With the mission to cure type 1 diabetes

NASDAQ First North Growth Market, ticker: DMYD B

DIAMYD MEDICAL

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Precision medicine for type 1 diabetes

Therapeutic preservation of pancreatic function for early reversal and treatment

Validated, 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

Strong regulatory alignment and milestones

- >$2 billion sales potential in the US alone for retogatein 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 Drug Designation, alignment for an accelerated approval pathway
- Phase 3 interim efficacy readout March 2026 to support potential accelerated BLA, full readout ~Q2 2027

Precision medicine - reversal and intervention

- Clinical development program, retogatein - 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

Corporate Status & Financials

- 30+ years of Scientific and Clinical development
- NASDAQ First North Growth Market, ticker: DMYD B
- Market Cap February 6 2026 ~ MSEK 2 250; Cash Nov 31, 2025, MSEK 233

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Significant unmet medical need and economic burden

35 years
shorter health span

>500 000
new cases of type 1 diabetes annually

>$90 billion
economic burden

Life long
dependence on insulin treatment and blood glucose measurements

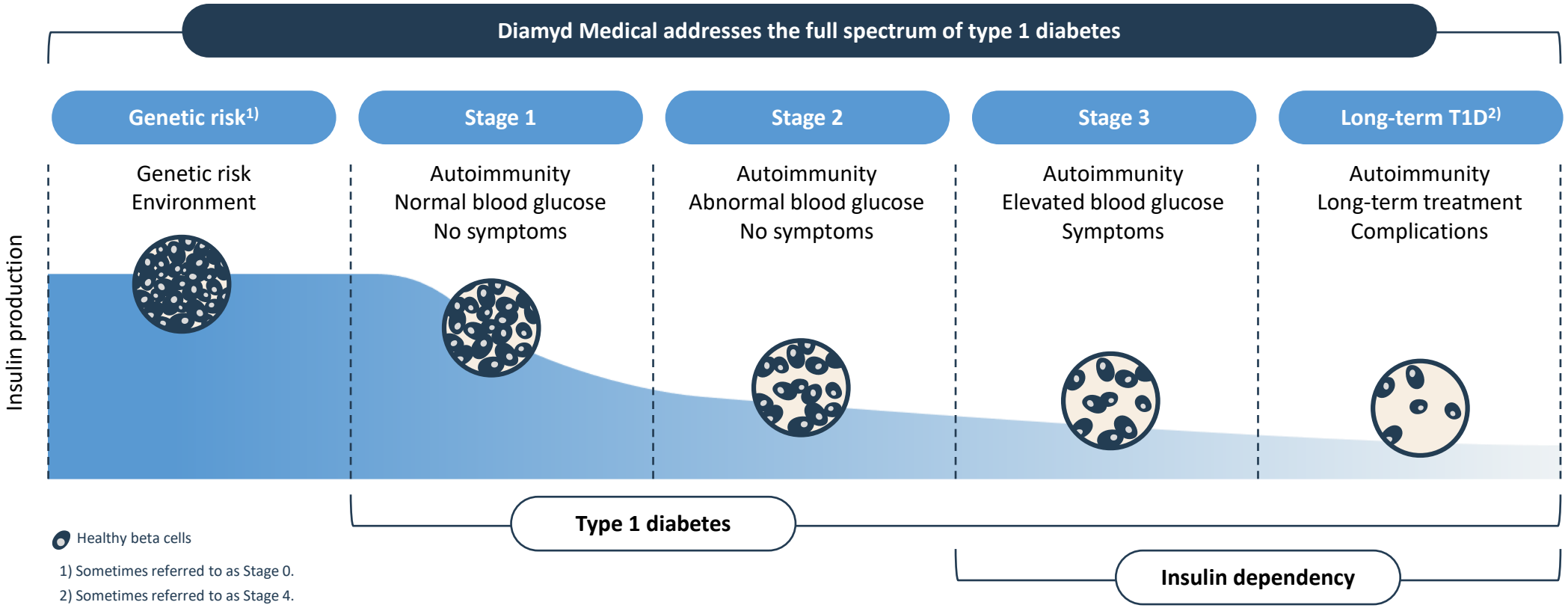
15 years
shorter life span

High risk
for serious complications incl. cardiovascular disease

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

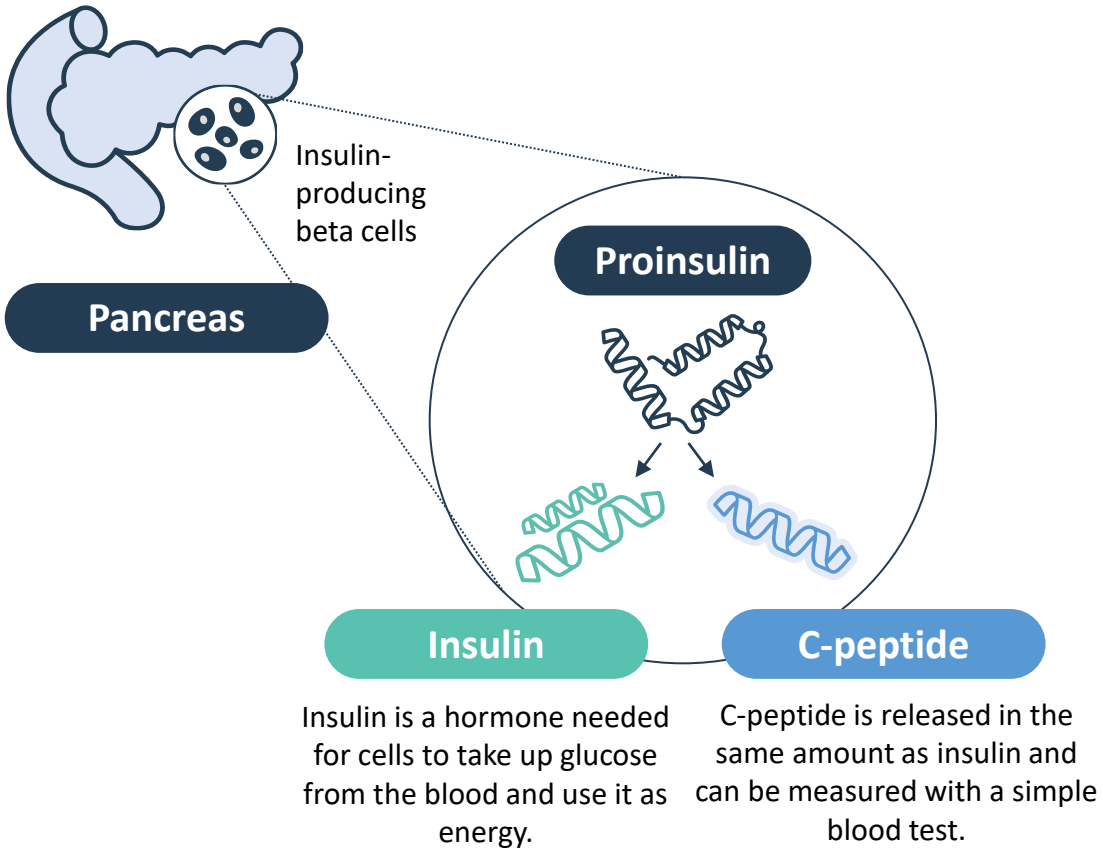
Type 1 Diabetes

Asymptomatic autoimmunity, incipient deficiencies in blood glucose monitoring and clinical diagnosis requiring lifelong insulin therapy



Preserving pancreatic function

Addressing the autoimmune destruction of insulin producing cells



- **Therapeutic targeting of the autoimmune destruction** of insulin-producing beta cells in the pancreas.
- **Preserving pancreatic function** (endogenous **insulin/C-peptide** production) is associated with:
  - Better glycemic control
  - Fewer complications

→Potential to **extend health and lifespan** by lowering risks of cardiovascular disease and long-term complications.

