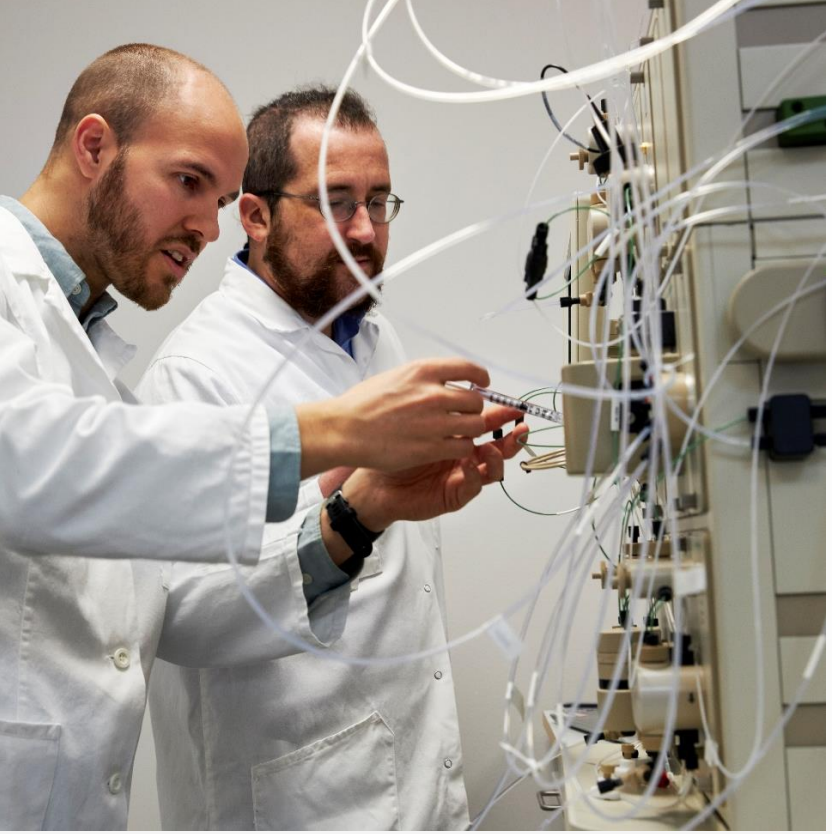

Leader in Precision Medicine for Autoimmune Diabetes

DIAMYD MEDICAL

DISCLAIMER

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TARGETING AUTOIMMUNE AND INSULIN DEFICIENT DIABETES

Leading clinical stage pipeline

- First-in-class **disease modifying therapies** Diamyd® and Remygen®
- **Pivotal program with a precision medicine approach**

De-risked development program

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

Strong growth opportunity

- **Phase IIa results** (Remygen®), **pivotal program** (Diamyd®), evaluation of **Accelerated Approval pathways** (Diamyd®) and establishing **GMP vaccine manufacturing facility**
- Cash-position of MSEK 193 (May 31, 2022). Market Cap ~MSEK 1,205 (June 20, 2022)

Experienced team

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

LEADING PIPELINE IN AUTOIMMUNE DIABETES

Product	Indication	Trial	Participants	Sponsor	Development Phase	Status
					Preclinical / I / IIa / IIb / III	
Diamyd®	T1D, intervention	DIAGNODE-3	~330	Diamyd Medical		**Randomization in Europe ongoing**
Diamyd®	T1D, intervention	DIAGNODE-2	109	Diamyd Medical		**Finalized. Results published**
Diamyd®	T1D, intervention	DIAGNODE-1	12	Linköping University		**Finalized. Results published**
Diamyd®	T1D, intervention	DIAGNODE-B (boosters)	~6	Linköping University		**Initiated**
Diamyd®	LADA, intervention	GADinLADA	15	NTNU, Trondheim		**Fully recruited / 5 month results released**
Remygen®	T1D, T2D	ReGenerate-1	36	Uppsala University		**Fully recruited / Stage 1 results published**

Completed
Ongoing

CLINICAL STAGE DISEASE MODIFYING THERAPIES

Inducing immunological tolerance to preserve endogenous insulin production. Stimulating regeneration of insulin producing beta cells and alleviating beta cell stress.

Diamyd® (rhGAD65/alum)

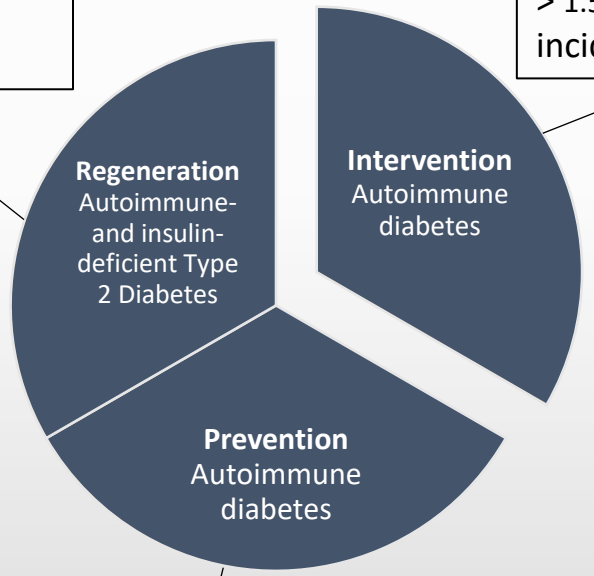
- First-in-class
- Antigen-specific immunotherapy
- Pivotal precision medicine program
- Strong support for clinical response and excellent safety profile

Remygen® (GABA)

- First-in-class
- Regeneration and immunomodulation
- Phase IIa clinical development
- Promising clinical results

The opportunity for regeneration
Approx. 25% of all diabetes patients

Primary indication and market
> 1.5 million incident cases



Label expansion
Estimated 2.3 million at-risk individuals

5

PRIORITIZING UNMET MEDICAL NEED

25% of the patients, autoimmune and severely insulin deficient diabetes, lack treatment options that address their underlying disease pathology

Prioritized subgroups

Autoimmune diabetes**
Approximately 10% of all diabetes patients have **severe autoimmune diabetes (SAID)**

→ **Therapeutic development:** Induce immunological tolerance to preserve endogenous insulin production. Stimulate regeneration of insulin producing beta cells and alleviate beta cell stress

Priority # 1

Insulin deficient non-autoimmune diabetes**
Approximately 15% of all diabetes patients have **severe insulin deficiency (SIDD)** in the absence of autoimmunity

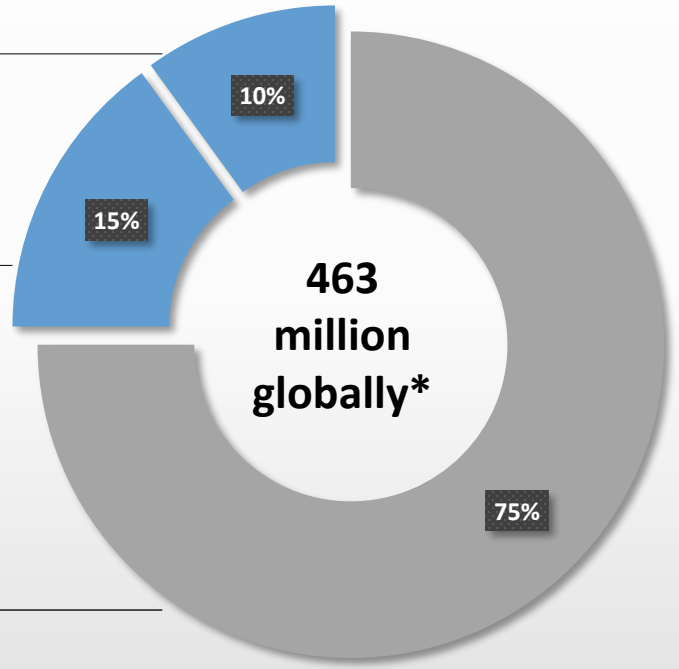
→ **Therapeutic development:** Stimulate regeneration of insulin producing beta cells and alleviate beta cell stress

Priority # 2

Insulin resistant, age-onset and obesity-onset diabetes**
Approximately 75% of diabetes patients are severely **insulin resistant** or have a disease related to either **age** or **obesity**

→ **Therapeutic development:** Better patient profiling to align existing therapies with treatment guidelines

Out of scope



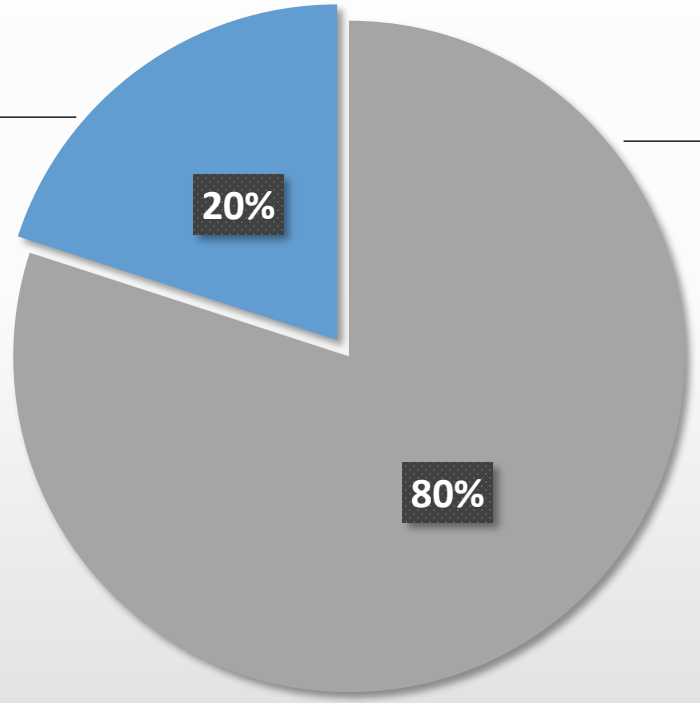
*IDF 2019 Atlas

** Subgroups based on Ahlqvist et al. Novel subgroups of adult-onset diabetes and their association with outcomes: a data-driven cluster analysis of six variables. Lancet, 2018

PRIORITY # 1 - AUTOIMMUNE DIABETES

Type 1 Diabetes
~ 300,000 new cases every year*
132,000 children and adolescents (0-20 years of age) and equally many adults are diagnosed with type 1 diabetes every year. It is more prevalent in western countries with the highest incidence in the Nordic countries.

The disease is characterized by life-long dependence on exogenous insulin therapy and blood glucose monitoring. **No disease modifying therapies are available** and the disease is associated with **severe short and long-term complications** that lead to shorter life-expectancy, decreased quality of life and significant health economic costs.

