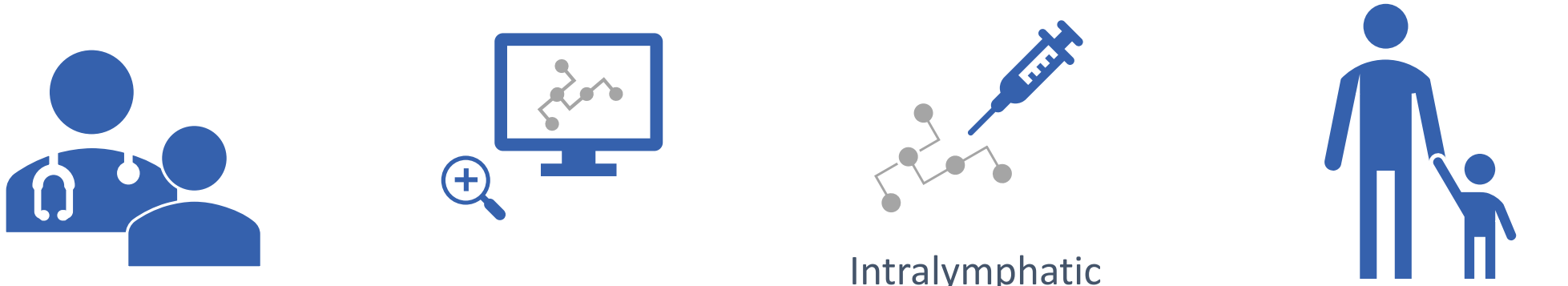
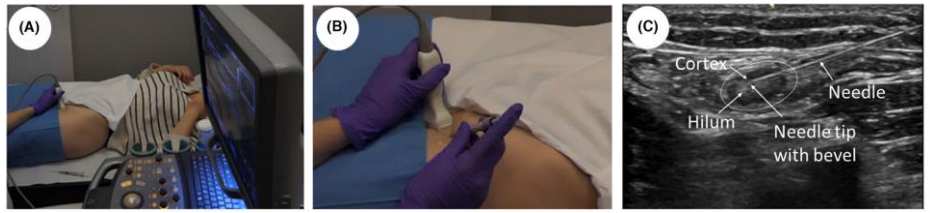
# Ultrasound-guided targeted injection

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

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# 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

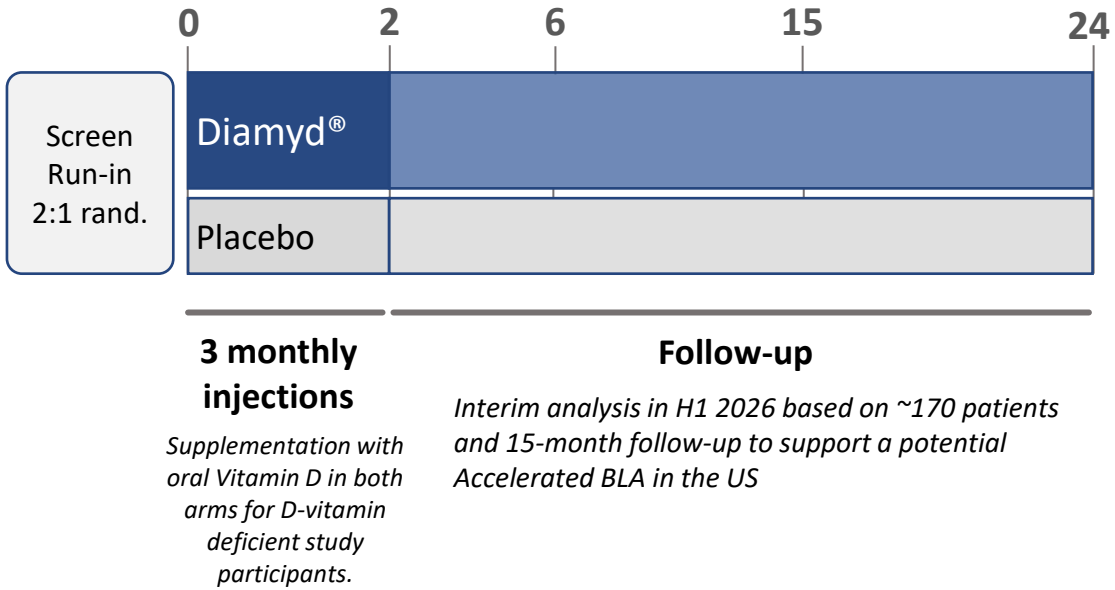
Breakthrough T1D™ Partner since 2023
Formerly JDRF

Diagnode-3 study

www.diagnode-3.com

# DIAGNODE-3 single pivotal precision medicine Phase 3 trial

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. Design aligned with the FDA and EMA. 60 clinics in the United States and Europe.