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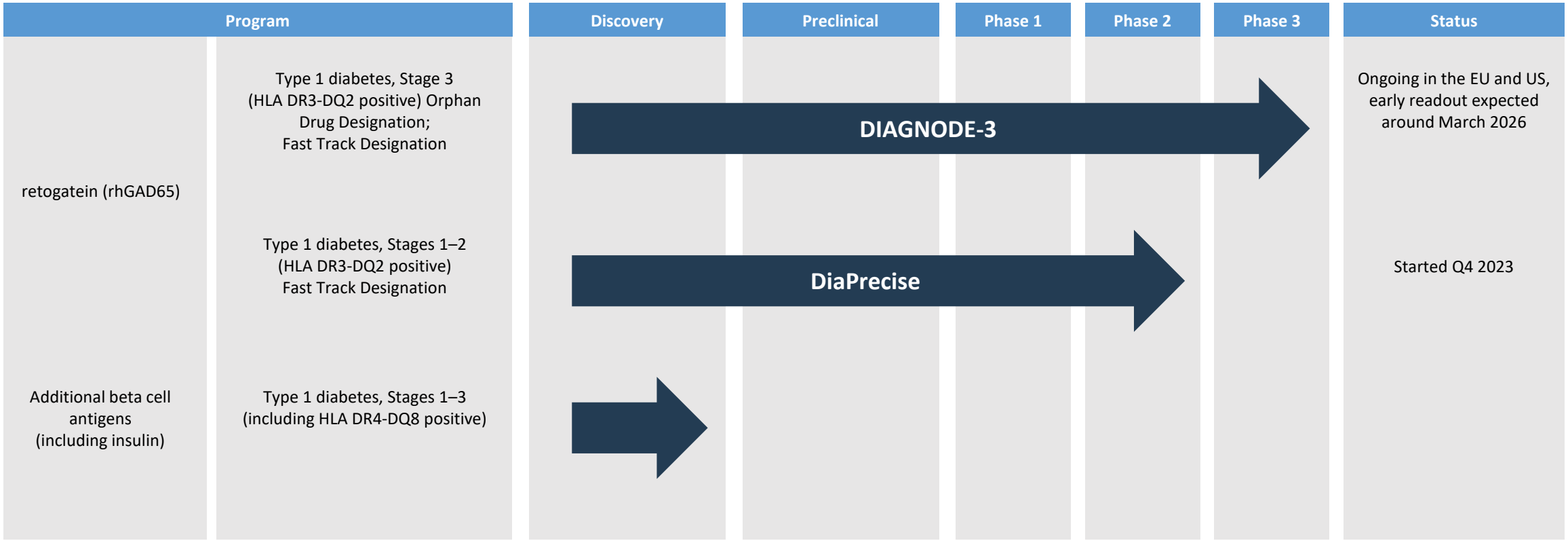
Pipeline overview

Targeted treatment across all stages of type 1 diabetes through HLA-specific antigen therapies



Retogatein - Recombinant Glutamic Acid Decarboxylase (GAD) formulated in Alum (rhGAD65/alum)

Therapeutic preservation of pancreatic function for early reversal and treatment

Primary Indication

- Type 1 diabetes (Stage 3) with residual beta cell function and HLA type DR3-DQ2
- Fast Track and Orphan Drug Designation

Primary Label Expansion

- Type 1 diabetes prevention (Stage 1 & 2 with HLA type DR3-DQ2), Fast Track Designation
- Adult-onset type 1 diabetes / LADA

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

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

Mechanism of Action

- Induce immunological tolerance against GAD65
- No immunosuppression

Licensing Status

- Global rights wholly owned by Diamyd Medical

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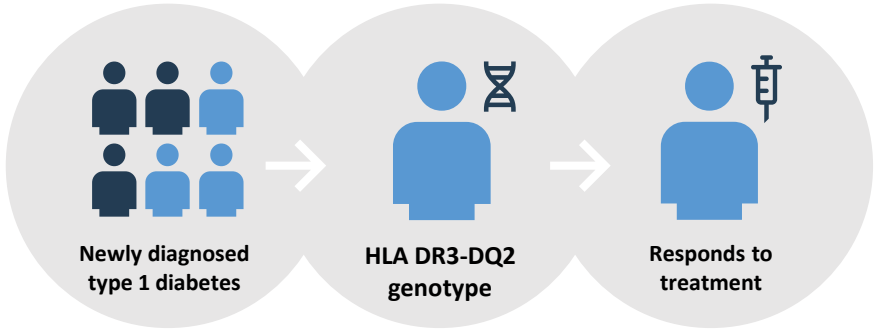
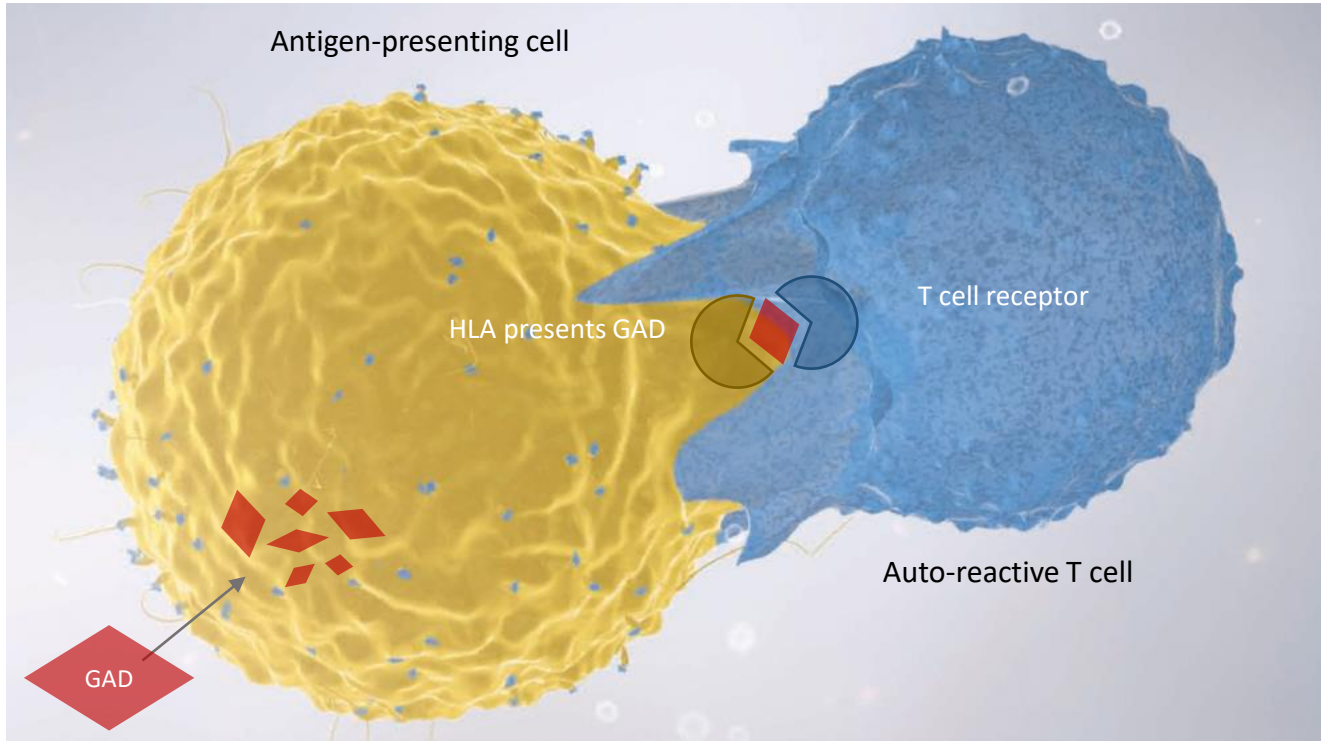
Genetically validated precision medicine approach

Retogatein (rhGAD65) targets the GADA-first type 1 diabetes endotype with HLA DR3-DQ2 positivity representing approximately 40% of of those living with type 1 diabetes



Individuals with newly diagnosed type 1 diabetes with HLA DR3-DQ2 present are selected for Phase 3 trial with rhGAD65