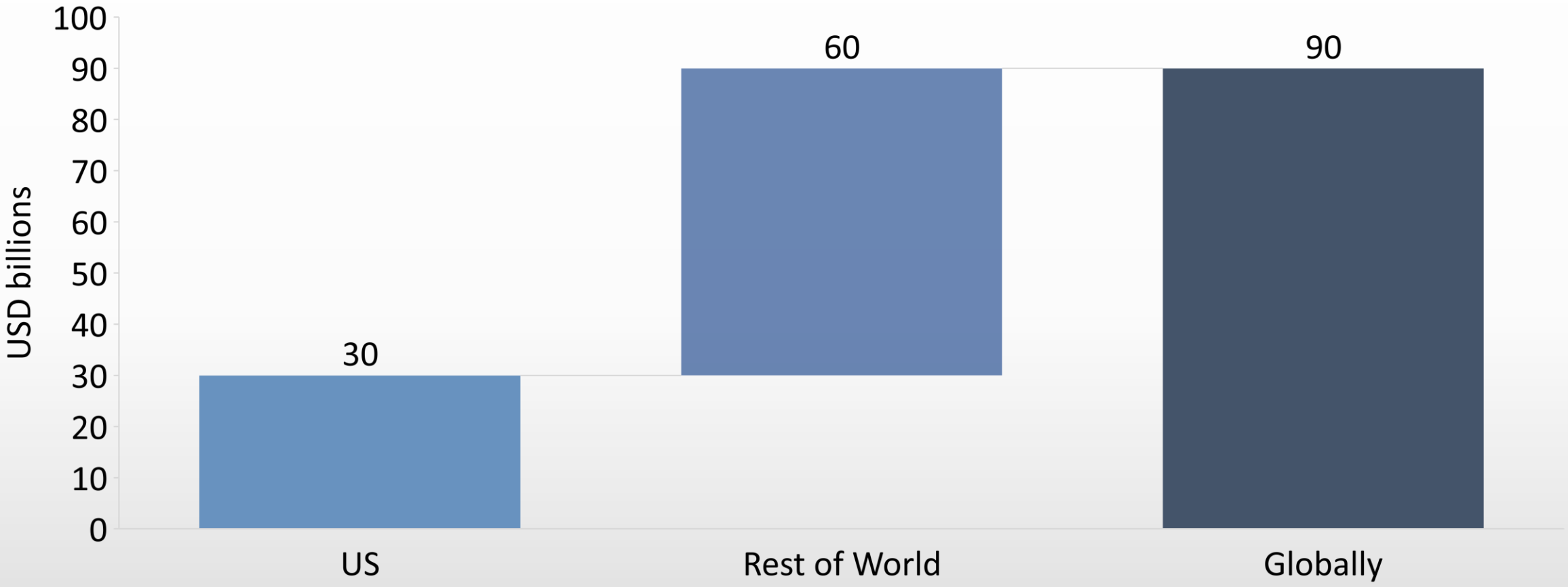


LADA
>1.2 million new cases every year**
It is estimated that up to 10% of all type 2 diabetes patients have autoimmune diabetes characterized by autoantibodies against GAD and faster progression to insulin dependence. While type 1 diabetes is rare in many non-western countries, LADA is a prevalent form not only in western countries but also in India, China and Japan.

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

* Incidence for children and adolescents from IDF 2019 Atlas
* Incidence for adult type 1 diabetes estimated from Thomas et al. Frequency and phenotype of type 1 diabetes in the first six decades of life: a cross-sectional, genetically stratified survival analysis from UK Biobank, The Lancet 2018
** 10% Prevalence of LADA based on Pozilli & Pieralice, Latent Autoimmune Diabetes in Adults: Current Status and New Horizons, Endocrinol Metab, 2018
** Incidence of 4/1000 for diabetes in adults based on Swedish numbers for adult diabetes patients requiring glucose lowering drugs (Norhammar et al, Incidence, prevalence and mortality of type 2 diabetes requiring glucose-lowering treatment, and associated risks of cardiovascular complications: a nationwide study in Sweden, 2006–2013, Diabetologia 2016). Note that incidence for diabetes in adults is 7/1000 in the US population.

SIGNIFICANT ANNUAL ECONOMIC BURDEN OF TYPE 1 DIABETES (T1D)

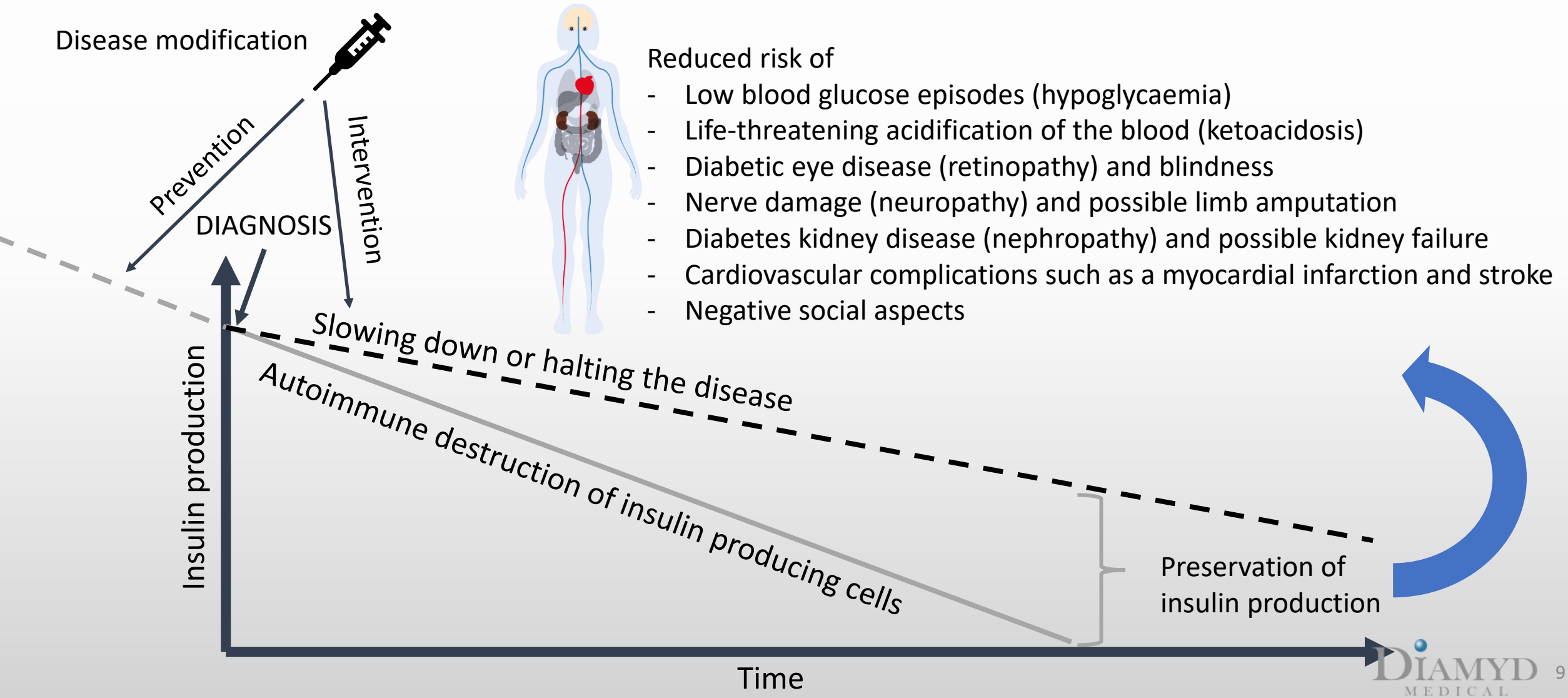


Disease modifying therapies for T1D are predicted to have a multibillion-dollar economic impact in the US alone

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

DIAMYD MEDICAL

A DISEASE MODIFYING THERAPY FOR T1D



Reduced risk of

- Low blood glucose episodes (hypoglycaemia)
- Life-threatening acidification of the blood (ketoacidosis)
- Diabetic eye disease (retinopathy) and blindness
- Nerve damage (neuropathy) and possible limb amputation
- Diabetes kidney disease (nephropathy) and possible kidney failure
- Cardiovascular complications such as a myocardial infarction and stroke
- Negative social aspects

DIAMYD MEDICAL

Diamyd®

Recombinant GAD65 Formulated in Alum (rhGAD65/alum)

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

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

Mechanism of Action
Induce immunological tolerance against GAD65

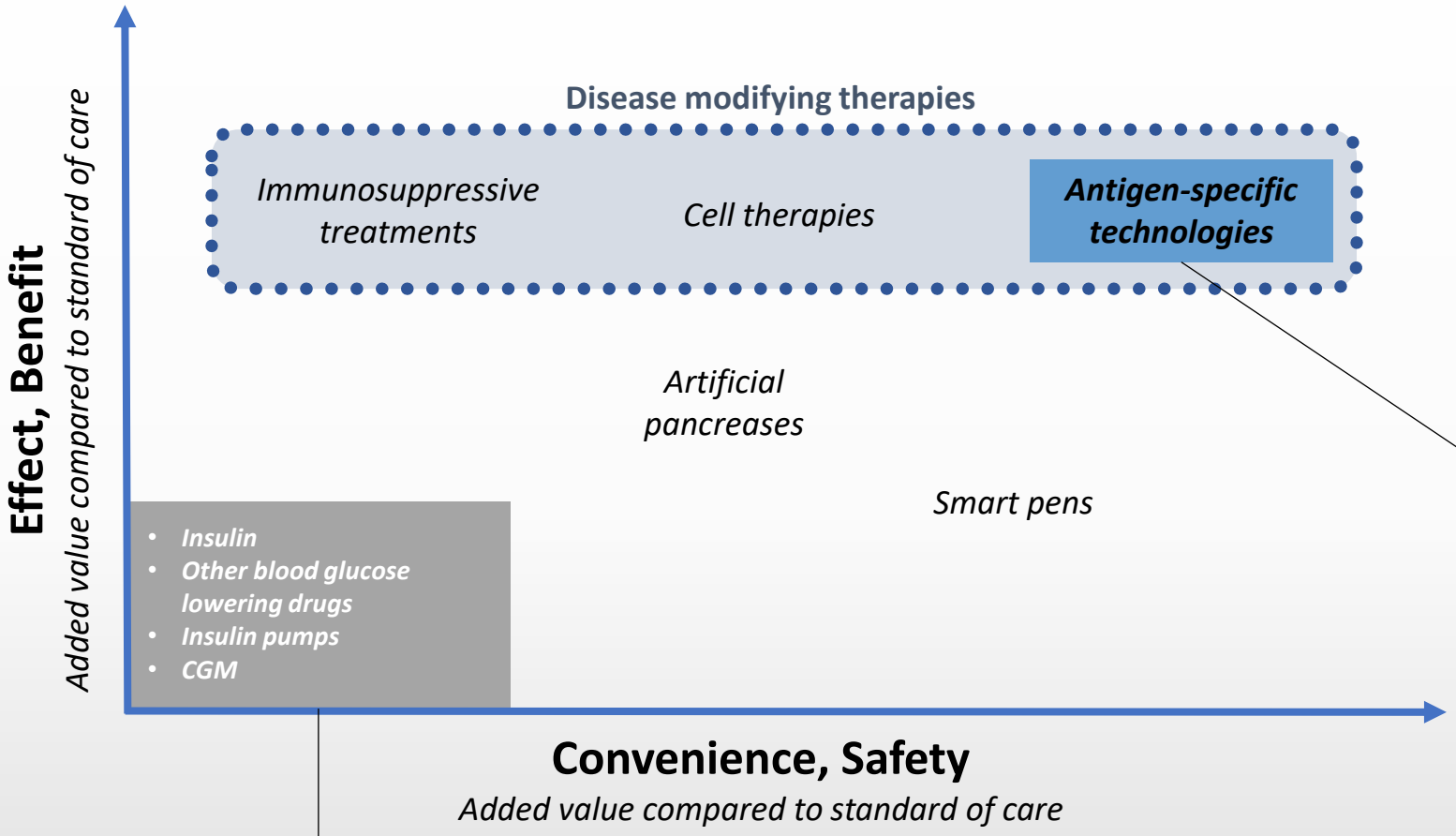
Clinical Effect and Benefit
Preserve the endogenous insulin production, improve glycemic control, reduce short- and long-term complications

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

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.

