

**DIAMYD**  
MEDICAL

**Developing Therapies for Autoimmune Diabetes**

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# Targeting Autoimmune and Insulin deficient Diabetes



## Leading clinical stage pipeline

- First-in-class **disease modifying therapies** (Diamyd® and Remygen®)
- Phase IIb development with upcoming **pivotal program**
- Addressable market encompassing **up to 25%** of all diabetes patients



## De-risked development program

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



## Strong growth opportunity

- Phase IIa and Phase IIb results as well as **start of pivotal program** the coming 18 months
- **Strong financials** with a monthly burn-rate of ~SEK 3 M and a cash-position of SEK 81.5 M (May 31, 2020). Market Cap ~SEK 2 075 M (August 10, 2020)



## Experienced team

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

# 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
- Phase IIb clinical development
- Strong clinical support for response and excellent safety profile

## Remygen® (GABA)

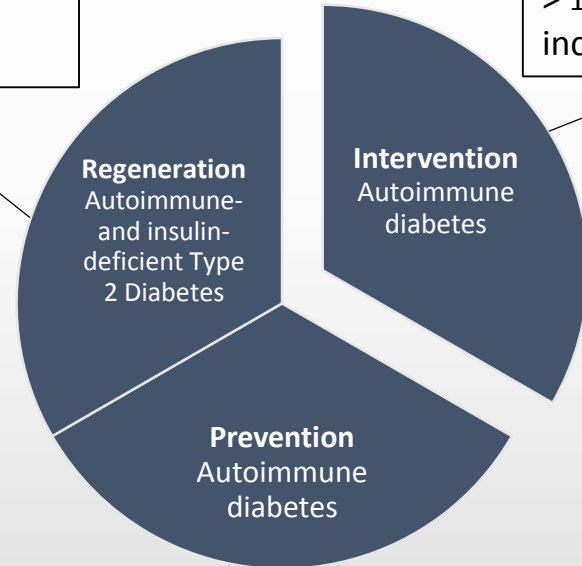
- First-in-class
- Regeneration and immunomodulation
- Phase IIa clinical development
- Promising clinical results

### 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

# 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

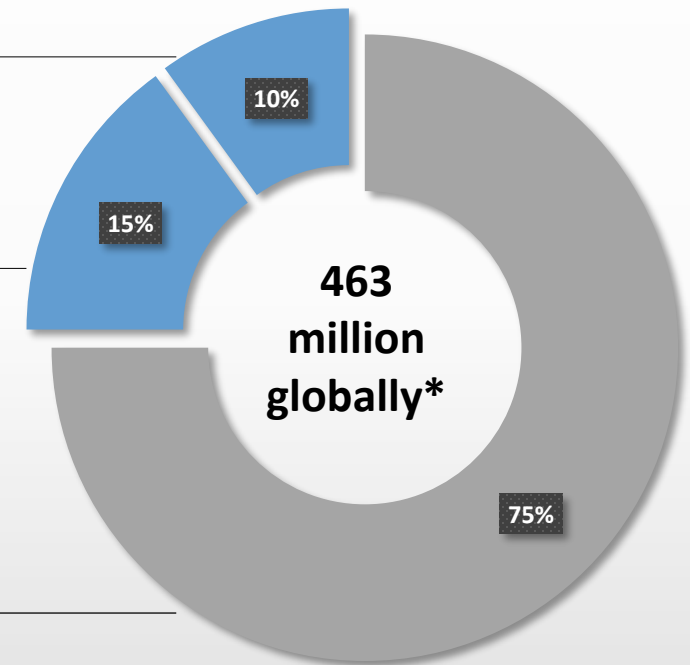
*Priority # 2*

### 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

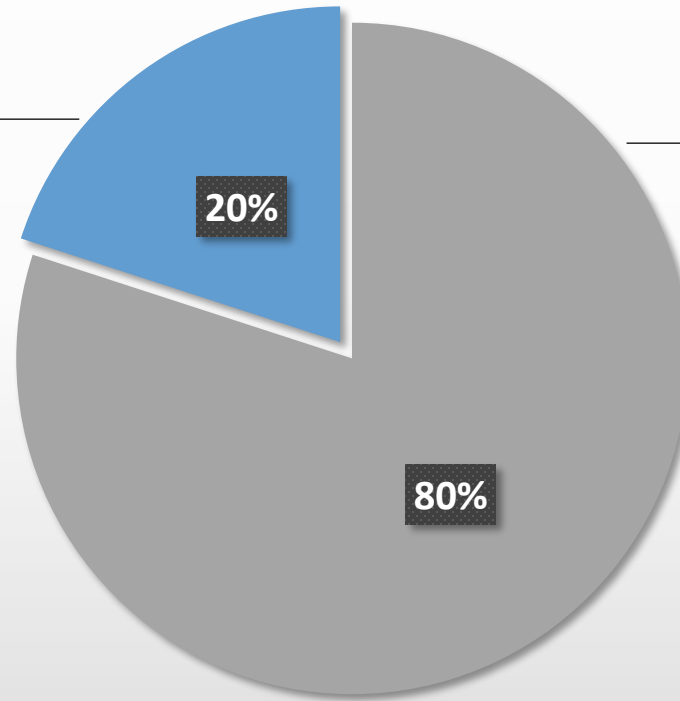
# Priority # 1 - Autoimmune diabetes

## 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.

# Annual economic burden of type 1 diabetes\*

>30 billion USD in the US





>90 billion USD globally

→ Disease modifying therapies for type 1 diabetes have a **multibillion-dollar economic impact** in the US alone