HLA is central to autoimmunity against GAD

Retogatein targets autoimmunity against dominant antigen

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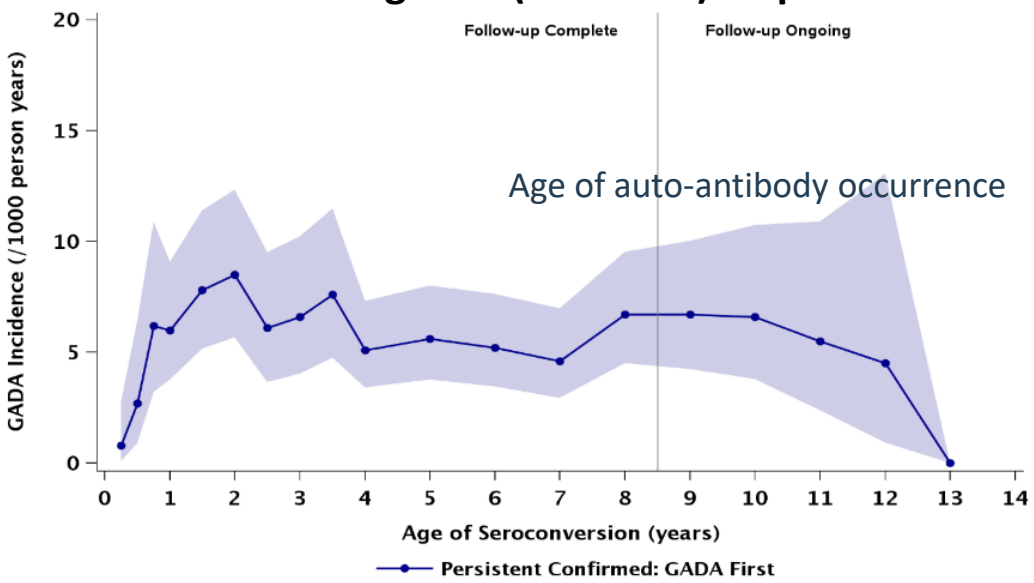
Genetically validated precision medicine approach

Retogatein (rhGAD65) targets the GADA-first type 1 diabetes endotype with HLA DR3-DQ2 positivity

Retogatein (rhGAD65) 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
**Identified and confirmed through retrospective and prospective clinical studies.*

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Regulatory & Commercial strategy

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Pathway to market for retogatein (rhGAD65)

Therapeutic preservation of pancreatic function for early reversal and treatment

Single pivotal Phase 3 trial (DIAGNODE-3)

- Aligned with both FDA and EMA

Fast Track Designation

- Fast Track Designation from the U.S. FDA for the treatment of Stage 1, 2 & 3 type 1 diabetes with HLA DR3-DQ2

Accelerated approval potential

- Alignment with the FDA
- Interim readout to support potential accelerated BLA March 2026
- C-peptide as the primary endpoint for accelerated BLA
- Full readout ~Q2 2027 to support a potential full BLA

Orphan Drug Designation

- Orphan drug designation from the U.S. FDA for the treatment of type 1 diabetes with residual beta cell function

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Estimated > $2 billion peak sales in the US alone

Retogatein (rhGAD65) 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 type 1 diabetes / LADA, booster courses
- Adult-onset type 1 diabetes / 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 retogatein (rhGAD65) 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/early reversal of HLA DR3-DQ2** subgroup with retogatein (rhGAD65) approved in Europe, Eurasia, Israel, Hong Kong, South Africa, Japan, South Korea, expiry **2038**, additional countries pending
- **Treatment/early reversal of HLA DR4-DQ8** with insulin as an antigen approved in Europe, South Korea, Eurasia, expiry **2038**, and pending in several territories

Regulatory exclusivity

- US BLA approval provides **12 years exclusivity** from market approval
- US Orphan Drug Designation provides **7 years exclusivity** from market approval
- European approval provides **10 years of exclusivity** from market approval

**Subject to any applicable patent term adjustments*

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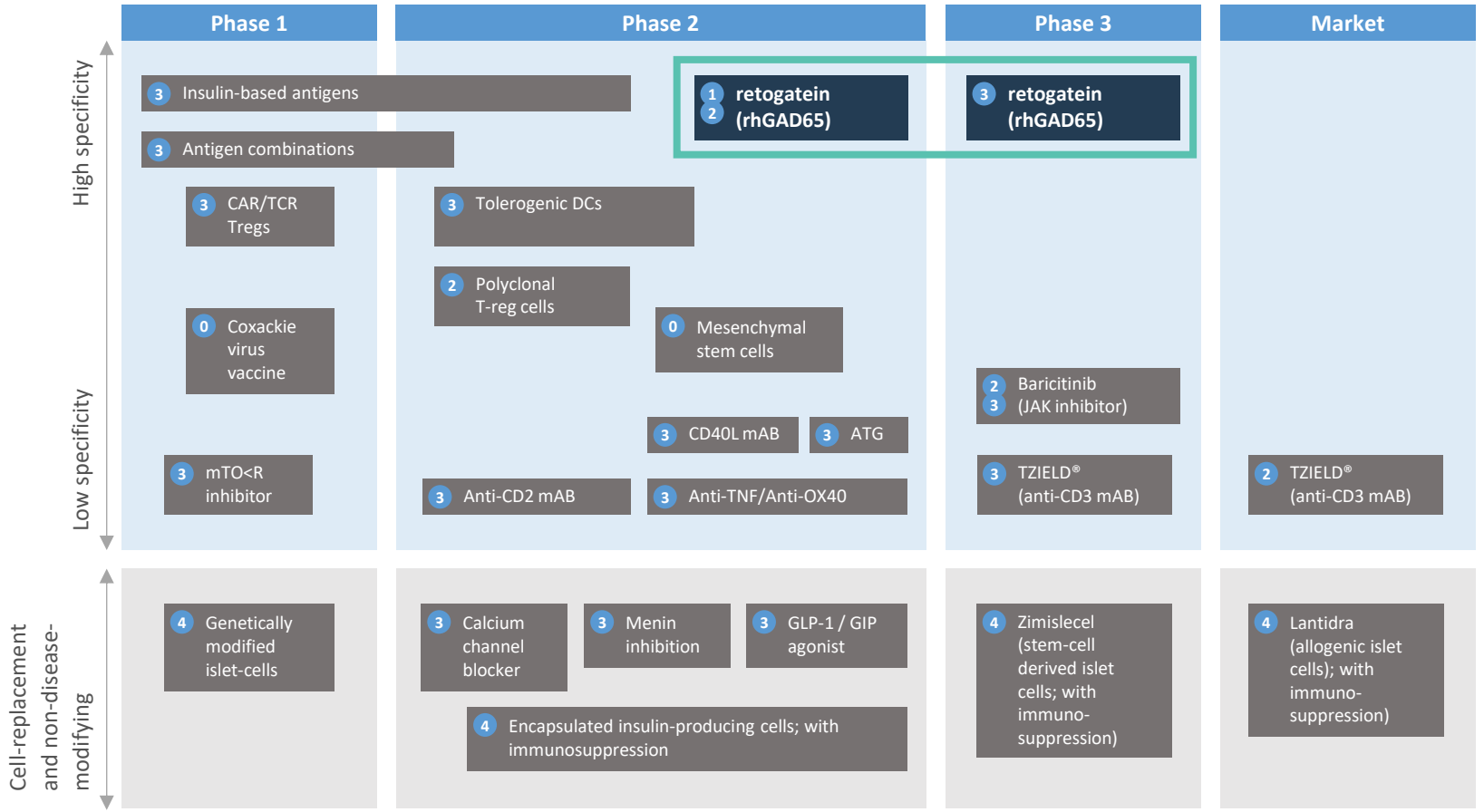
Competitive positioning

Based on late-stage development, unique modality and favorable safety profile

The illustration shows examples of mainly company-driven projects in the field and is representative of the ongoing development, though not exhaustive.

Diamyd Medical is at the forefront of the development of disease-modifying treatments for type 1 diabetes.



Stage: 0 1 2 3 4 Stage 0 and Stage 4 are most often referred to as genetic risk and long-term type 1 diabetes.
Specificity refers to how precisely a treatment targets the root cause of the disease.

