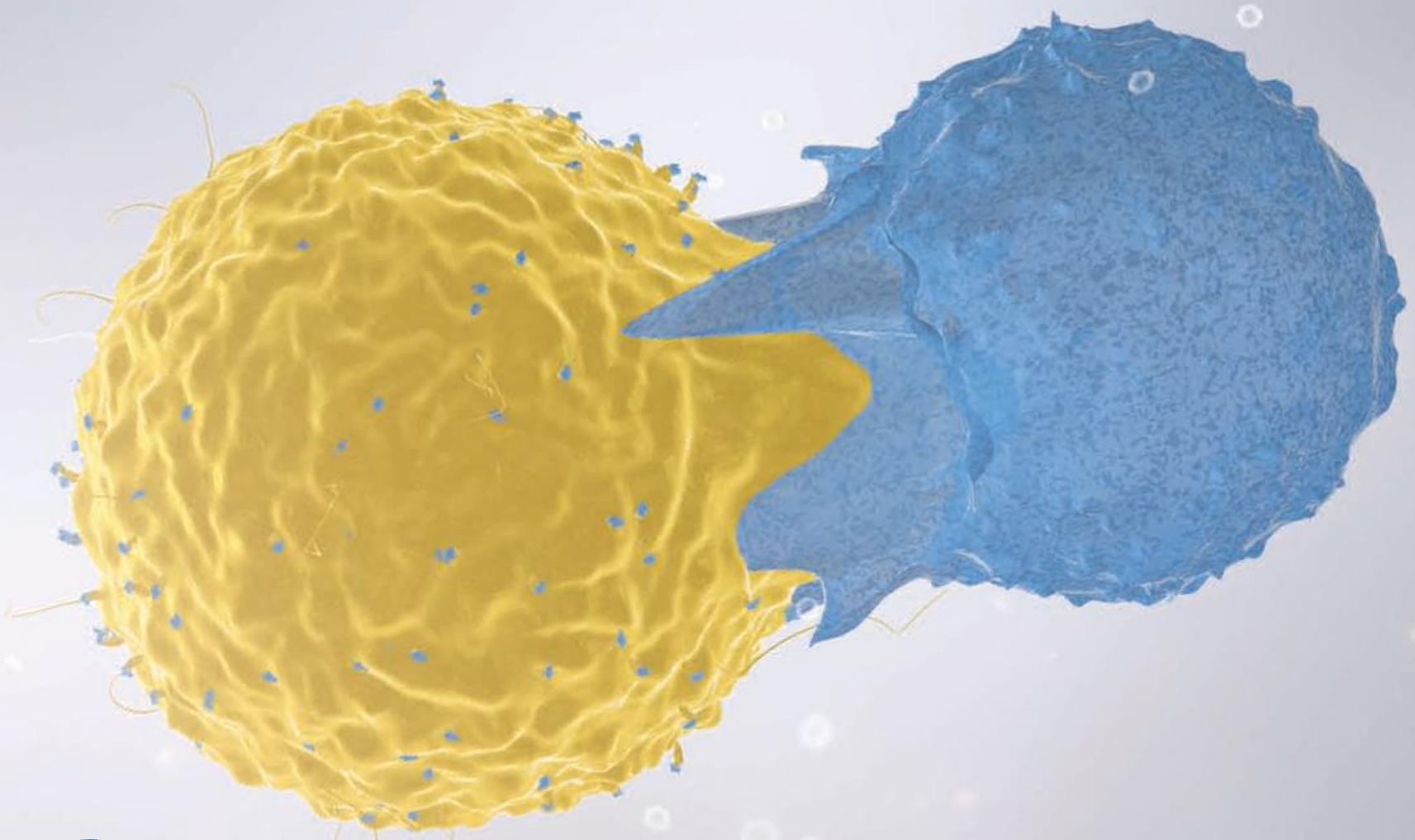

DIAMYD MEDICAL

Developing Therapies for Autoimmune Diabetes

Disclaimer

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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 88 M

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)

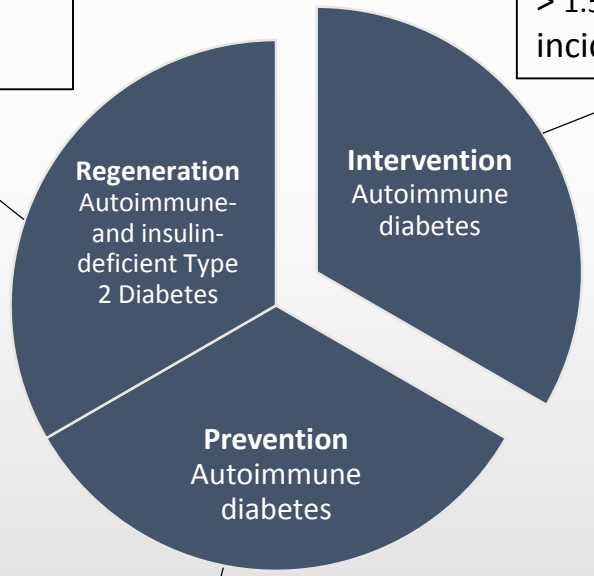
- First-in-class
- Antigen-specific immunotherapy
- Phase IIb clinical development
- Strong clinical support for response and excellent safety profile