\*Modelling the total economic value of novel type 1 diabetes (T1D) therapeutic concepts, January 2020, Health Advances



# Leading pipeline in autoimmune diabetes

Product	Indication	Trial	Participants	Sponsor	Clinical Phase					Status
					0	I	IIa	IIb	III	
<b>Diamyd®</b>	Type 1 diabetes, intervention	DIAGNODE-2	109	Diamyd Medical						Topline results September 2020
	LADA, intervention	DIAGNODE-1	12	Linköping University						Results available
	LADA, intervention	GADinLADA	15	NTNU, Trondheim						Recruiting
<b>Remygen®</b>	Type 1 diabetes	ReGenerate-1	36	Uppsala University						Recruiting

**Primary indication for Diamyd®:** intervention in type 1 diabetes (new-onset type 1 and LADA patients). **Phase III program** (one pivotal trial) expected to start 2021

**Primary indication for Remygen®:** regeneration of insulin producing cells in long-term type 1 diabetes patients. Potential to expand into insulin-deficient type 2 diabetes. Phase IIa results will determine design and final indication of pivotal trial(s). Follows 505b(2) regulatory pathway



# Diamyd®



## **Recombinant GAD65 Formulated in Alum (rhGAD65/alum)**

### **Primary Indication**

*New-onset type 1 Diabetes*

### **Label expansion**

*Type 1 Diabetes prevention, LADA*

### **Mechanism of Action**

*Induce immunological tolerance against GAD65*

### **Clinical Effect and Benefit**

*Preserve the endogenous insulin production, reduce short- and long-term complications*

### **Mode of Administration**

*Three intranodal injections one month apart*

### **Development Status**

*Phase IIb ongoing*

### **Licensing Status**




*Global rights available*

# Responders to Diamyd® treatment identified

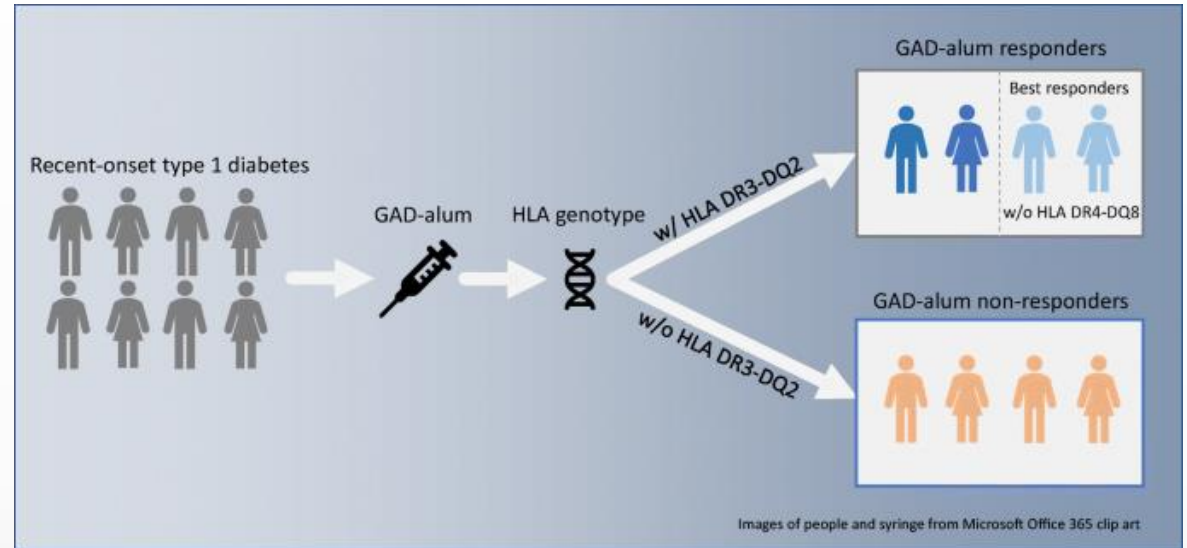
Diabetologia  
<https://doi.org/10.1007/s00125-020-05227-z>

## SHORT COMMUNICATION

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

Ulf Hannelius<sup>1</sup>  • Craig A. Beam<sup>2</sup>  • Johnny Ludvigsson<sup>3,4</sup> 