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Life-cycle management opportunities

Retogatein offers unique opportunities to drive innovation, expand reach and maximize impact throughout the product life cycle

Potential for regular boosters

- Dose-response demonstrated
- Boosters feasible and safe
- Potential for differentiation, new label claims, cumulative revenue, remission-level disease modification

Combination therapies

- Unique and specific MoA
- Favorable safety across >1,200 treated individuals
- Potential for cornerstone role in combo regimens, e.g. GLP1:s

Label expansion

- Studies across Stage 1 & Stage 2 type 1 diabetes, adult-onset type 1 diabetes (LADA): appr. 10% type 2 diabetes
- Potential for full-spectrum growth across type 1 diabetes
- Subcutaneous product development opportunities (data available)
- Extended pediatric use (lower age groups)

Genetic personalization & optimization

- HLA genetics central to efficacy
- Potential for enhanced pricing strategy, market segmentation, remission-level disease modification

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Clinical Data

Supporting launch indication retogatein (rhGAD65)

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First in class, best in class and disease modifying

Clinical summary of retogatein (rhGAD65) in Stage 3 type 1 diabetes

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 retogatein (rhGAD65) vs placebo on C-peptide and HbA1c in individuals with HLA DR3-DQ2, using IL administration
- Strong safety profile (1,278 patients treated with retogatein; no safety issues)
- Interim efficacy read-out end of March 2026; potential for accelerated approval

Favorable safety and tolerability profile

Retogatein (rhGAD65) in Stage 3 type 1 diabetes

Summary of clinical safety data

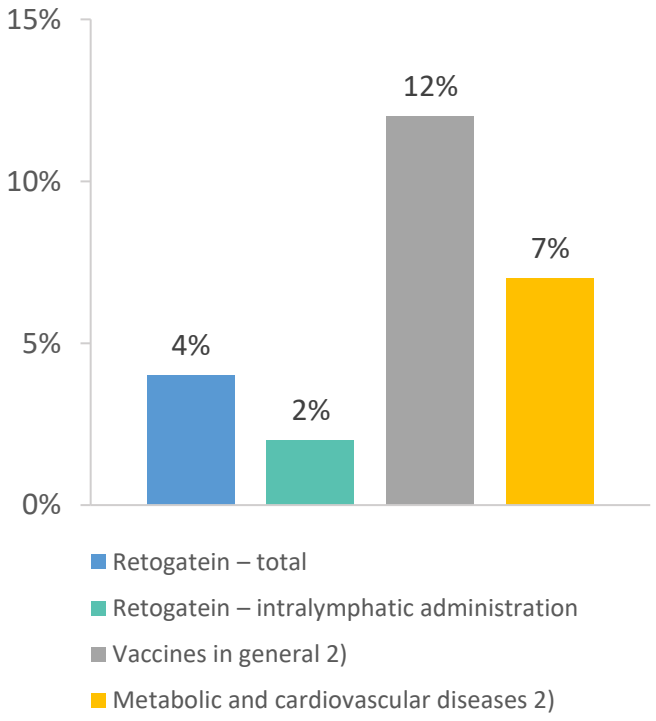
- No new or unexpected safety signals noted
- No suspected unexpected serious adverse reactions (SUSAR) reported in conjunction with intralymphatic (IL) administration (1 SUSAR in total, reported in adult type 1 diabetes patient)
- Most common adverse events: transient tenderness, redness and edema at injection site
- <2% subject drop-out rate in trials with IL administration
- Safety profile assessed in clinical trials that included persons aged 4–70 years, with Stage 1–3 type 1 diabetes

Total patient exposure in 16 trials[1]

Placebo
692
PATIENTS

Retogatein (rhGAD65)
1,278
PATIENTS

Patient drop-out rate in clinical trials



1) November 2025.
2) CenterWatch, "Recruitment Rates Rising, but Retention Rates Fall, According to New Study" (February 2, 2020) by Leslie Ramsey.

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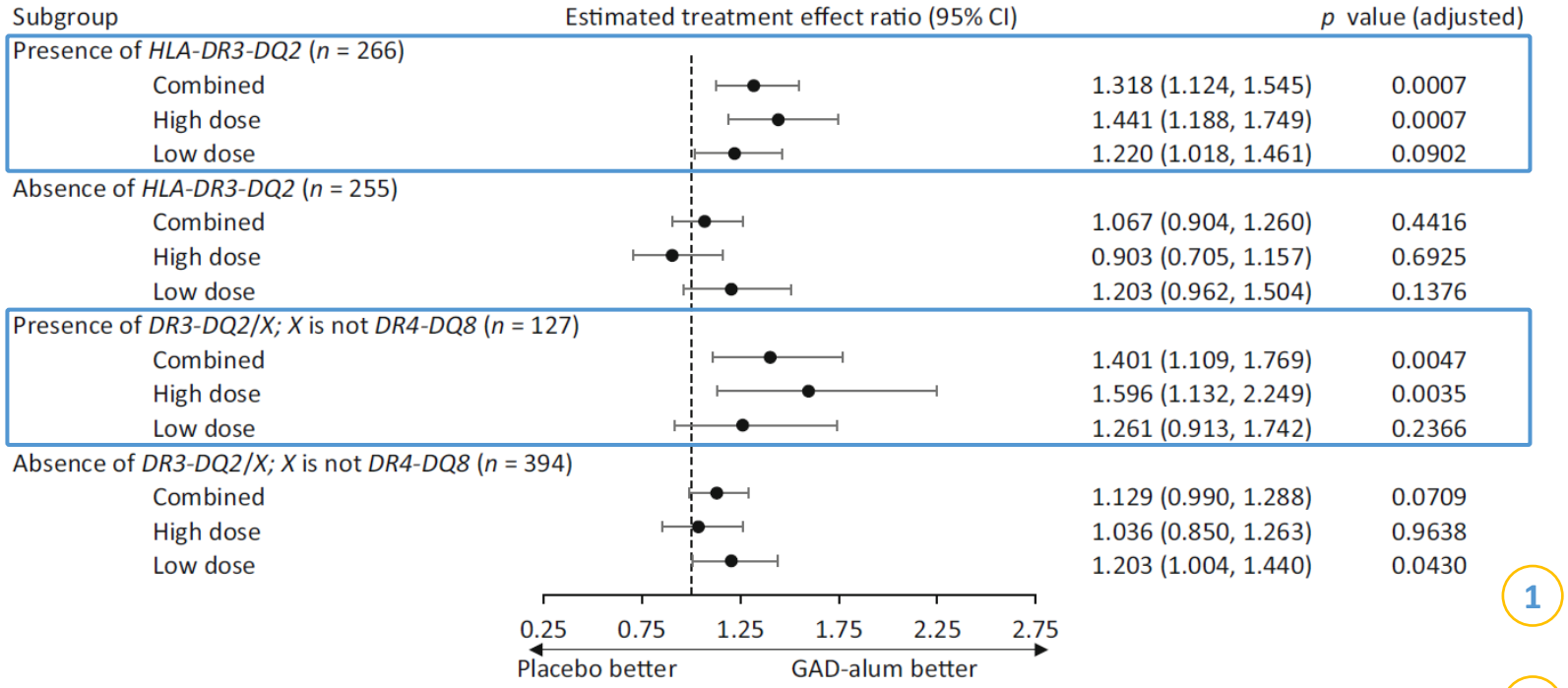
Meta-analysis of genetic responder group

Meta-analysis of 3 randomized controlled clinical trials with subcutaneous retogatein (rhGAD65) 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 retogatein (rhGAD65)