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

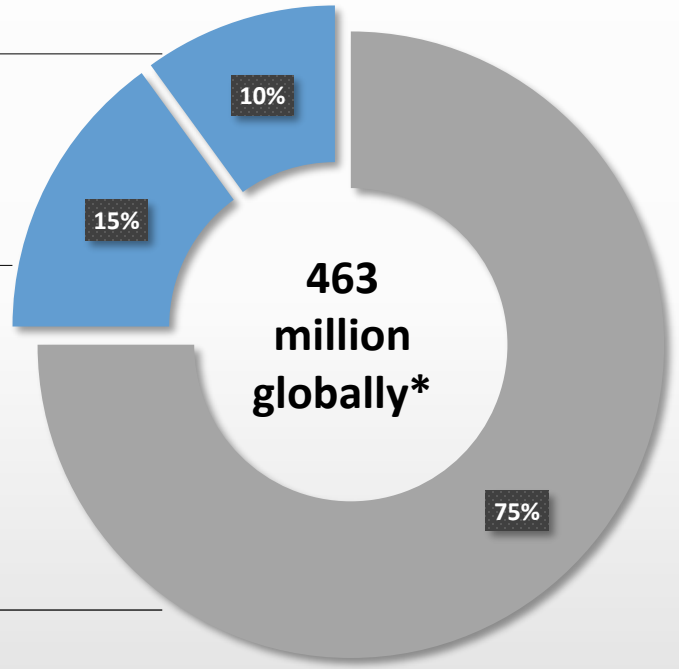
→ **Therapeutic development:** Stimulate regeneration of insulin producing beta cells and alleviate beta cell stress

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



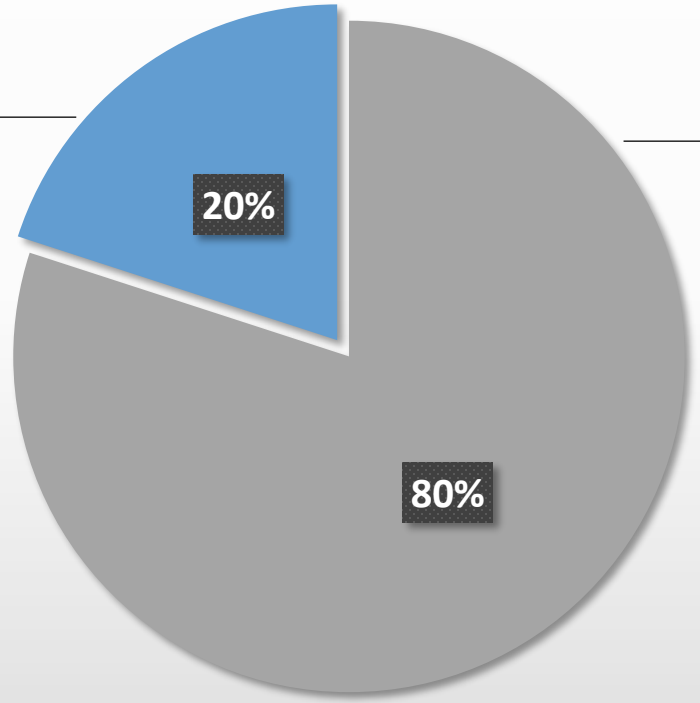
*IDF 2019 Atlas

** 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 0 I IIa IIb III	Status
Diamyd®	Type 1 diabetes, intervention	DIAGNODE-2	109	Diamyd Medical		Topline results Q3 2020
		DIAGNODE-1	12	Linköping University		Results available
	LADA, intervention	GADinLADA	15	NTNU, Trondheim		Recruiting
Remygen®	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

- HLA influences effect of Diamyd®
- Clinical effect ratio of **60%** compared to placebo in responder group

→ Supports enhanced effect of the diabetes vaccine Diamyd® in genetically defined subgroup

→ Aligned with the notion of precision medicine in type 1 diabetes*

Analysis of 500+ patients from 3 clinical trials spanning 2 continents (submitted for publication)

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

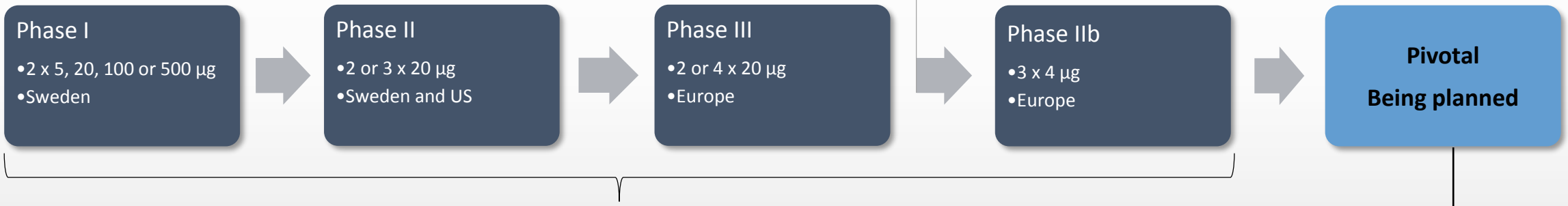
De-risked clinical development program for Diamyd®