Received: 28 April 2020 / Accepted: 11 June 2020  
© The Author(s) 2020



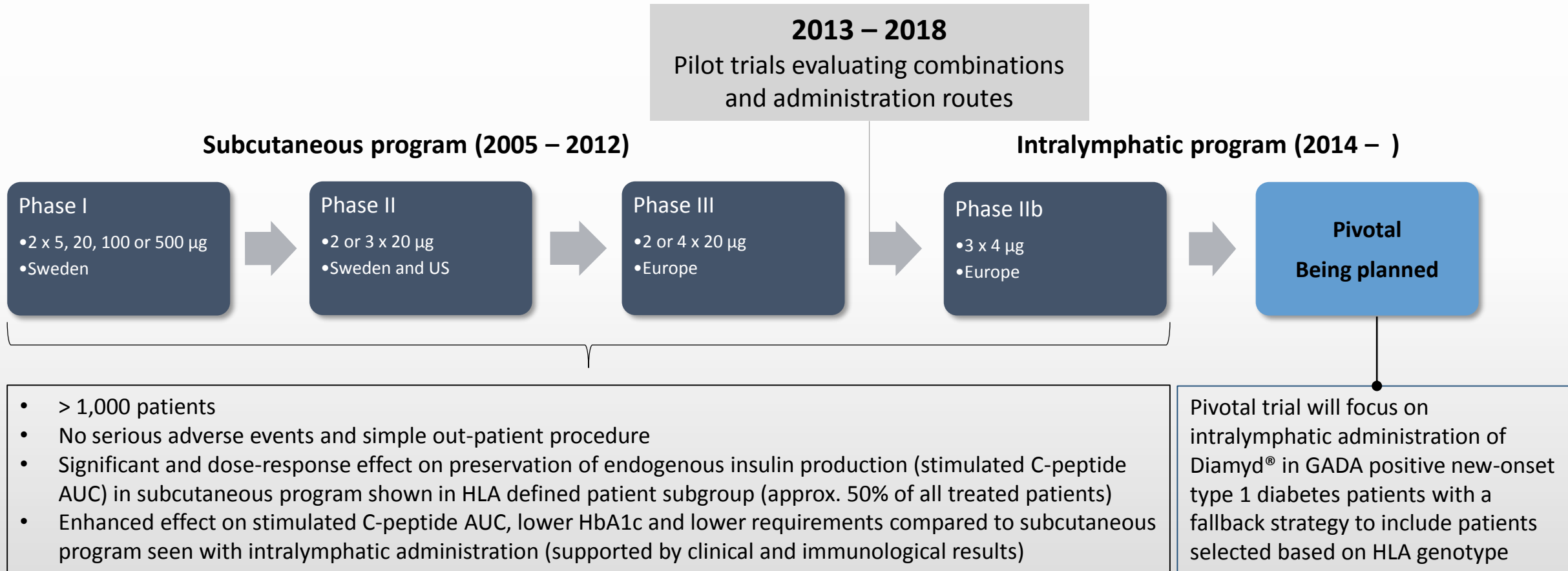
- Publication supports significant clinical effect of the diabetes vaccine Diamyd® in genetically defined subgroup\*
- Aligned with the notion of Precision Medicine in type 1 diabetes\*\*

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

\*\*Introducing the Endotype Concept to Address the Challenge of Disease Heterogeneity in Type 1 Diabetes, Bottaglia et al 2020, *Diabetes Care*

# De-risked clinical development program for Diamyd®

Supported by large safety database, identification of responders and enhanced efficacy with novel administration route



Agardh, C.D., et al., Clinical evidence for the safety of GAD65 immunomodulation in adult-onset autoimmune diabetes. J Diabetes Complications, 2005. 19(4): p. 238-46.