## 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 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

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

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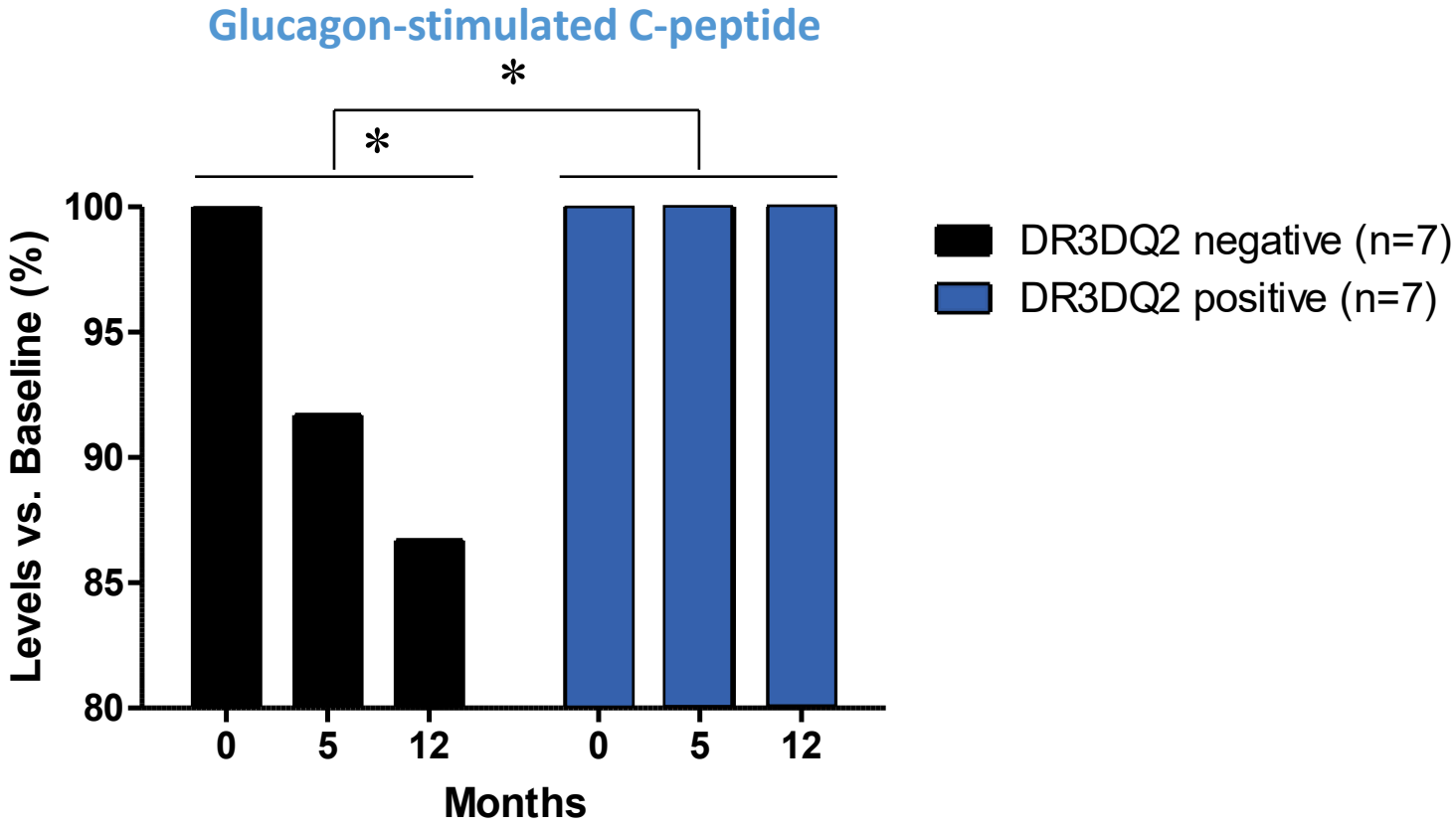
# Phase 2 trial with Diamyd® in up to 70-year-old LADA patients