CRUCIAL RESEARCH ADVANCES IN PRECISION MEDICINE FOR TYPE 1 DIABETES

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 Hannelius[1] · Craig A. Beam[2] · Johnny Ludvigsson[3,4]

Received: 28 April 2020 / Accepted: 11 June 2020 / Published online: 5 August 2020

Diabetes Care Volume 44, July 2021

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

Johnny Ludvigsson,[1] Zdenek Sumnik,[2] Terezie Pelikanova,[3] Lia Nattero Chavez,[4] Elena Lundberg,[5] Itxaso Rica,[6] Maria A. Martínez-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-Gila,[14] Marcus Lind,[15,16] Marta Ferrer Lozano,[17] Theo Sas,[18] Ulf Samuelsson,[1] Stepanka Pruhova,[2] Fabricia Dietrich,[19] Sara Puente Marin,[19] Anders Nordlund,[20] Ulf Hannelius,[21] and Rosaura Casas[19]

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

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

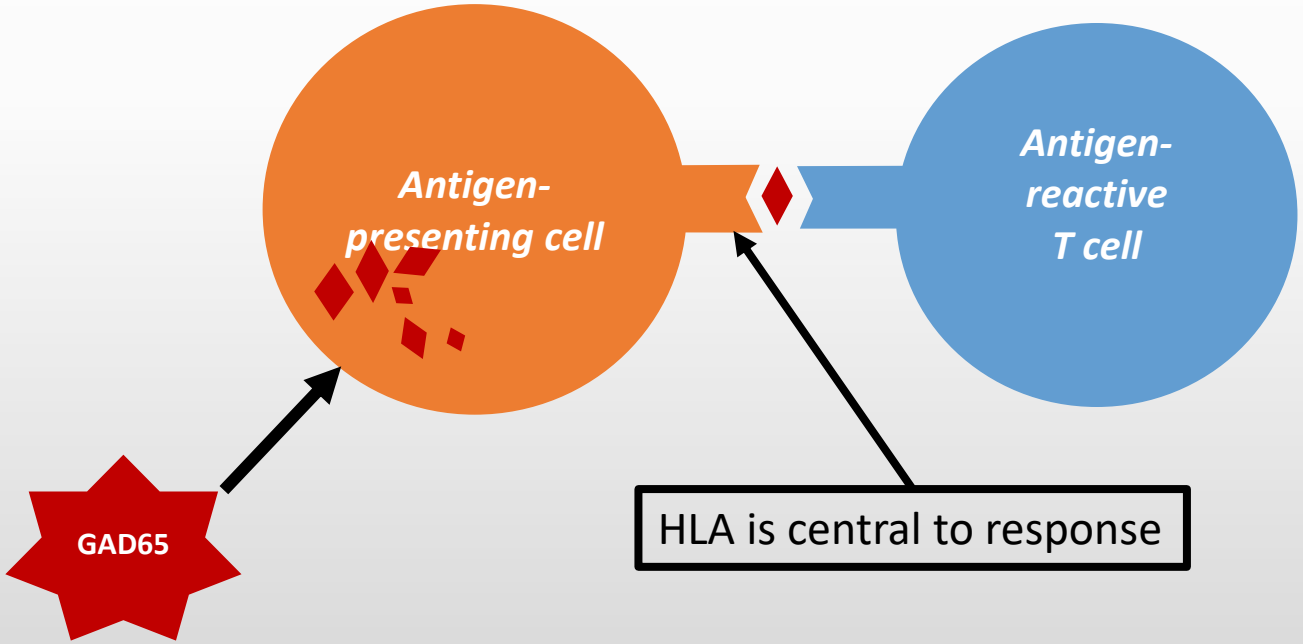
J Clin Endocrinol Metab. 2022 Jun 6;dgac343. doi: 10.1210/clinem/dgac343. Online ahead of print.

Intralymphatic GAD-alum (Diamyd®) improves glycaemic control in Type 1 diabetes with HLA DR3-DQ2

Christoph Nowak [1,2], Marcus Lind [3], Zdenek Sumnik [4], Terezie Pelikanova [5], Lia Nattero Chavez [6], Elena Lundberg [7], Itxaso Rica [8], Maria A Martínez-Brocca [9], Mari Sol Ruiz de Adana [10], Jeanette Wahlberg [11,12], Ragnar Hanas [13], Cristina Hernandez [14], Maria Clemente León [15], Ana Gómez-Gila [16], Marta Ferrer Lozano [17], Theo Sas [18], Stepanka Pruhova [4], Fabricia Dietrich [19], Sara Puente Marin [19], Ulf Hannelius [2], Rosaura Casas [20], Johnny Ludvigsson [20]

Affiliations + expand

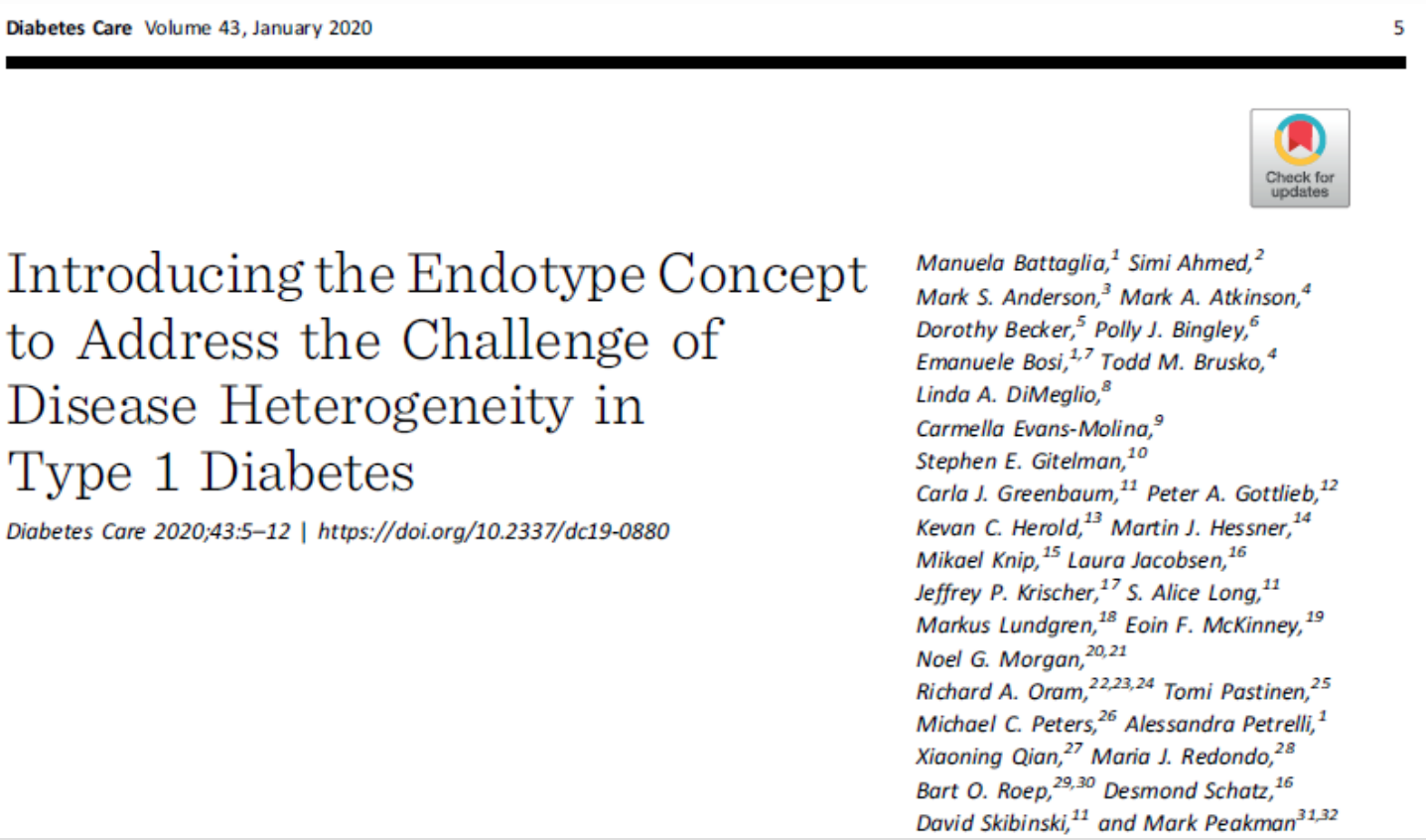
PMID: 35665810 DOI: 10.1210/clinem/dgac343



ACKNOWLEDGED PRECISION MEDICINE APPROACH

Highlights

- New medical consensus regarding genetically defined groups of T1D
- Strong case for the emerging precision medicine – in line with Diamyd Medical's approach



Diabetes Care Volume 43, January 2020 5

Check for updates

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

META-ANALYSIS BASED ON DATA FROM MORE THAN 500 INDIVIDUALS IDENTIFIES RESPONDERS TO DIAMYD® TREATMENT

Diabetologia
https://doi.org/10.1007/s00125-020-05227-z

SHORT COMMUNICATION

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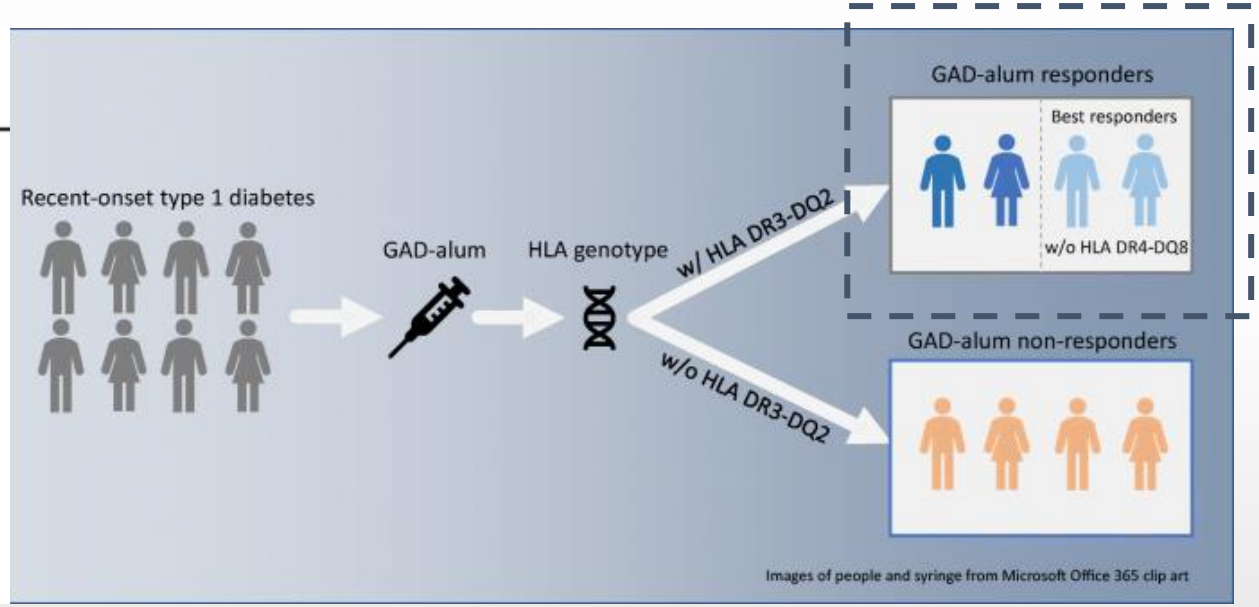

Meta-analysis based on 521 individuals from three placebo-controlled randomized trials (Phase III Europe, Phase II Sweden, Phase II US). Low dose = 2 injections; High dose = 3 och 4 injections

Effect on preserving endogenous insulin production in genetically predefined group of T1D

Hannelius et al, Efficacy of GAD-alum immunotherapy associated with HLA-DR3-DQ2 in recently diagnosed type 1 diabetes, Diabetologia 2020.