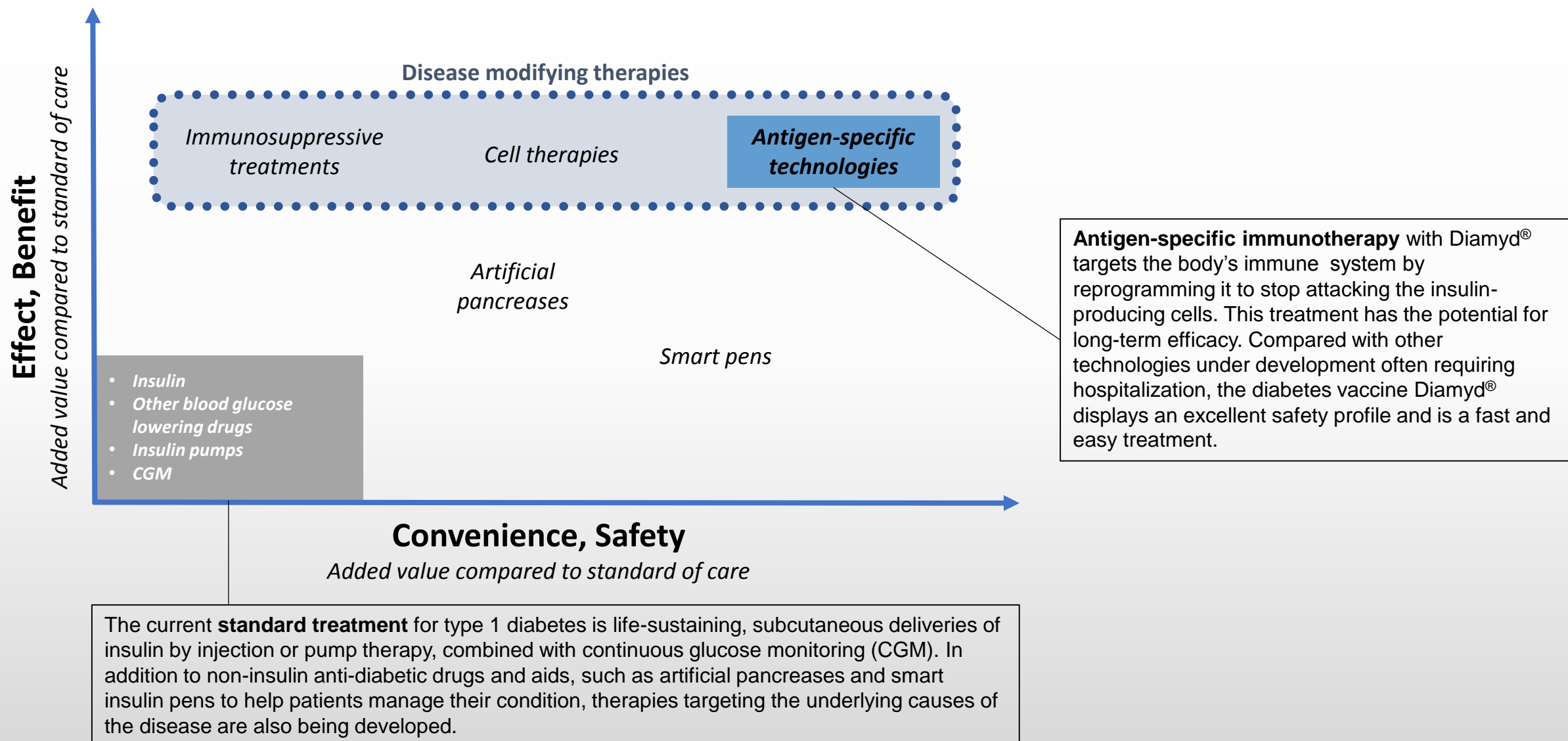
Ludvigsson, J., et al., GAD treatment and insulin secretion in recent-onset type 1 diabetes. N Engl J Med, 2008. 359(18): p. 1909-20.

Wherrett, D.K., et al., Antigen-based therapy with glutamic acid decarboxylase (GAD) vaccine in patients with recent-onset type 1 diabetes: a randomised double-blind trial. Lancet, 2011. 378(9788): p. 319-27.

Ludvigsson, J., et al., GAD65 antigen therapy in recently diagnosed type 1 diabetes mellitus. N Engl J Med, 2012. 366(5): p. 433-42.

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

# Position Diamyd® to maximize Efficacy, Safety and Convenience

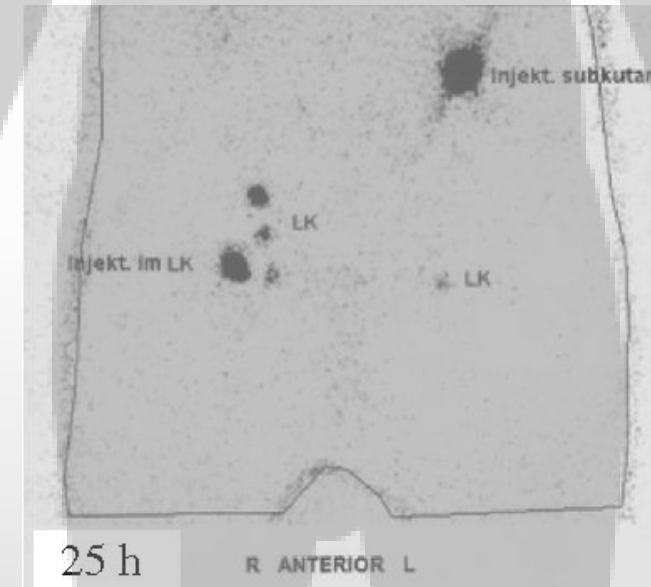
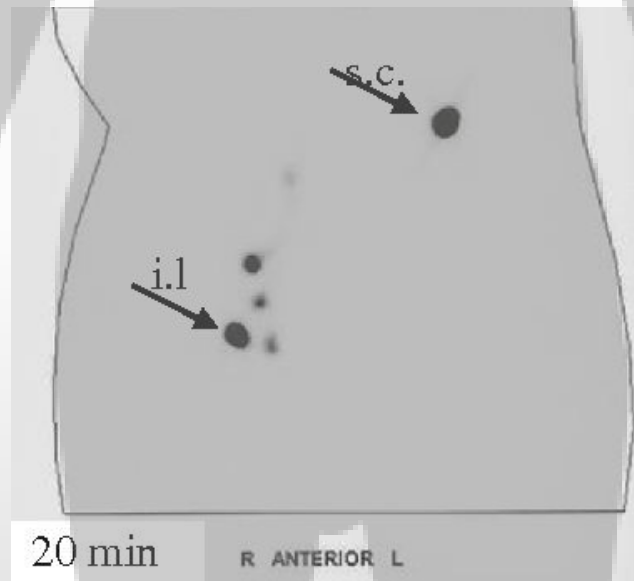


An anatomical illustration of a human torso from the waist up, showing the skin and underlying muscles. A network of blue lymphatic vessels is overlaid on the torso, with several blue lymph nodes visible. A syringe with a blue plunger and a silver needle is shown injecting a blue liquid into one of the lymph nodes. The background is a dark, solid color.