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*

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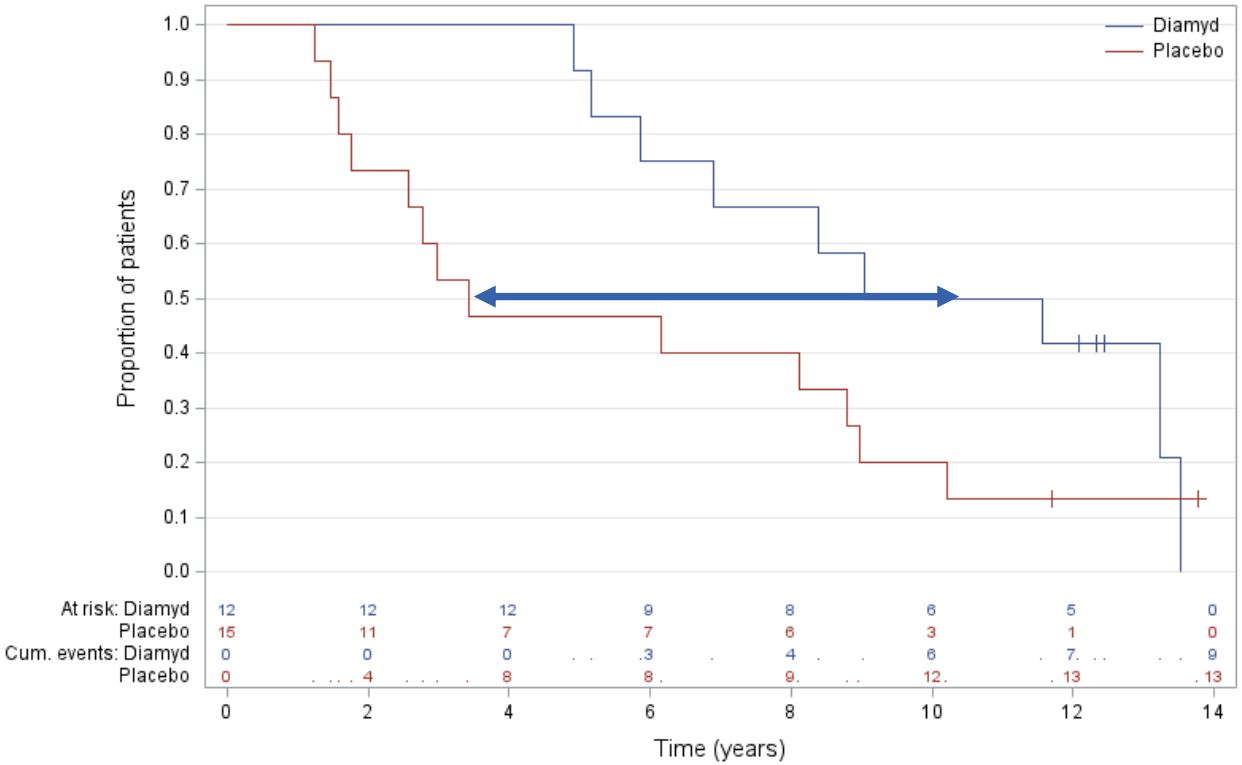
# Clinical data in stage 1/ stage 2 Type 1 Diabetes

## 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*

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# 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

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# Manufacturing of Diamyd®

Wholly-owned biomanufacturing plant

# Full control over the manufacturing of recombinant GAD65


## Commercial-scale production of rhGAD65 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
- GMP certification of facility ongoing
- Independence from CDMOs, third parties
- In control of costs and resource allocation
- Potential beyond GAD manufacturing

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# 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**


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# Management

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

**Martina Widman, MSc**
Chief Operating Officer

**Anna Styrud, BSc***
Chief Financial Officer

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Team with extensive experience from biotech and pharma including Horizon Pharma, GSK, Genentech, Johnsson & Johnsson, Sanofi
*Niklas Axelsson appointed CFO; to start in August 2025

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