PHASE IIB RESULTS PROSPECTIVELY SUPPORT CLINICAL EFFECT IN GENETICALLY DEFINED PATIENT POPULATION

Diabetes Care Volume 44, July 2021 1

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

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UPDATED META-ANALYSIS BASED ON 600+ INDIVIDUALS STRONGLY SUPPORTS POSITIVE DISEASE-MODIFYING EFFECT IN HLA DR3-DQ2 POSITIVE INDIVIDUALS

DIABETES, OBESITY AND METABOLISM
A JOURNAL OF PHARMACOLOGY AND THERAPEUTICS

RESEARCH LETTER

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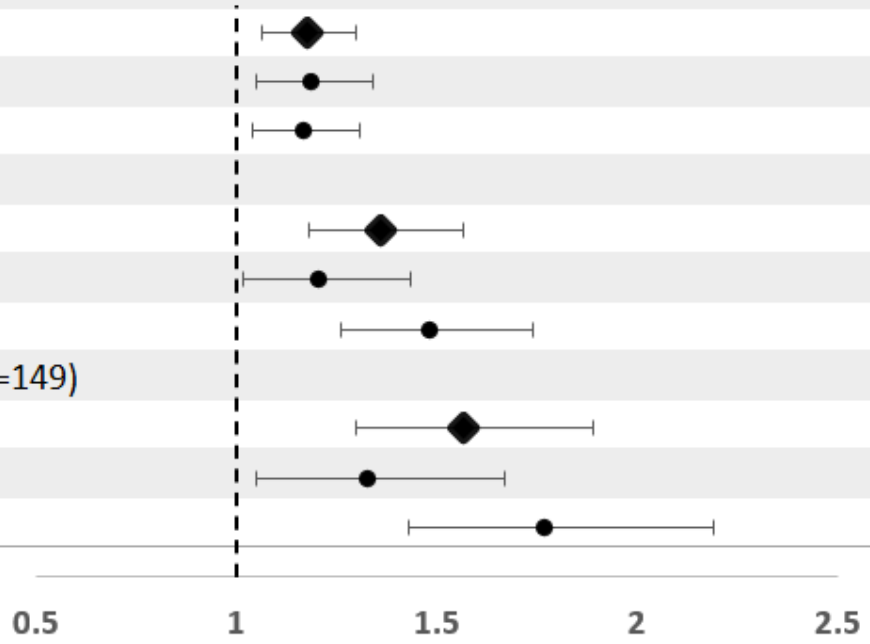
Change in stimulated C-peptide AUC 15 months from baseline

Subgroup	Estimated treatment effect ratio (95% CI)	*p* value
All individuals (*n* =627)		
Combined	**1.176 (1.065, 1.298)**	**0.0013**
2 injections	1.188 (1.049, 1.344)	0.0066
3-4 injections	1.166 (1.041, 1.308)	0.0083
Presence of HLA DR3-DQ2 (*n* =313)		
Combined	**1.361 (1.183, 1.566)**	**<0.0001**
2 injections	1.208 (1.017, 1.434)	0.0316
3-4 injections	1.484 (1.264, 1.741)	<0.0001
Presence of HLA DR3-DQ2/X, X not DR4-DQ8 (*n* =149)		
Combined	**1.567 (1.299, 1.890)**	**<0.0001**
2 injections	1.326 (1.052, 1.671)	0.017
3-4 injections	1.771 (1.431, 2.191)	<0.0001



Meta-analysis based on 627 individuals from four placebo-controlled randomized trials (Phase III Europe, Phase II Sweden, Phase II US, Phase IIb Europe). Low dose = 2 injections; High dose = 3 och 4 injections

Association between treatment effect on C-peptide preservation and HbA1c in meta-analysis of GAD-alum immunotherapy in recent-onset Type 1 diabetes, Nowak et al, Diabetes Obes Metab, 2022 Apr 17.

META-ANALYSIS SUPPORTS SIGNIFICANT TREATMENT EFFECT ON HBA1C (MMOL/MOL) IN HLA DR3-DQ2 POSITIVE INDIVIDUALS

Subgroup	Estimated treatment effect (95% CI)	*p* value
Presence of HLA DR3-DQ2 (*n* =313)		
Combined	-3.120 (-5.970, -0.269)	0.032
2 injections	-1.112 (-4.560, 2.336)	0.5268
3-4 injections	-4.789 (-8.078, -1.500)	0.0044

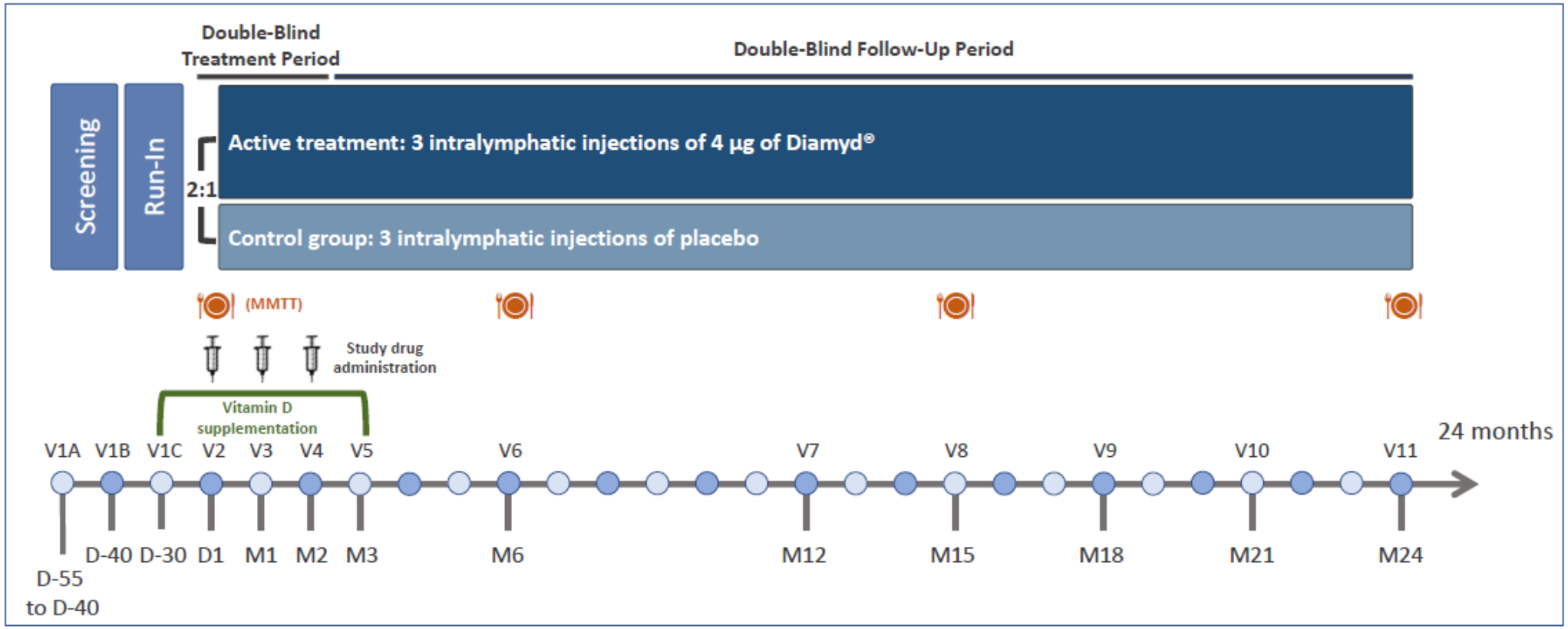
Subgroup	Estimated treatment effect (95% CI)	*p* value
Presence of HLA DR3-DQ2/X, X not DR4-DQ8 (*n* =149)		
Combined	-4.668 (-9.999, -0.336)	0.0348
2 injections	-1.663 (-6.868, 3.542)	0.5293
3-4 injections	-6.840 (-11.712, -1.969)	0.0061

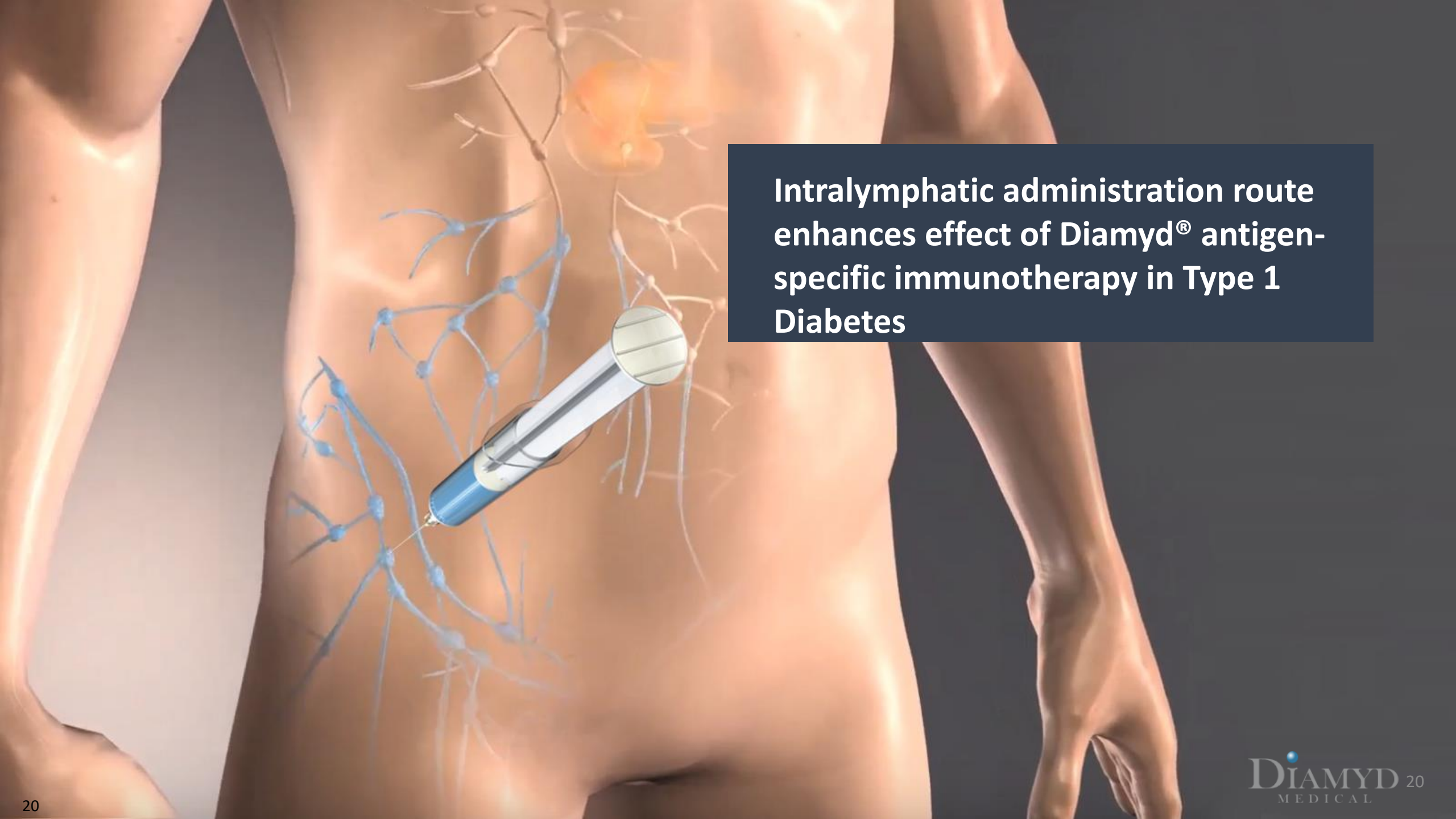
Meta-analysis based on 627 individuals from four placebo-controlled randomized trials (Phase III Europe, Phase II Sweden, Phase II US, Phase IIb Europe).