**Intralymphatic administration route  
enhances effect of antigen-specific  
immunotherapy Diamyd® in type 1  
diabetes**

# More efficient uptake in and drainage to lymph nodes following intralymphatic compared to subcutaneous administration

Lessons Learned from Allergy Immunotherapy trials

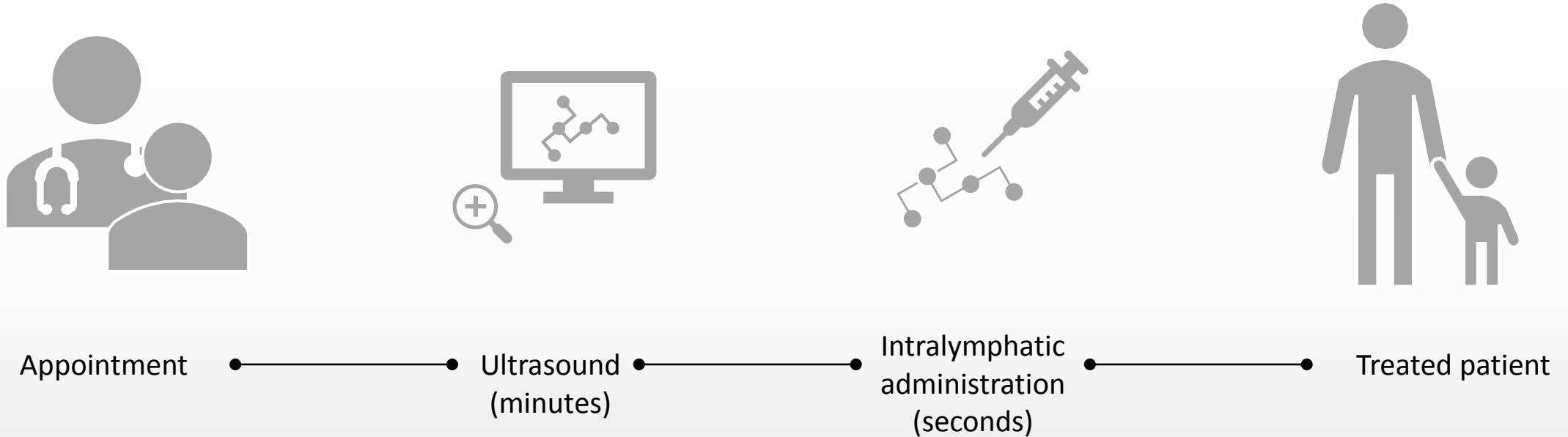


Subcutaneously (S.C.) injected large molecules including proteins do not effectively spread to the draining lymphnodes. Intranasal (I.L.) injections lead to immediate spreading to deeper lymphnodes. The image depicts radio tracing of labeled IgG at 20 minutes and 25 hours after subcutaneous and intranasal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



# Simple 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



# DIAGNODE-1 Phase IIa trial (results available)

## Intralymphatic administration of Diamyd® in new-onset Type 1 Diabetes

### Treatment

- 3 intralymphatic injections (outpatient procedure) of 4µg Diamyd® one month apart
- Oral supplementation of Vitamin D

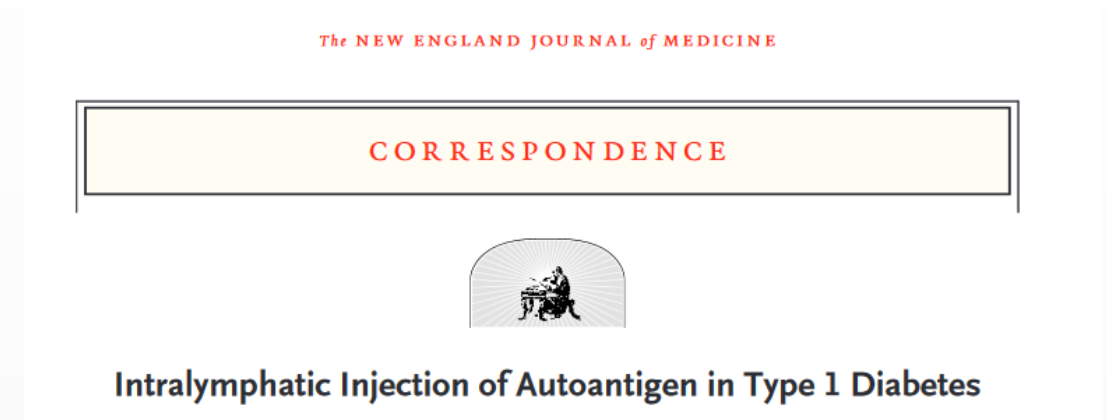
### Population

- 12-24 old type 1 diabetes patients diagnosed within the last 6 months from screening
- N = 12, followed for 30 months, 3 patients (booster injection at 32 months) followed for 43 months

### Clinical Endpoints

- Endogenous insulin production (stimulated C-peptide AUC), HbA1c, insulin dose and insulin adjusted HbA1c (IDAAC) at 30 months
- Historical controls from placebo treated patients from previous Diamyd® trial used to compare effect and immunological response