**C-peptide measures endogenous insulin production*

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

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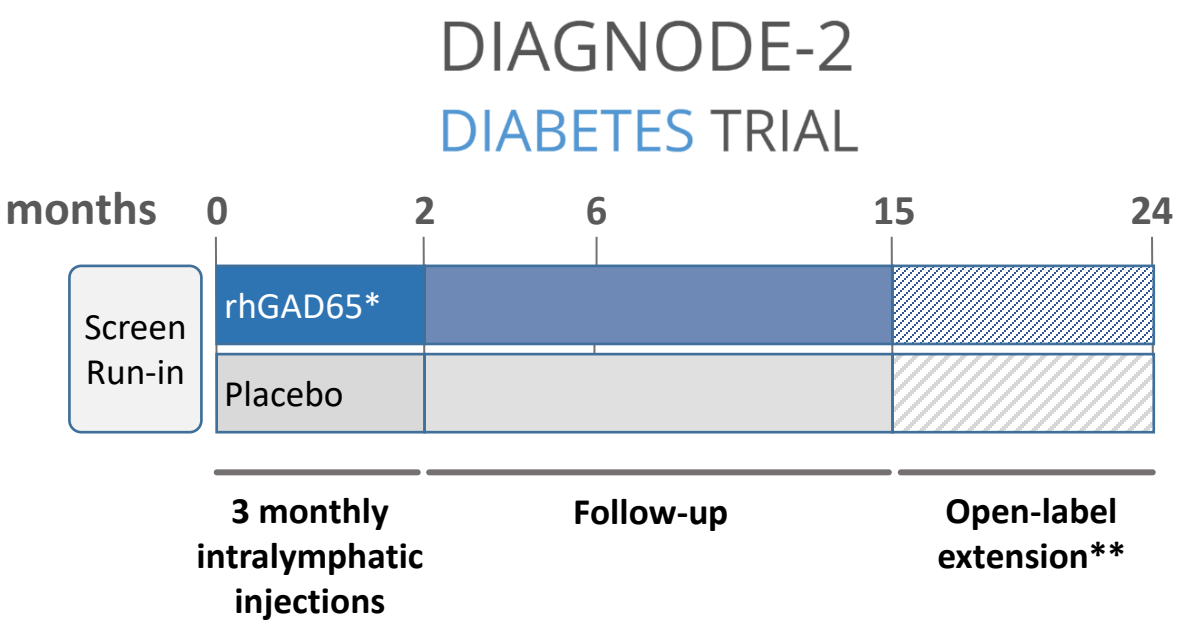
DIAGNODE-2 Phase 2b trial confirmed responder patients

European, multinational, randomized, placebo-controlled, 2-arm trial
assessing 3 targeted injections of retogatein (rhGAD65) given on top of standard of care



4 µg / inj, supplemented with oral Vitamin D

***Subgroup of patients (50 out of 109)*

Primary Endpoint

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

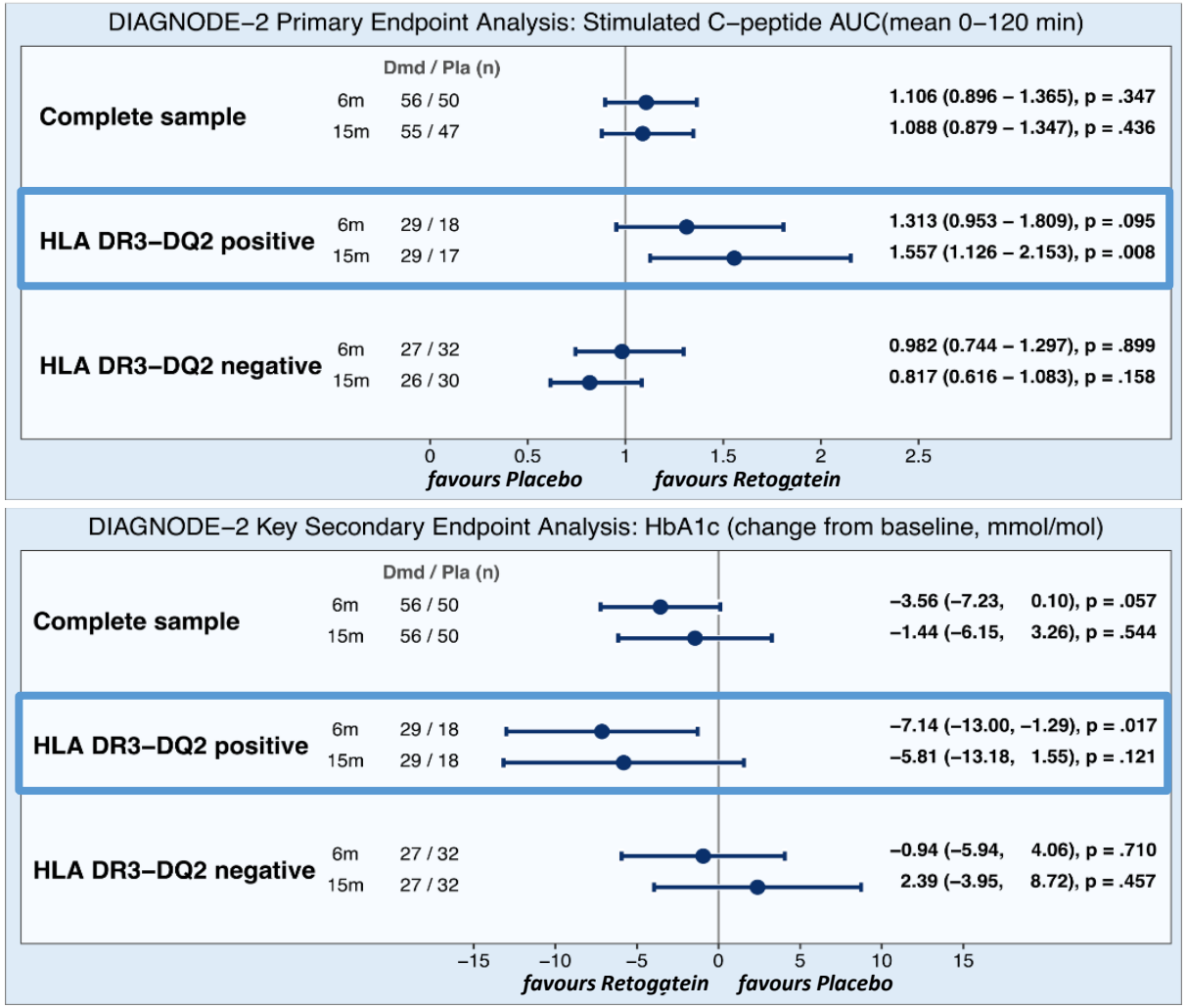
Key Secondary Endpoint

- 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

DIAGNODE-2 Phase 2b trial confirmed responder patients



Retogatein (rhGAD65) 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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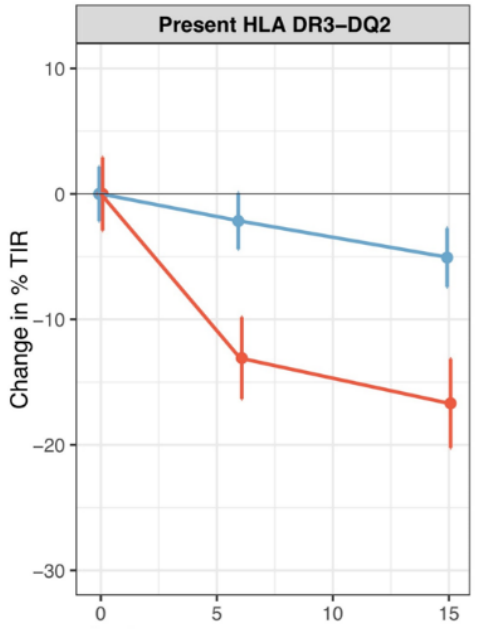
DIAGNODE-2 Phase 2b trial confirmed responder patients

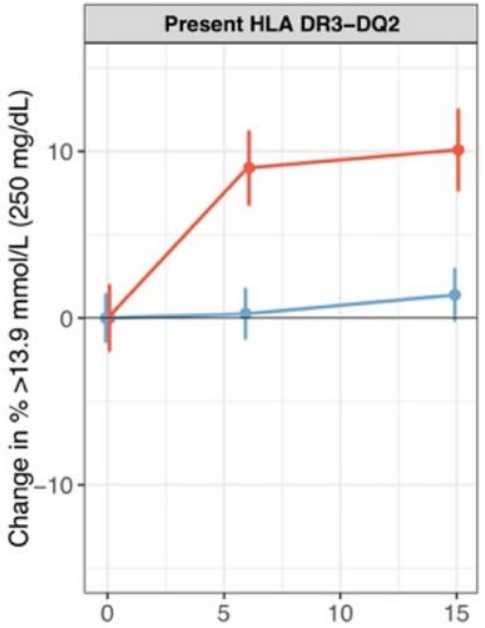
In exploratory analyses, retogatein (rhGAD65) achieved statistically significant benefit on Continuous Glucose Monitoring (CGM) outcomes in patients carrying the HLA DR3-DQ2 responder gene