Association between treatment effect on C-peptide preservation and HbA1c in meta-analysis of GAD-alum immunotherapy in recent-onset Type 1 diabetes, Nowak et al, Diabetes Obes Metab, 2022 Apr 17.

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

- **Responder population HLA DR3-DQ2 (40-50%) with GADA, 12-27yo, <6m T1D**
- **Intralympatic injections (superior to subcutaneous injections)**
- **3 monthly injections (superior to 2 injections)**
- **Co-primary endpoints C-peptide and HbA1c (baseline to Month 24)**
- **Total n = 330, blinded interim analysis n=100, 6M**



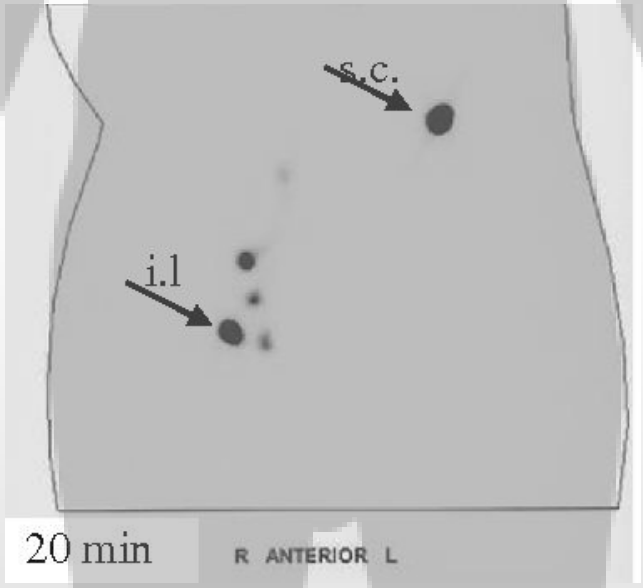


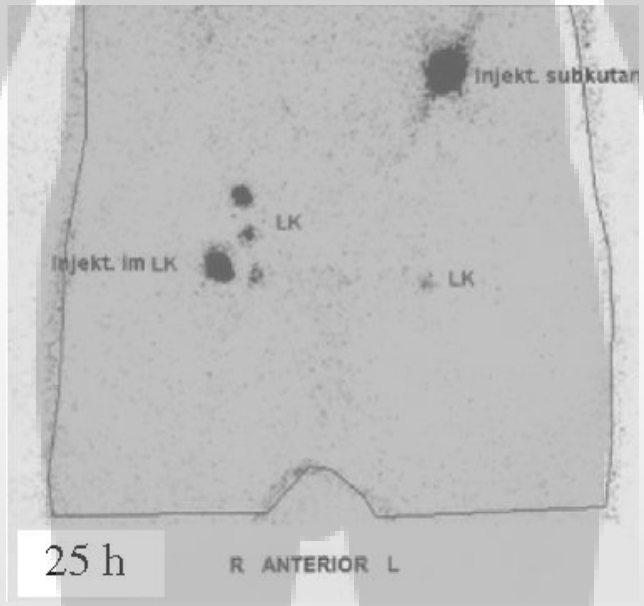
Intralymphatic administration route enhances effect of Diamyd® antigen-specific immunotherapy in Type 1 Diabetes

DIAMYD MEDICAL 20

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

Lessons Learned from Allergy Immunotherapy Trials





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

Adapted from: Intralymphatic immunotherapy, Senti & Kündig, World Allergy Organization Journal 2015

CONVENIENT OUTPATIENT PROCEDURE ENHANCES VALUE PROPOSITION FOR DIAMYD®

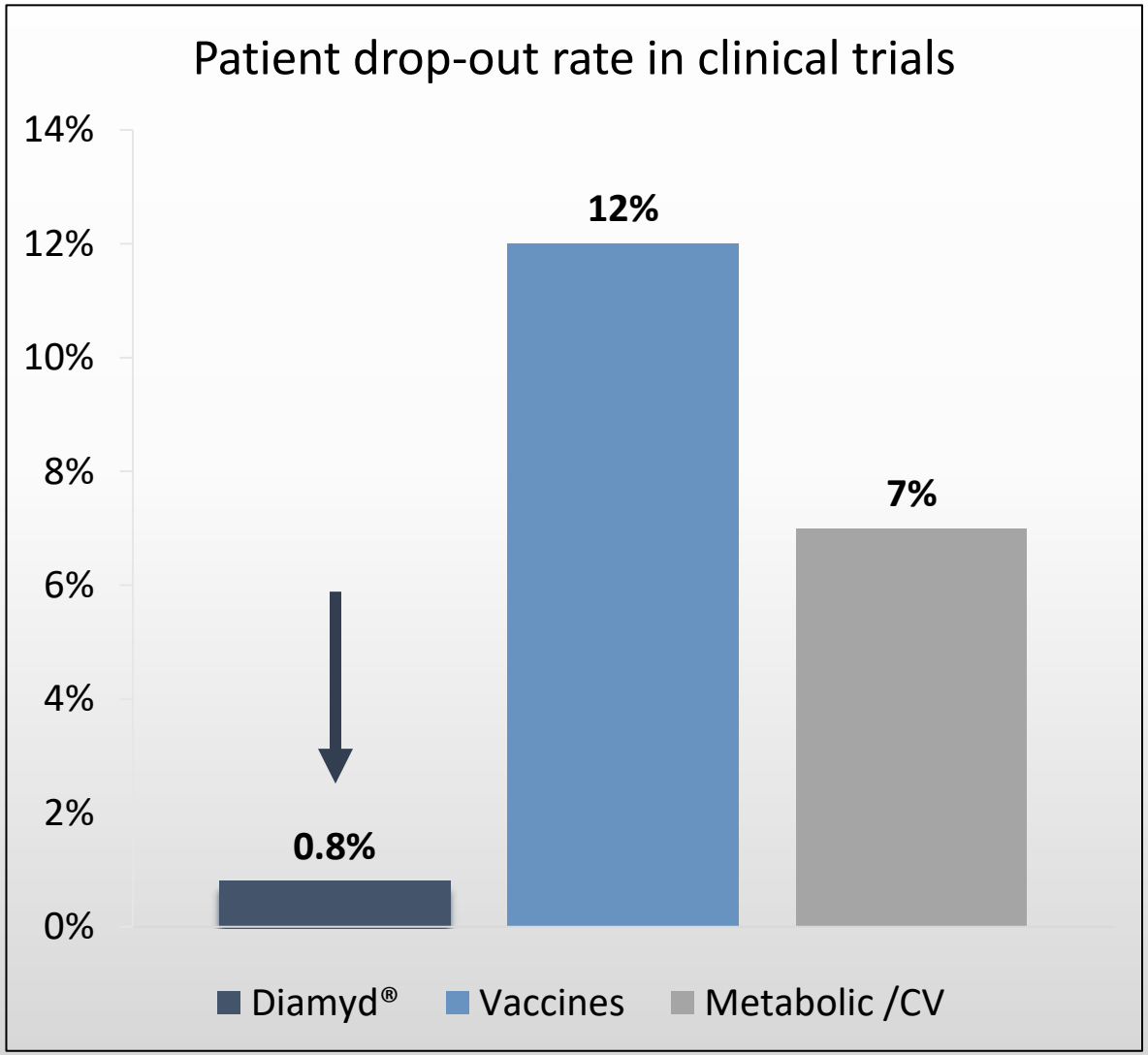
Potential to reach patients outside specialized clinics and avoiding costs related to hospitalization

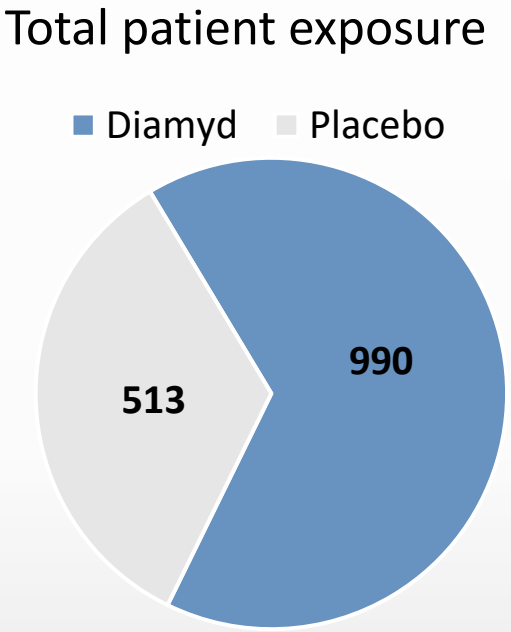
The procedure is performed by a radiologist by way of ultrasound guided injections that are given three times, one month apart. Clinical results and safety support the addition of annual booster injections in the pivotal trial.

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

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

SUPERIOR SAFETY PROFILE





Most commonly reported adverse events:

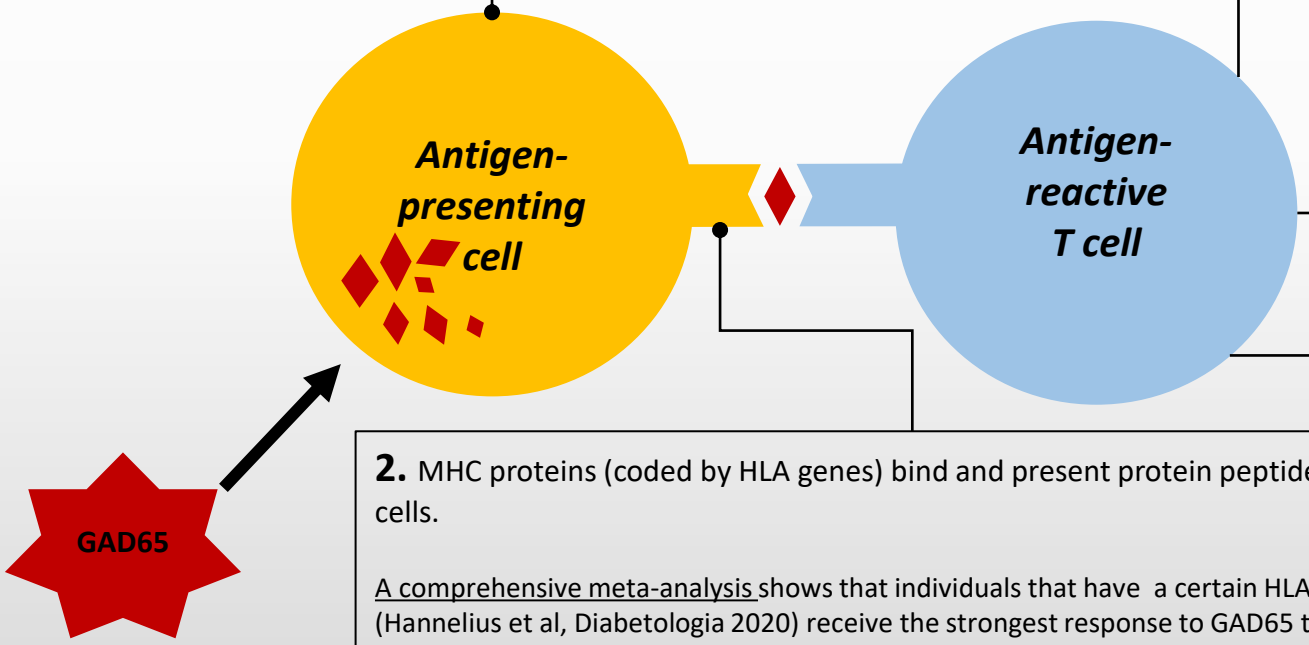
- tenderness, injection site edema, injection site pain and injection site reaction.
- no difference in the rate of occurrence of the adverse events between active Diamyd® treatment and placebo

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

CLINICAL AND IMMUNOLOGICAL RESULTS FROM DIAMYD® TRIALS SUPPORT THE MECHANISTIC RATIONAL FOR ANTIGEN-SPECIFIC REPROGRAMMING OF THE IMMUNE RESPONSE

1. GAD65 is taken up, processed and presented by APCs to T-cells by MHC Class II protein complexes.

Clinical and immunological results show that the dose and dosage of the antigen as well as the route of administration influence the tolerogenic effect.