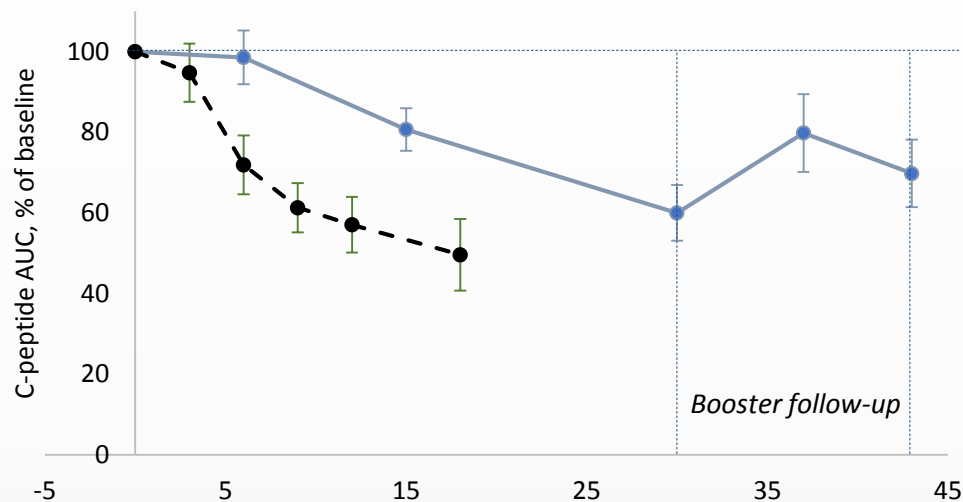
See also publications and company press releases for additional details



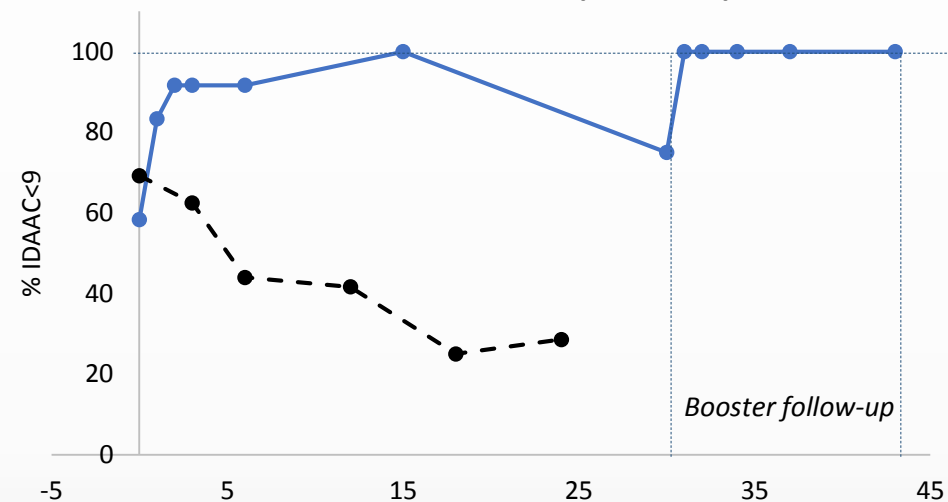
# Clinical results support enhanced effect of intralymphatic Diamyd®

12 patients followed for 30 months (main study). 3 patients followed for 42 months (follow-up study evaluating 4th booster injection)

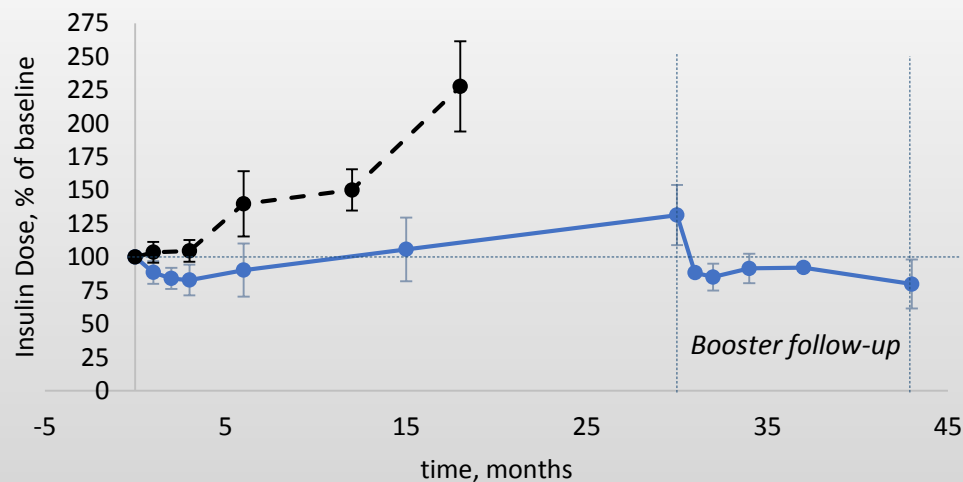
## Preserved endogenous insulin production (C-peptide AUC)