Time in Range



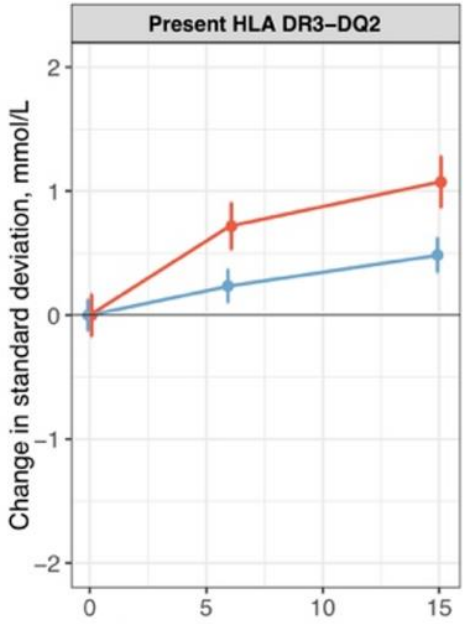
% change from Baseline to Month 15

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

Treatment
Diamyd
Placebo

Nowak et al. JCEM 2022
Independent Commentary by Lunati & Fiorina, JCEM 2022

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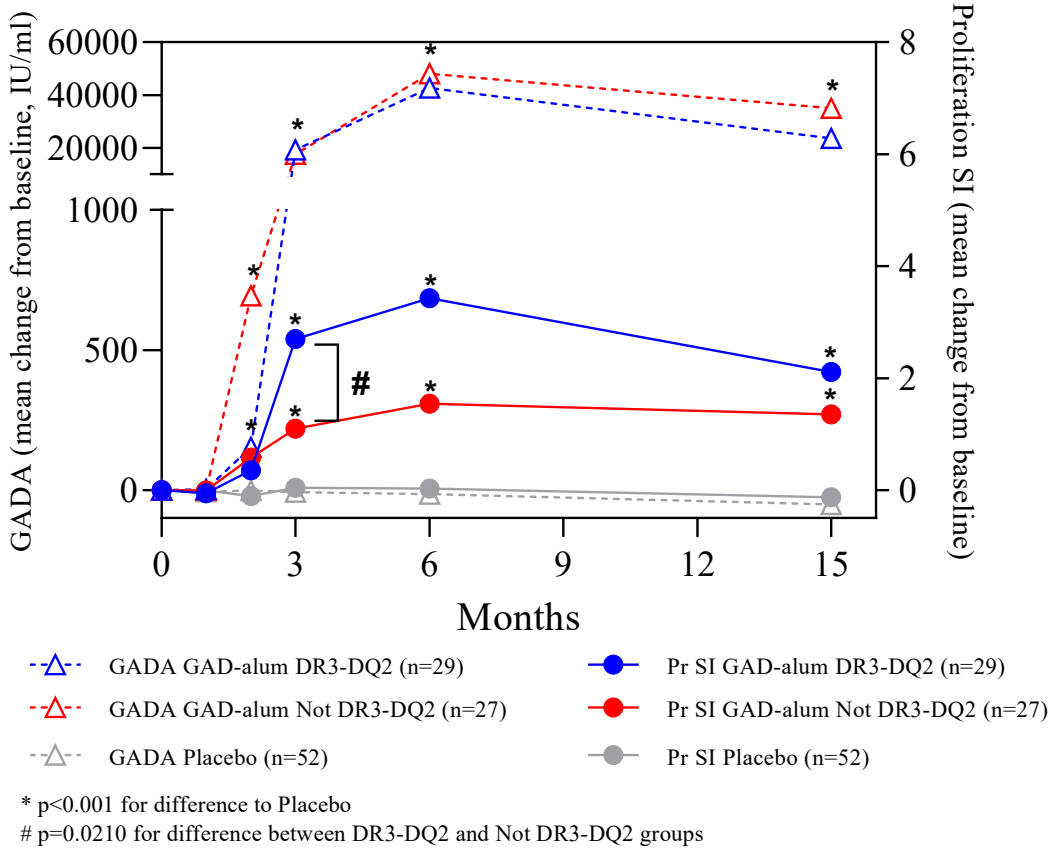
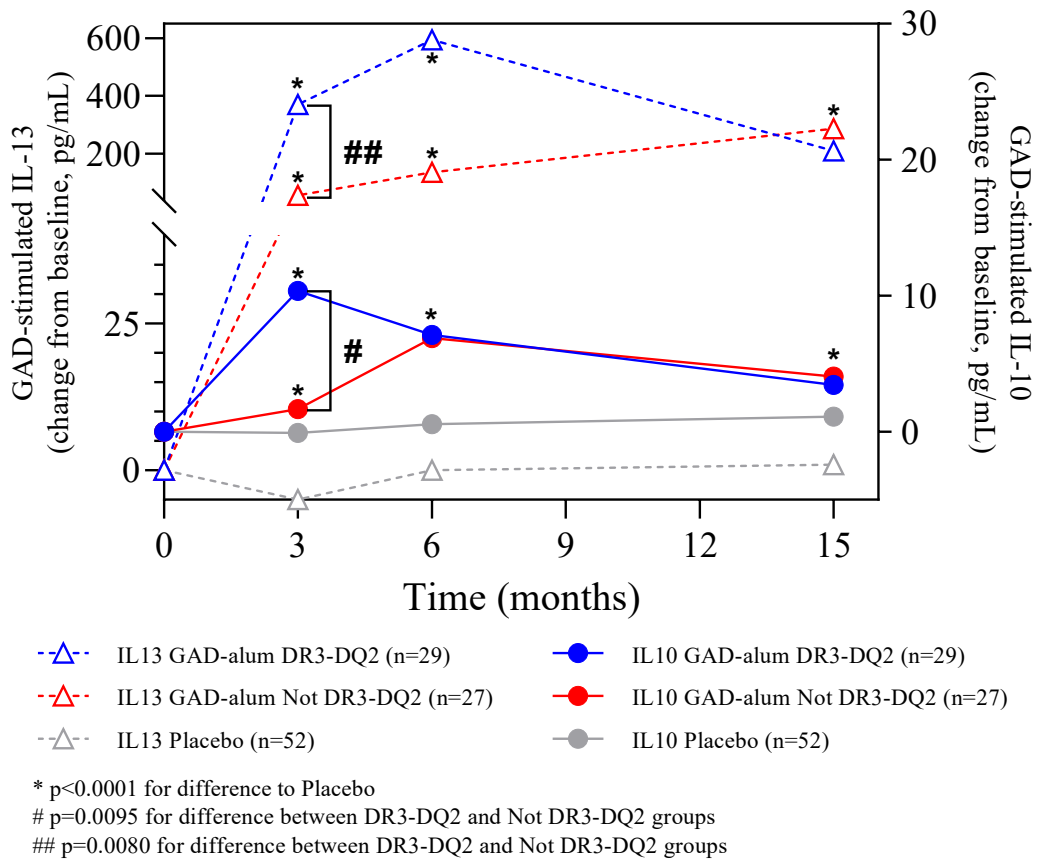
DIAGNODE-2 Phase 2b trial biomarker data support HLA-specific response