2. MHC proteins (coded by HLA genes) bind and present protein peptides to T cells.

A comprehensive meta-analysis shows that individuals that have a certain HLA protein (Hannelius et al, Diabetologia 2020) receive the strongest response to GAD65 therapy.

Different MHC proteins present peptides differently and recent research highlighting the rational of focusing on HLA defined endotypes of type 1 diabetes.

3. T-cell deactivation

Immunological results from clinical trials show that malignant GAD-reactive T-cells are deactivated following GAD therapy.

These cells are responsible for tissue damage.

4. Induction of regulatory T cells

Immunological results from clinical trials indicate that GAD-reactive T-regs are formed/activated following GAD therapy.

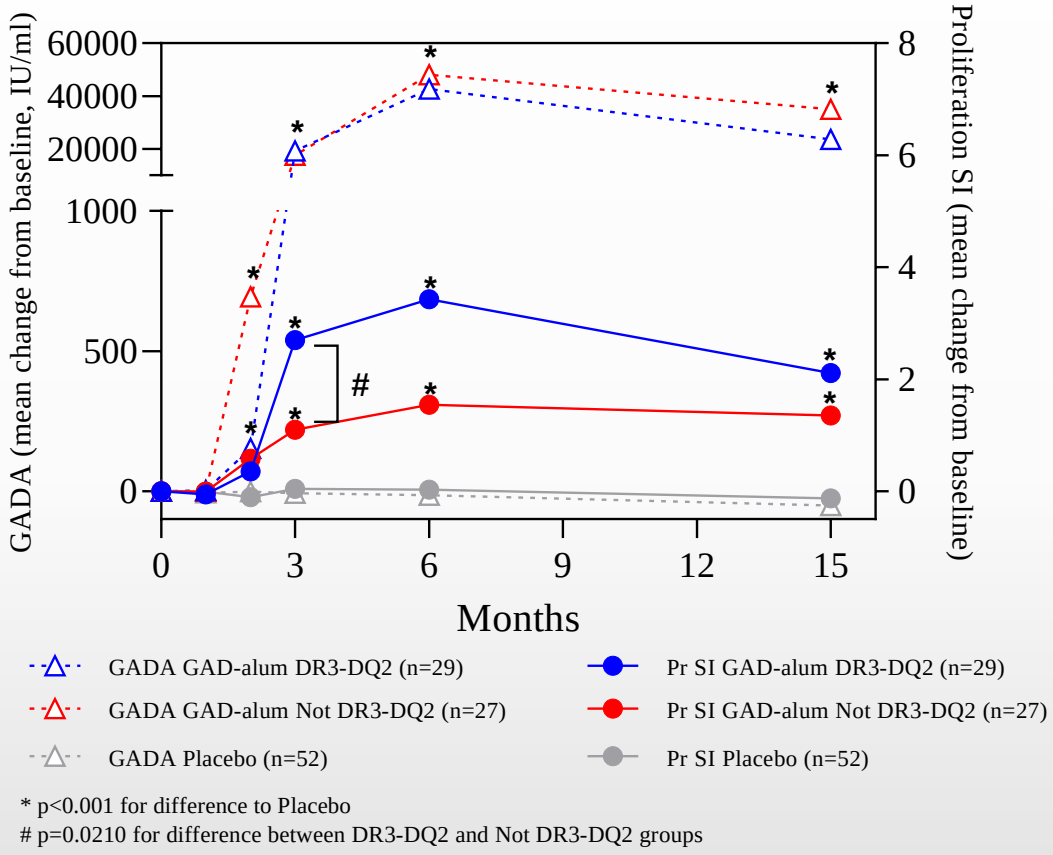
These cells deactivate tissue-damaging immune processes in the islets in response to GAD65.

5. Modulation of T cell function

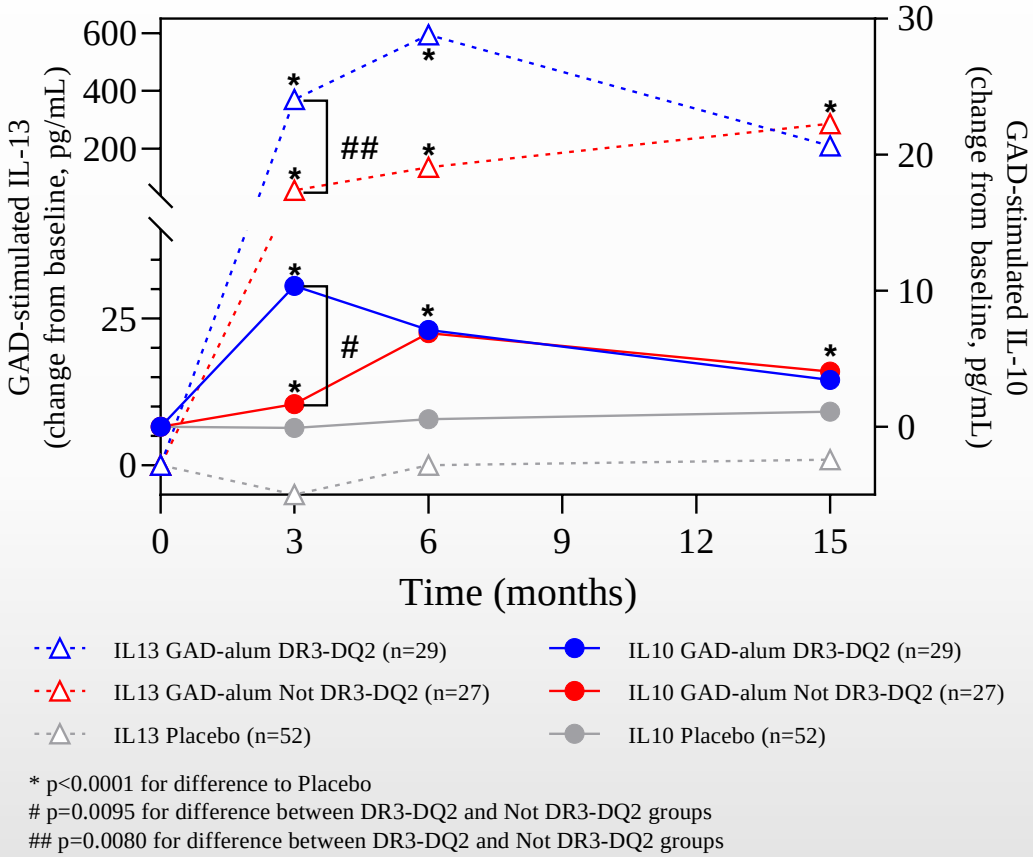
Immunological results from clinical trials show an increase in non-Th1 T-cells (elevated regulatory molecules e.g. IL-10; reduced effector cytokines INFγ) following GAD therapy.

These cells help redirect the balance of immune reaction in response to GAD65 in the islets and decrease tissue damage cellular homing.

GADA RESPONSE AND GAD STIMULATED PROLIFERATION AND CYTOKINE SECRETION FURTHER SUPPORT HLA SPECIFICITY OF DIAMYD® TREATMENT WITH STRONGER RESPONSE IN HLA DR3-DQ2 POSITIVE INDIVIDUALS



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

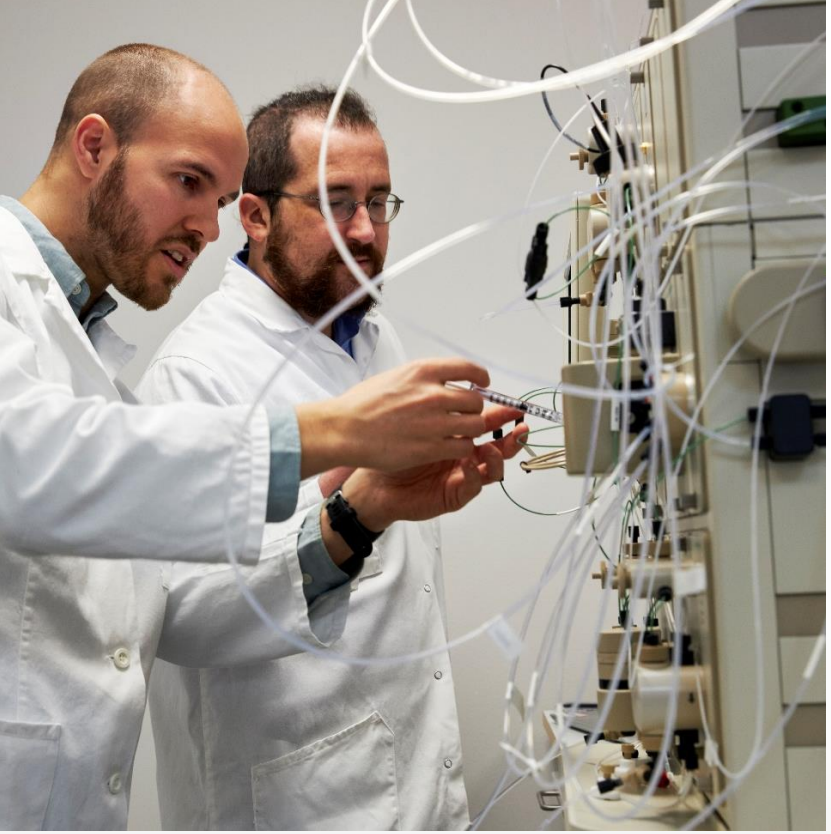


* p<0.0001 for difference to Placebo
# p=0.0095 for difference between DR3-DQ2 and Not DR3-DQ2 groups
p=0.0080 for difference between DR3-DQ2 and Not DR3-DQ2 groups

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.