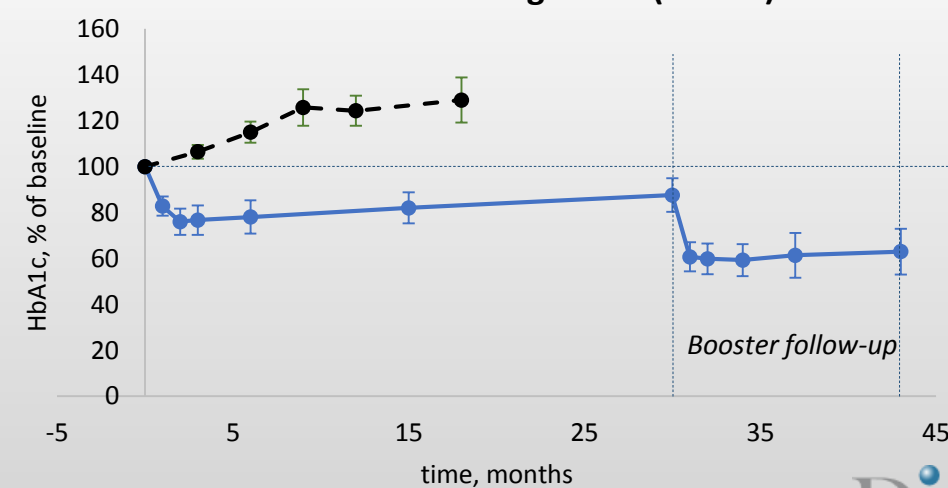
## Partial remission (IDAAC≤9)



## Lower requirements for exogenous insulin



## Lower blood glucose (HbA1c)



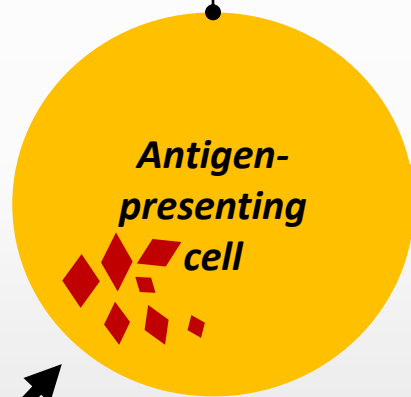
—●— DIAGNODE-1 (12-25)    -●- TrialNet Placebo (12-25)

—●— DIAGNODE-1 (12-25)    -●- TrialNet Placebo (12-25)

# Clinical and immunological results from Diamyd® trials support the mechanistic rationale 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 tolerogenic 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.

**Antigen-reactive T cell**

**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 INF $\gamma$ ) 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.

# DIAGNODE-2 Phase IIb trial

## Intralymphatic administration of Diamyd® in new-onset Type 1 Diabetes

### Treatment

- 3 intralymphatic injections (outpatient procedure) of 4µg Diamyd® one month apart
- Oral supplementation of Vitamin D

### Population

- 12-24 old type 1 diabetes patients diagnosed within the last 6 months from screening
- N = 109, followed for 15 months
- Clinics in Sweden, Czech Republic, Spain and the Netherlands

### Clinical Endpoints

- Endogenous insulin production (stimulated C-peptide AUC), HbA1c, insulin dose and insulin adjusted HbA1c (IDAAC) at 15 months
- A subset of patients followed for 24 months

### Status

- Fully recruited in May 2019
- All patients treated, no serious adverse events reported
- All patients completed 15 month visit
- Topline results expected September 2020

# Diamyd® market exclusivity and manufacturing



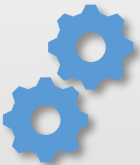
## Core Intellectual Property

- **Substance of matter** in the US until **2032**
- Intralymphatic administration of Diamyd® in Europe, Japan, Australia and Russia, additional countries pending, expiry **2035**. HLA subgroups and biomarkers in national phase with expiry **2035 and later 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**



## 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

# Vaccine Manufacturing in Umeå



10,000 square foot site comprising clean rooms, laboratory facilities and office space taking over manufacturing of recombinant GAD65 (active pharmaceutical ingredient in the diabetes vaccine Diamyd®)



## 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*

# Remygen®





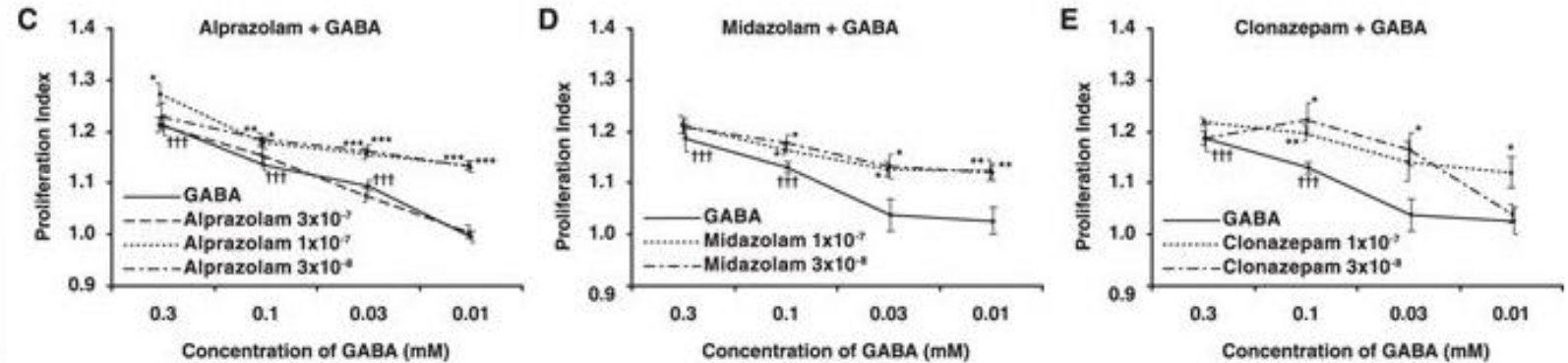
## Clinical results with attractive path to market for Remygen®