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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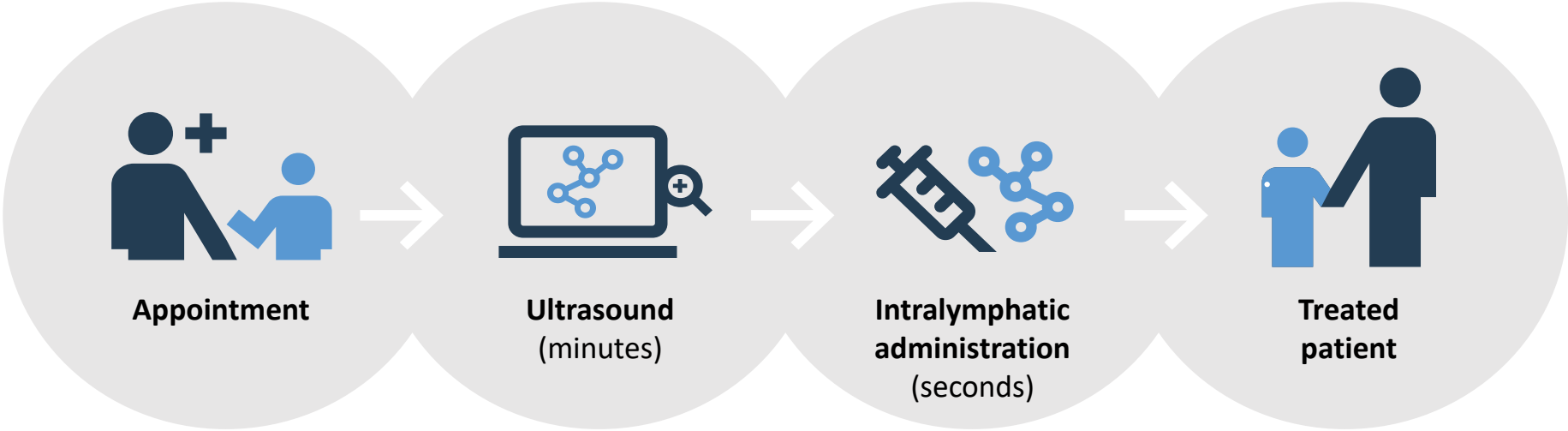
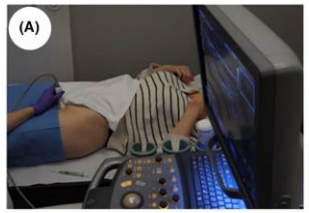
Ultrasound-guided targeted injection

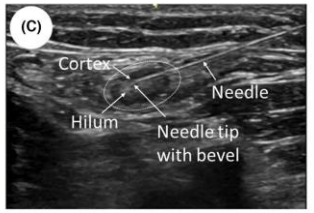
Quick, low-key outpatient procedure with discomfort comparable to venepuncture.
Targets superficial lymph node to enhance immunological response



- 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

Retogatein (rhGAD65) in individuals recently diagnosed with Stage 3 type 1 diabetes and positive for the HLA DR3-DQ2 haplotype

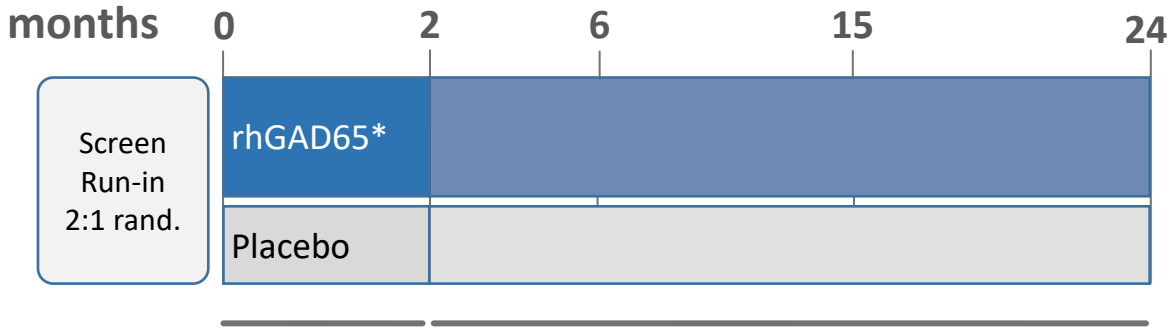
Breakthrough T1D™ Partner since 2023
Formerly JDRF

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 retogatein (rhGAD65) given on top of standard of care. Design aligned with the FDA and EMA.
57 clinics in the United States and Europe.



3 monthly injections

Supplementation with oral Vitamin D in both arms for D-vitamin deficient study participants

Follow-up

- *Interim analysis in March 2026, ~170 patients and 15-month follow-up to support a potential Accelerated BLA in the US*
- *Primary readout, ~310-320 patients and 15-month follow-up to support full-BLA*
- *Long-term durability readout at 24 months*

**4 µg / inj, supplemented with oral Vitamin D*

Co-Primary Endpoints

- Stimulated C-peptide area under the curve, change from Baseline to Month 15 in Mixed Meal Tolerance Test (MMTT)
- HbA1c, change from Baseline to Month 15

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 15
- Proportion of patients with insulin dose-adjusted HbA1c (IDAA1c) ≤9 (partial remission) at Month 15
- Number of episodes per patient of severe hypoglycemia between Baseline and Month 15
- Number of episodes per patient of diabetic ketoacidosis (DKA) between Baseline and Month 15

Population

- Persons diagnosed with type 1 diabetes 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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Significant momentum and near-term clinical and regulatory catalysts

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 Type 1 Diabetes

FDA grants Fast Track Designation for retogatein (rhGAD65) 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 retogatein (rhGAD65)

July 2024
Positive non-futility analysis

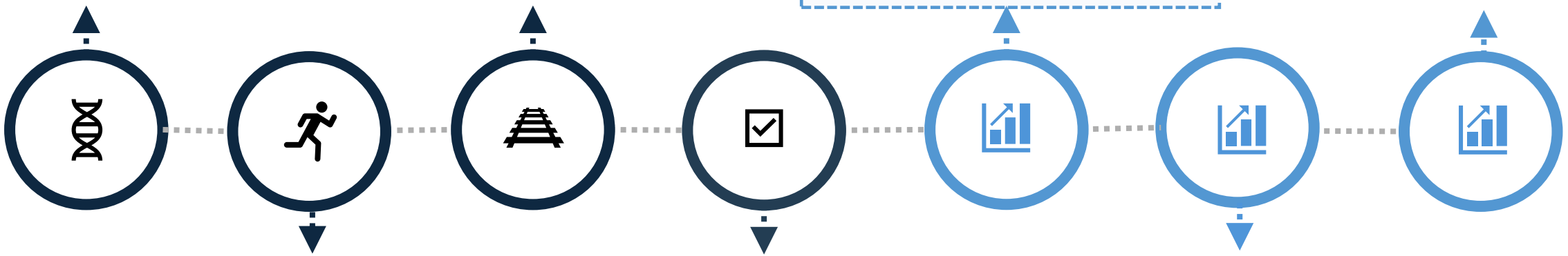
DSMB recommendation to continue the trial unmodified

March 2026
Interim efficacy readout

~170 patients, 15 months. **Potential for accelerated approval.**
Interim readout, aligned with the FDA

~Q2 2027
Primary full readout ~310-320 patients, 15 months

~Q1 2028
Long-term durability readout, ~310-320 patients, 24 months



Supportive Clinical Data

Stage 1 & 2 type 1 diabetes and adult-onset type 1 diabetes (LADA)