Data from the phase IIb trial DIAGNODE-2



Vaccine manufacturing – control and predictability

- 10,000 square feet site comprising clean rooms, laboratory facilities and office space
- Taking over manufacturing of recombinant GAD65 (active pharmaceutical ingredient in the diabetes vaccine Diamyd®)
- The manufacturing facility property acquired in September 2021
- Making Diamyd Medical independent of third parties

DIAMYD® (rhGAD65/ALUM) MANUFACTURING

Upstream process:

Baculovirus expression system
&
Insect cells

Downstream process:

Clarification
Capture
Polish
Nanofiltration

DP formulation

DIAMYD® MARKET EXCLUSIVITY AND MANUFACTURING

Core Intellectual Property

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

Regulatory exclusivity

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

Manufacturing

- Formulated drug product (Diamyd®) **in place for ongoing trials and phase III**
- Transfer of drug substance (GAD) manufacturing process to own manufacturing facility to **secure core asset and prepare for commercial readiness**

COMPREHENSIVE KNOWLEDGE SUPPORTING PHASE III

1

Presence of HLA DR3-DQ2 increases effect of GAD-alum

2

Additional subcutaneous injections further increases effect of GAD-alum

3

Superior safety profile and convenience

4

Intralymphatic injections of GAD-alum superior to subcutaneous injections

Diamyd® has been evaluated without safety concerns in clinical trials encompassing more than 1,000 individuals

MILESTONES

Seek Regulatory position on Accelerated Approval pathway for Diamyd®

Full control and predictability over recombinant GAD, a key asset

Diamyd® trial to target the genetically predefined group with intralymphatic treatment

Building commercial organization and establishing global partnerships

Remygen®

Modified Release GABA

Primary Indication
Type 1 diabetes

Label expansion
LADA, Insulin-deficient type 2 diabetes

Mechanism of Action
Activate GABA-receptors in the pancreas

Clinical Effect
- *Regenerate endogenous insulin production, reduce short- and long-term complications*
- *Prevention of hypoglycemia*

Mode of Administration
Oral

Development status
Phase Ib/IIa ongoing

Licensing Status
Global rights available

CLINICAL RESULTS WITH ATTRACTIVE PATH TO MARKET FOR REMYGEN®

- Ongoing clinical Phase IIa trial*
  - ReGenerate-1 at the University of Uppsala where Remygen® (proprietary formulation of GABA) alone and in combination with low-dose alprazolam (GABA receptor modulator to enhance effect, see next slide) are being evaluated in long-standing type 1 diabetes patients
- Clinical effects (dose-escalation) from ReGenerate-1 shown on **preventing hypoglycemia by correcting the counter regulatory hormone response** and **increasing time-in-range** in long-term type 1 diabetes*
- Clinical effects of GABA shown on **decreasing glucagon secretion** in recent-onset type 1 diabetes**
- Preclinical effects on insulin secretion, glucagon secretion and beta cell regeneration
- Endogenous substance with very good safety profile***

*Favorable clinical effects following dose-escalation communicated in November 2019
**Preliminary results presented at EASD 2019 by Professor Kenneth McCormick, University of Alabama at Birmingham
***Favorable safety review following dose-escalation in November 2019 and combination with Alprazolam in January 2021

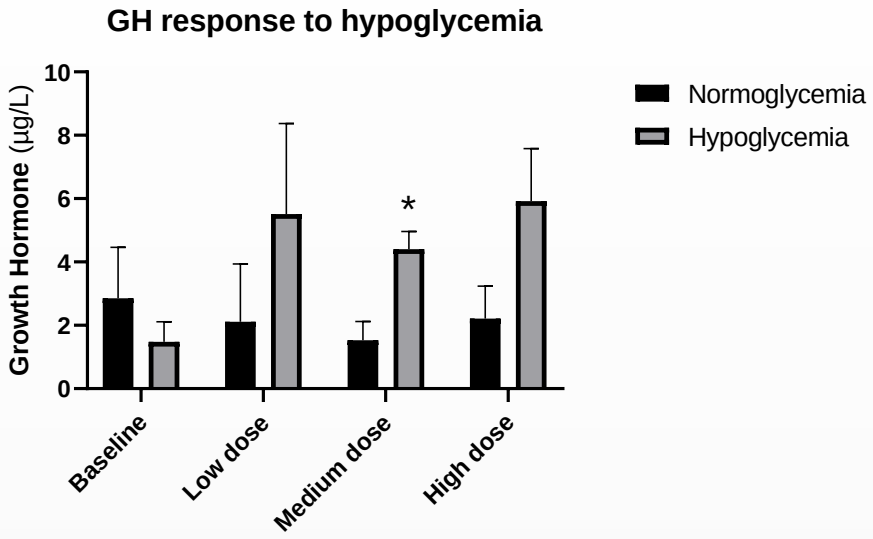
Open access Original research

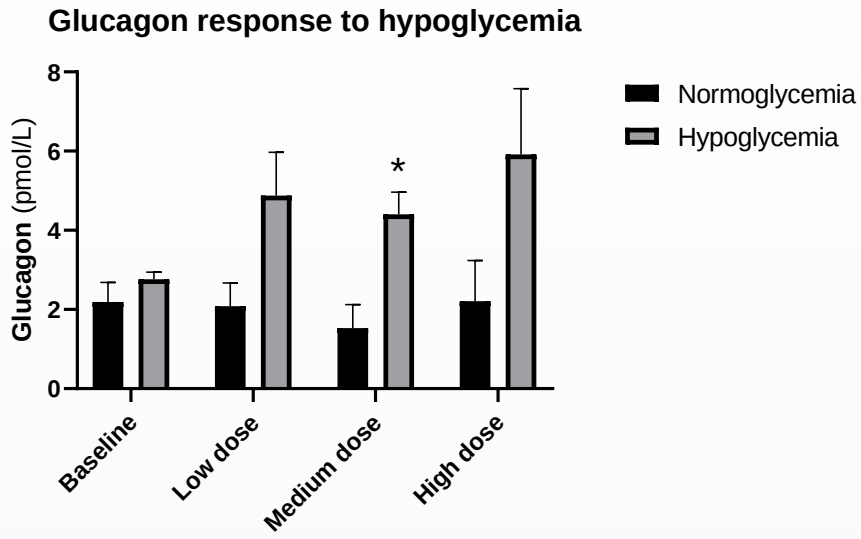
BMJ Open Diabetes Research & Care

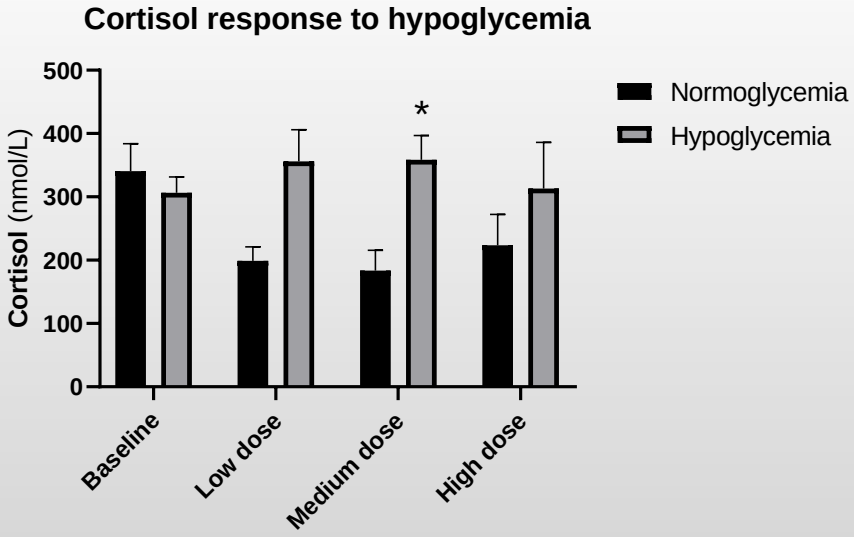
GABA induces a hormonal counter-regulatory response in subjects with long-standing type 1 diabetes

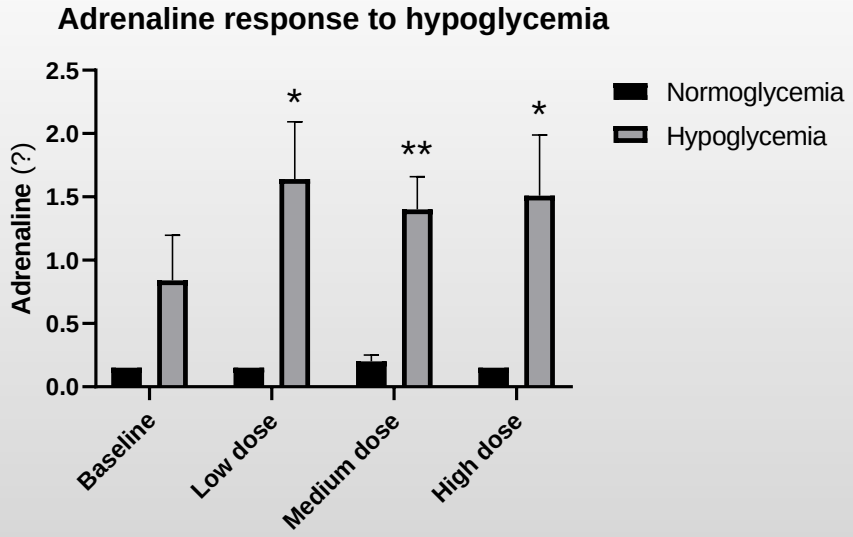
Daniel Espes ,[1,2] Hanna Liljebäck,[3,4] Henrik Hill,[5] Andris Elksnis,[3] José Caballero-Corbalan,[4] Per-Ola Carlsson[3,4]

GABA TREATMENT IMPROVES THE HORMONAL RESPONSE TO HYPOGLYCEMIA





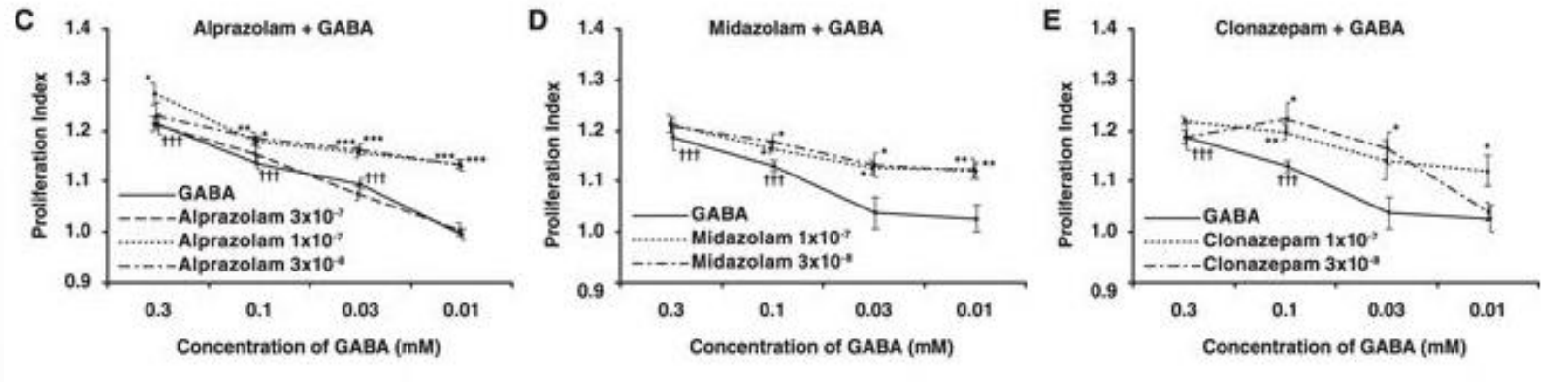




Comparisions between noro- and hypoglycemia for the respective group using a multiple T-test with p-values corrected for multiple testing using the Holm-Sidak method.
* denotes $p<0.05$, ** <0.01
Values are given as mean±SEM

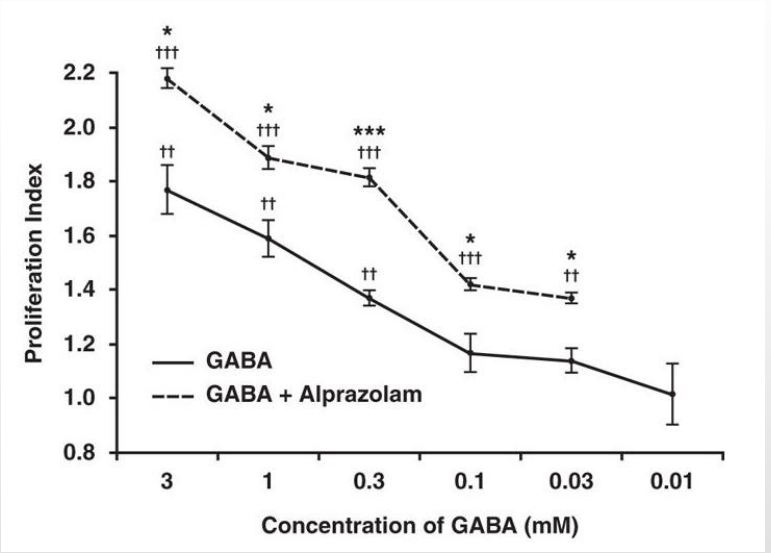
Data based on ReGenerate-1 clinical trial. First presented by professor Per-Ola Carlsson om the Word Diabetes Day 2020

Positive allosteric modulators enhance GABA:s beta cell regenerative effects*



Effect of PAMs on INS-1 cell proliferation. INS-1 cells were cultured with the indicated PAM at a dose range of 10^{-9} to 10^{-6} M and assessed for their proliferation. Data shown are the average rate of proliferation relative to that of cultures with media alone (designated as 1).