- 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 and increasing time-in-range\***
- 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 safety review and clinical effects following dose-escalation communicated in November 2019

\*\*Preliminary results presented at EASD 2019 by Professor Kenneth McCormick, University of Alabama at Birmingham

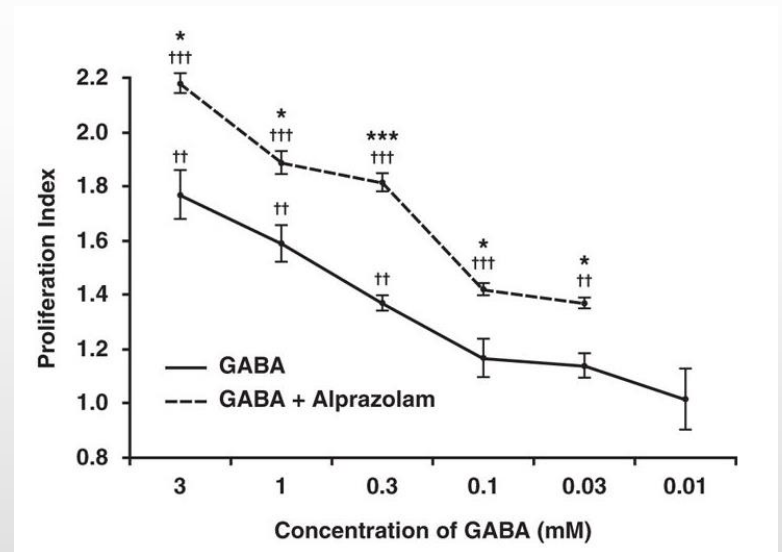
# Positive allosteric modulators enhance GABA:s beta cell regenerative effects\*



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  $^3\text{H}$  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  $\beta$ -cell replication. *Sci Rep.* 2017 Mar 23

# Remygen<sup>®</sup> market exclusivity and manufacturing



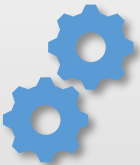
## Core Intellectual Property

- **Exclusive license from UCLA** on treating diabetes and other inflammatory diseases with GABA
- **Formulation patent** application (Remygen<sup>®</sup>). Application in national phase.
- **Exclusive license from UCLA** on GABA in combination with GABA receptor modulators to enhance the regenerative and immunomodulatory 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<sup>®</sup>) manufacturing in place



# Board, Management and Scientific Advisors

# Board of Directors



Erik Nerpin

Independent of the Company and its principal owners. Chairman since March 2015, Board member since 2012. Other assignments include 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, 2019: 41 065 B-shares.



Anders Essen-Möller

Founder of and CEO during 1996-2007 of Diamyd Medical and Chairman 2007 –2015. Founder of Synectics Medical AB, sold to Medtronic, Inc. in 1996. Chairman of the associated company NextCell Pharma AB.

Holdings in Diamyd Medical as of August 31, 2019: 2 556 223 A-shares and 7 333 040 B-shares.



Maria-Teresa Essen-Möller

CEO of Health Solutions AB. Previous experience include Digital Marketing Manager at Sanofi and Account Director at Creuna. Board member since 2009.

Holdings in Diamyd Medical as of August 31, 2019: 63 998 B-shares.



Torbjörn Bäckström

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, 2019: -



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. Board member since 2018.

Holdings in Diamyd Medical as of August 31, 2019:-



# Management



**Ulf Hannelius**  
Chief Executive Officer

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.

Holdings in Diamyd Medical as of August 31, 2019: 136 666 B shares.



**Martina Widman**  
Director Clinical Development

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, 2019: 20 000 B shares.



**Anna Styrud**  
Chief Financial Officer

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, 2019: 100 000 B-shares.



**Anton Lindqvist**  
Chief Scientific Officer

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, 2019: -

# Top Worldwide Experts

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



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 Aug 10, 2020 ~ MSEK 2 075
- Burn rate / month ~ MSEK 3.0
- Cash May 31, 2020: MSEK 81.5

## INDICATIONS

- Diabetes
- Autoimmunity

## PRODUCT CANDIDATES

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

## INVESTMENTS

- Next Cell Pharma (Stockholm, Sweden)
- Companion Medical (San Diego, USA)



# Diamyd Medical

[www.diamyd.com](http://www.diamyd.com)