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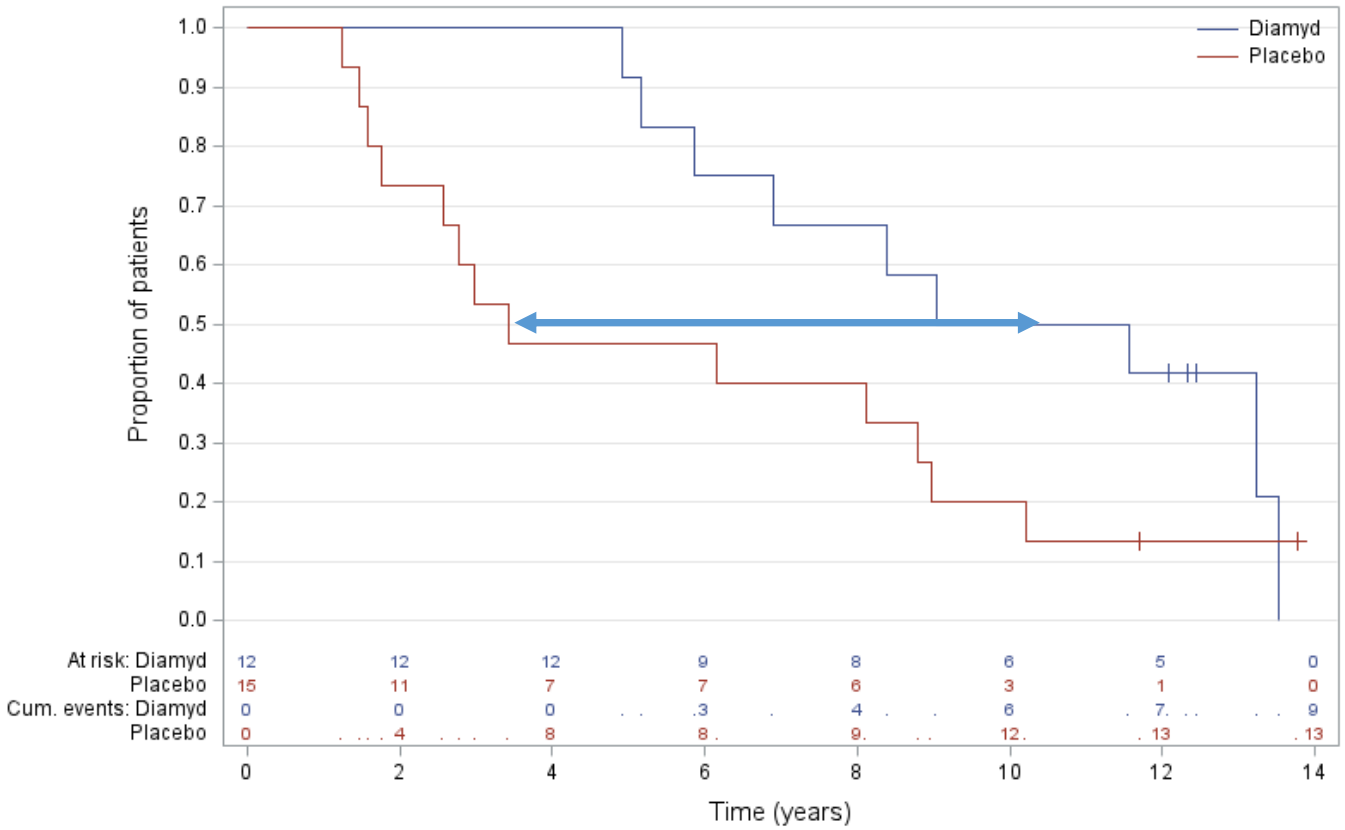
Clinical data in Stage 1 and Stage 2 type 1 diabetes

Long-Term follow-up of DiAPREV-IT shows that two subcutaneous injections of retogatein (rhGAD65) may delay type 1 diabetes onset by nearly 7 years



DiAPREV-IT: 2 subcutaneous injections of retogatein (rhGAD65) in 50 children positive for two or more islet autoantibodies.

Analysis shows that 2 subcutaneous injections of retogatein (rhGAD65) 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.

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.

Poster presented at ISPAD 2024, unpublished

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

1-year pilot study of targeted injections of retogatein (rhGAD65) in individuals with adult-onset type 1 diabetes (latent autoimmune diabetes in adults (LADA)). No safety concerns.

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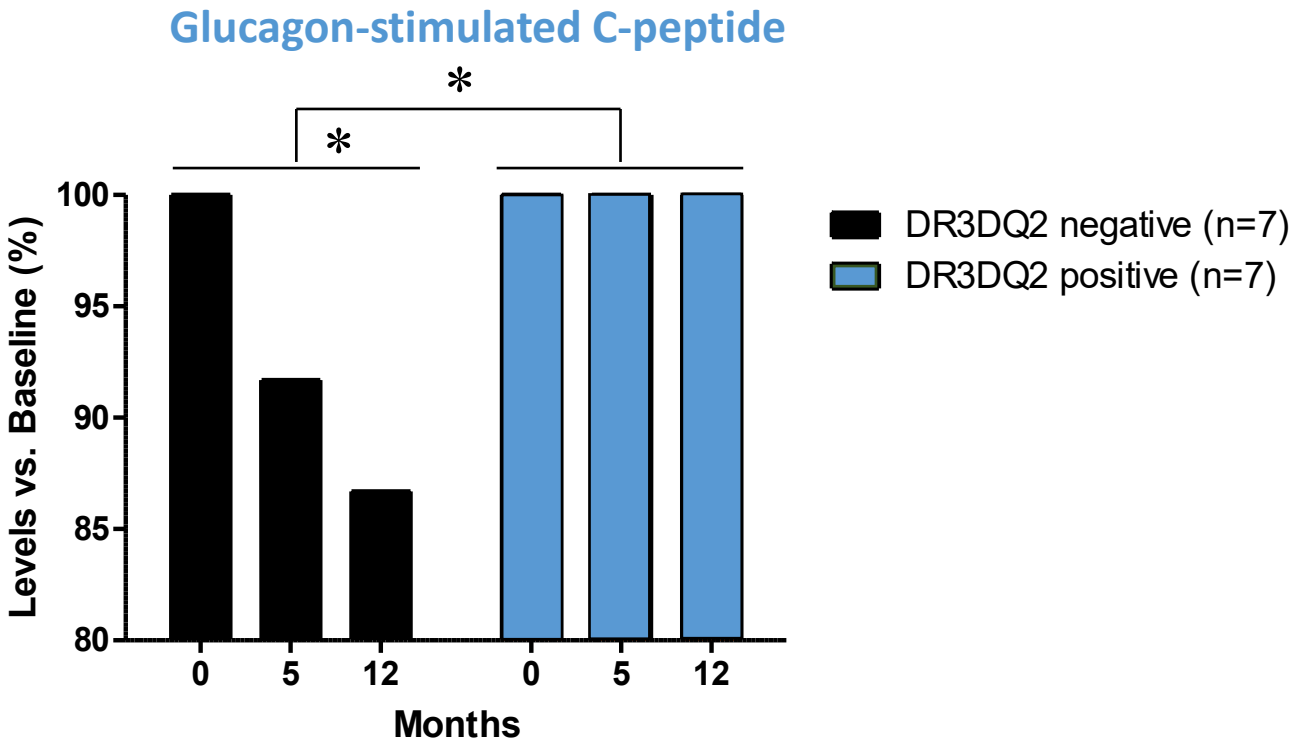

Unchanged glucagon-stimulated C-peptide levels

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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Manufacturing of retogatein (rhGAD65)

Wholly-owned biomanufacturing plant

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Biomanufacturing facility - retogatein (rhGAD65)

Commercial-scale production

- 24,000 square feet facility, comprising clean rooms, laboratory facilities and office space
- Commercial-scale production of retogatein (rhGAD65) to be ready for BLA/MAA and market entry
- GMP certification of facility ongoing
- Independence from CDMOs, third parties
- In control of costs and resource allocation
- Potential beyond GAD manufacturing

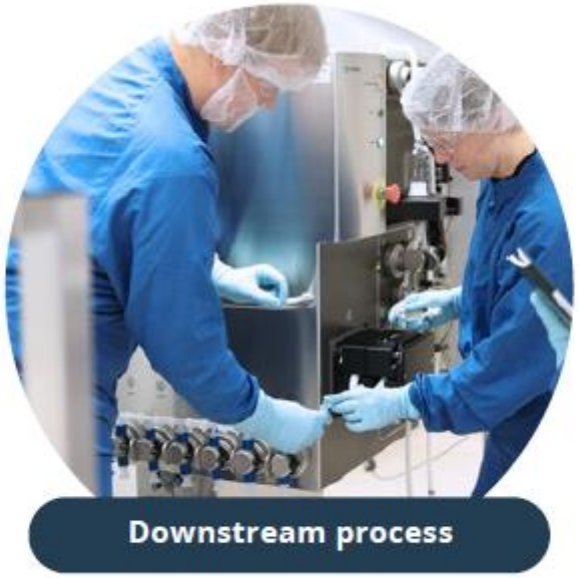
Umeå, Sweden

Manufacturing process

Diamyd Medical's biomanufacturing facility in Umeå 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

- rhGAD65/alum
- Formulated externally

DIAMYD MEDICAL

Management

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Chief Operating Officer

Niklas Axelsson, MSc
Chief Financial Officer

Anton Lindqvist, MSc
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