Alprazolam enhances GABA's ability to promote human islet cell replication. Human islets were incubated with a dose range of GABA together with alprazolam (100 ng/ml) for 4 days in the presence of ^{3}H thymidine. Data shown are the average rate of proliferation relative to that of cultures with medium alone (designated as 1) in a representative study. N = two independent studies with triplicate cultures. The results were very similar in both studies. $^{††}p < 0.01$ and $^{†††}p < 0.001$for GABA, or GABA + alprazolam vs. control medium alone; $*p < 0.05$ and $***P < 0.01$ for GABA + alprazolam vs. GABA alone, determined by Student T-test.



→ Potential to safely enhance GABA:s regenerative effects on beta cells by using a small (sub-CNS) dose of benzodiazepines

*Clinically applicable GABA receptor positive allosteric modulators promote ß-cell replication. ***Sci Rep. 2017 Mar 23***

REMYGEN® MARKET EXCLUSIVITY AND MANUFACTURING

Core Intellectual Property

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

Regulatory exclusivity

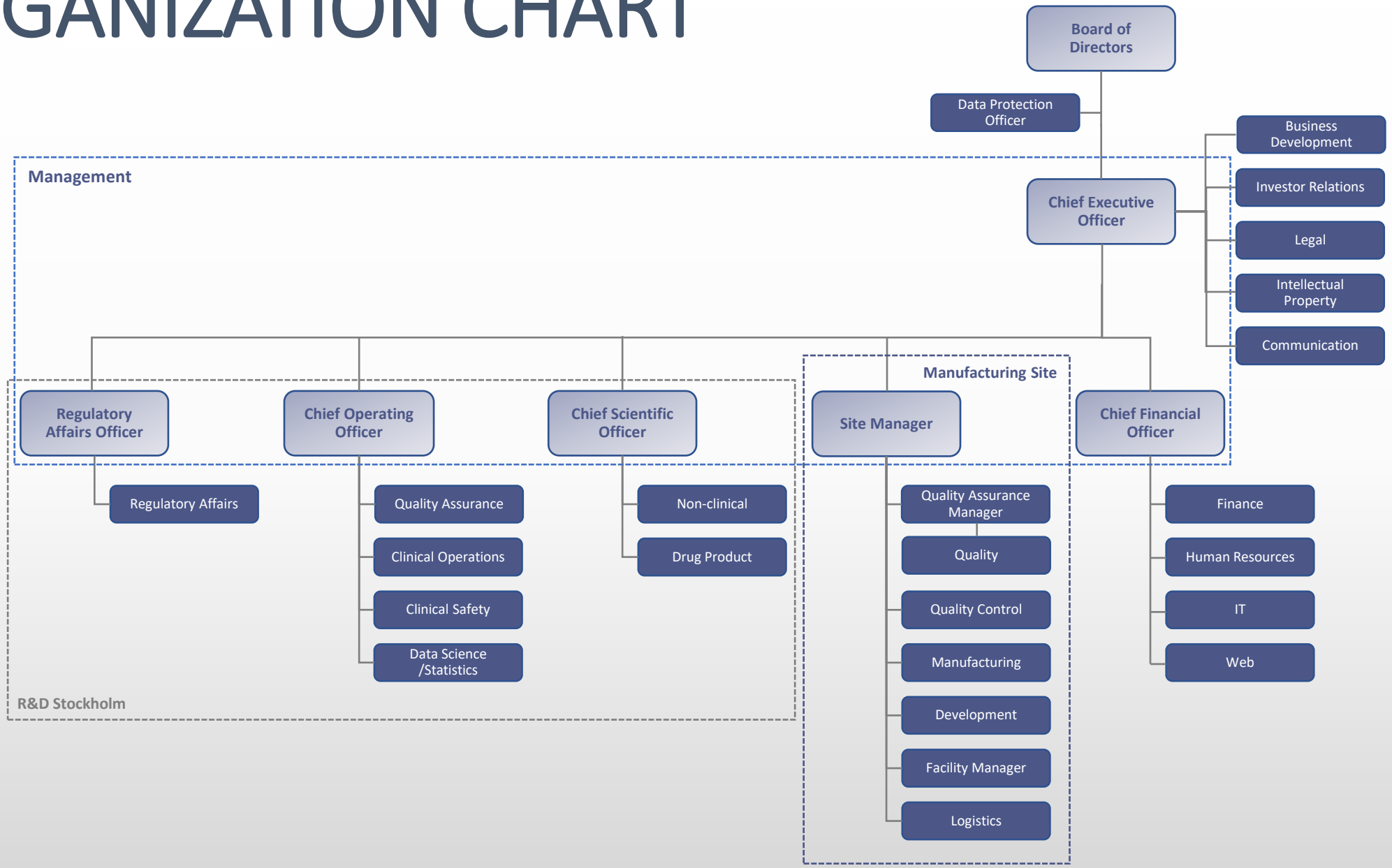
- 505(b)(2) regulatory pathway in the US provides potentially faster time to market at reduced cost

Manufacturing

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

Organization, Board, Management and Scientific Advisors

ORGANIZATION CHART



BOARD OF DIRECTORS

Erik Nerpin

Born in 1961. Lawyer. Self-employed with Advokatfirman Nerpin AB. Independent of the Company and its principal owners. Board member since 2012. Chairman of Kancera AB and Blasieholmen Investment Group AB and Board member in among others Effnetplattformen AB.

Holdings in Diamyd Medical as of August 31, 2021:
41 065 B-shares.

Anders Essen-Möller

Born in 1941. M.Sc. Founder of and CEO during 1996-2007 of Diamyd Medical and Chairman 2007 –2015. Independent of the Company, principal owner. Founder of Synectics Medical AB, sold to Medtronic, Inc. in 1996. Chairman of NextCell Pharma AB.

Holdings in Diamyd Medical as of August 31, 2021:
2 556 223 A-shares and 5 313 040 B-shares. Essen-Möller also holds 1 545 000 B-shares via an endowment insurance.

Maria-Teresa Essen-Möller

Born in 1970. M.Sc. in Business Administration. Independent to the Company, not independent to its principal owners. Chief Commercial Officer at ScientificMed AB. Previous experience include CEO of Health Solutions AB, Digital Marketing Manager at Sanofi and Account Director at Creuna. Board member since 2009.

Holdings in Diamyd Medical as of August 31, 2021:
463 998 B-shares.

Torbjörn Bäckström

Born in 1948. MD, PhD. CEO of Umecrine AB. Independent of the Company and its principal owners. Board member since 2017. Head of Neurosteroid Research Centre in Umeå and Senior Professor in the Department of Clinical Science, Obstetrics and Gynecology at Umeå University.

Holdings in Diamyd Medical as of August 31, 2021: 1 000 B-shares via company.

Mark A. Atkinson

Born in 1961. PhD. Professor of Diabetes Research, Department of Pathology, Immunology and Laboratory Medicine, University of Florida, USA. American Diabetes Association Eminent Scholar for Diabetes Research. Director, UF Diabetes Institute, University of Florida. Independent of the Company and its principal owners. Board member since 2018.

Holdings in Diamyd Medical as of August 31, 2021:
16 750 B-shares.

Karin Hehenberger

Born in 1972. M.D., Ph.D, Karolinska Institute, Post-doc at the Joslin center, Harvard Medical School. Founder and CEO of Lyfebulb, Member of the 3B Future Health Ventures Advisory board, Board observer AADI pharmaceuticals, Board member Rolf Luft Foundation for Diabetes research, Board member American Diabetes Association NY/NJ Community Board. Affiliated Board member since April 2021.

Holdings in Diamyd Medical as of August 31, 2021: 10 000 B-shares.

MANAGEMENT

Ulf Hannelius
Chief Executive Officer

Born in 1975. PhD in Molecular Biology from Karolinska Institutet in Stockholm and Executive MBA from Stockholm School of Economics. Prior experience from business development in the biotech and medtech industries as well as from academic research in the fields of genetics and molecular biology. Joined Diamyd Medical in 2015, CEO since 2016.

Holdings in Diamyd Medical as of August 31, 2021:

155 000 B shares.

Martina Widman
Chief Operating Officer

Born in 1981. M.Sc. in Mechanical Engineering from the Royal Institute of Technology in Stockholm, with a specialization in Biomedical Engineering. Prior experience of clinical operation from the pharmaceutical industry. Joined Diamyd Medical in 2008.

Holdings in Diamyd Medical as of August 31, 2021:

10 000 B shares.

Anna Styrud
Chief Financial Officer

Born in 1961. B.Sc. in Business Administration from Uppsala University. Prior experience include Treasurer of Vasakronan AB and various positions in finance and control within real estate and engineering industry. Joined Diamyd Medical in 2010.

Holdings in Diamyd Medical as of August 31, 2021:

105 000 B-shares.

Anton Lindqvist
Chief Scientific Officer

Born in 1980. M.Sc in Molecular Biotechnology Engineering from Uppsala University. Research experience from University of Pittsburgh, Uppsala University, the Royal Institute of Technology and Karolinska Institutet. Prior experience in managing technical development at several bio-tech companies. Joined Diamyd Medical in 2013.

Holdings in Diamyd Medical as of August 31, 2021: -

Maja Johansson
Head of Production Facility

Born in 1962. PhD in Biochemistry from Umeå University and Associate professor in neuroendocrinology. Prior experience from biotech companies. Joined Diamyd Medical in May 2020.

Holdings in Diamyd Medical as of August 31, 2021: -

Eva Karlström
Regulatory Affairs Officer

Born in 1964. M.Sc. in Pharmacy from Uppsala University. Prior experience of Regulatory Affairs from the pharmaceutical industry in positions at Astra Zeneca. Joined Diamyd Medical in August 2020.

Holdings in Diamyd Medical as of August 31, 2021: -

TOP WORLDWIDE EXPERTS

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

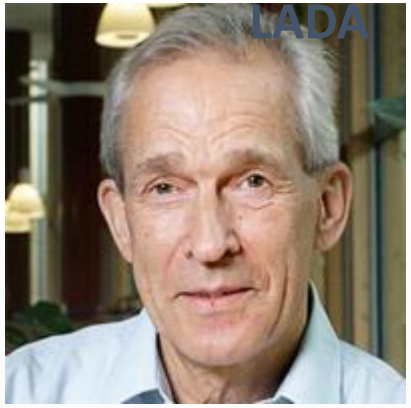
Prof. Johnny Ludvigsson

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

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

Prof. David Leslie

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



Prof. Åke Lernmark

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

Prof. Daniel Kaufman

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

Prof. Mark A. Atkinson

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

Diamyd Medical Board member.

DIAMYD MEDICAL

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

FINANCES

- Market Cap Jun 20, 2022 ~ MSEK 1,205
- Cash May 31, 2022: MSEK 193

INDICATIONS

- Diabetes
- Autoimmunity

PRODUCT CANDIDATES

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

INVESTMENTS

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

Diamyd Medical

www.diamyd.com

DIAMYD MEDICAL