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

2013 – 2018
Pilot trials evaluating combinations and administration routes

Subcutaneous program (2005 – 2012)

Intralymphatic program (2014 –)

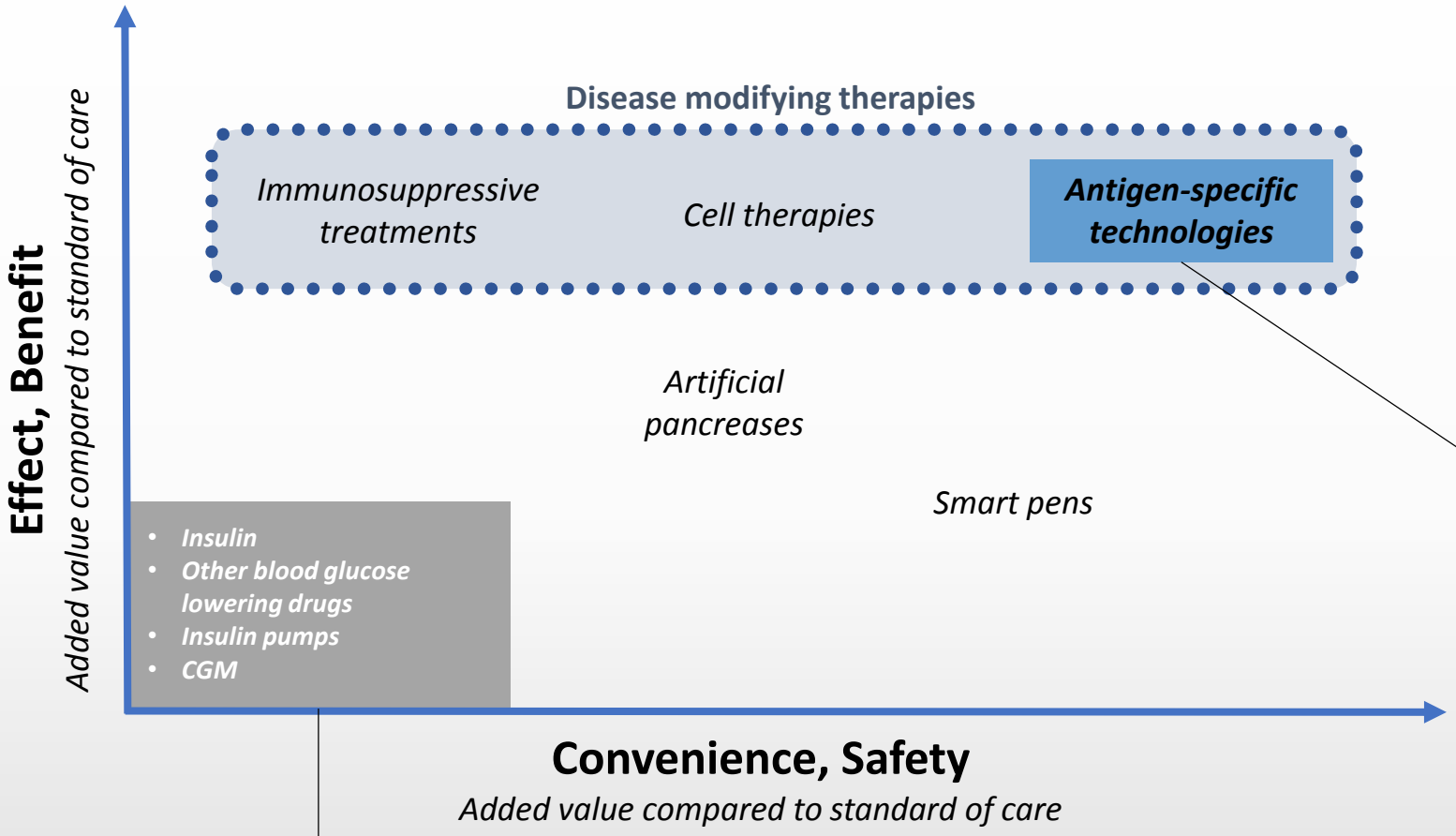


- > 1,000 patients
- Excellent safety profile and simple out-patient procedure
- Significant and dose-response effect on preservation of endogenous insulin production (stimulated C-peptide AUC) in subcutaneous program shown in HLA defined patient subgroup (approx. 50% of all treated patients)
- Enhanced effect on stimulated C-peptide AUC, lower HbA1c and lower requirements compared to subcutaneous program seen with intralymphatic administration (supported by clinical and immunological results)

Pivotal trial will focus on intralymphatic administration of Diamyd® in GADA positive new-onset type 1 diabetes patients with a fallback strategy to include patients selected based on HLA genotype

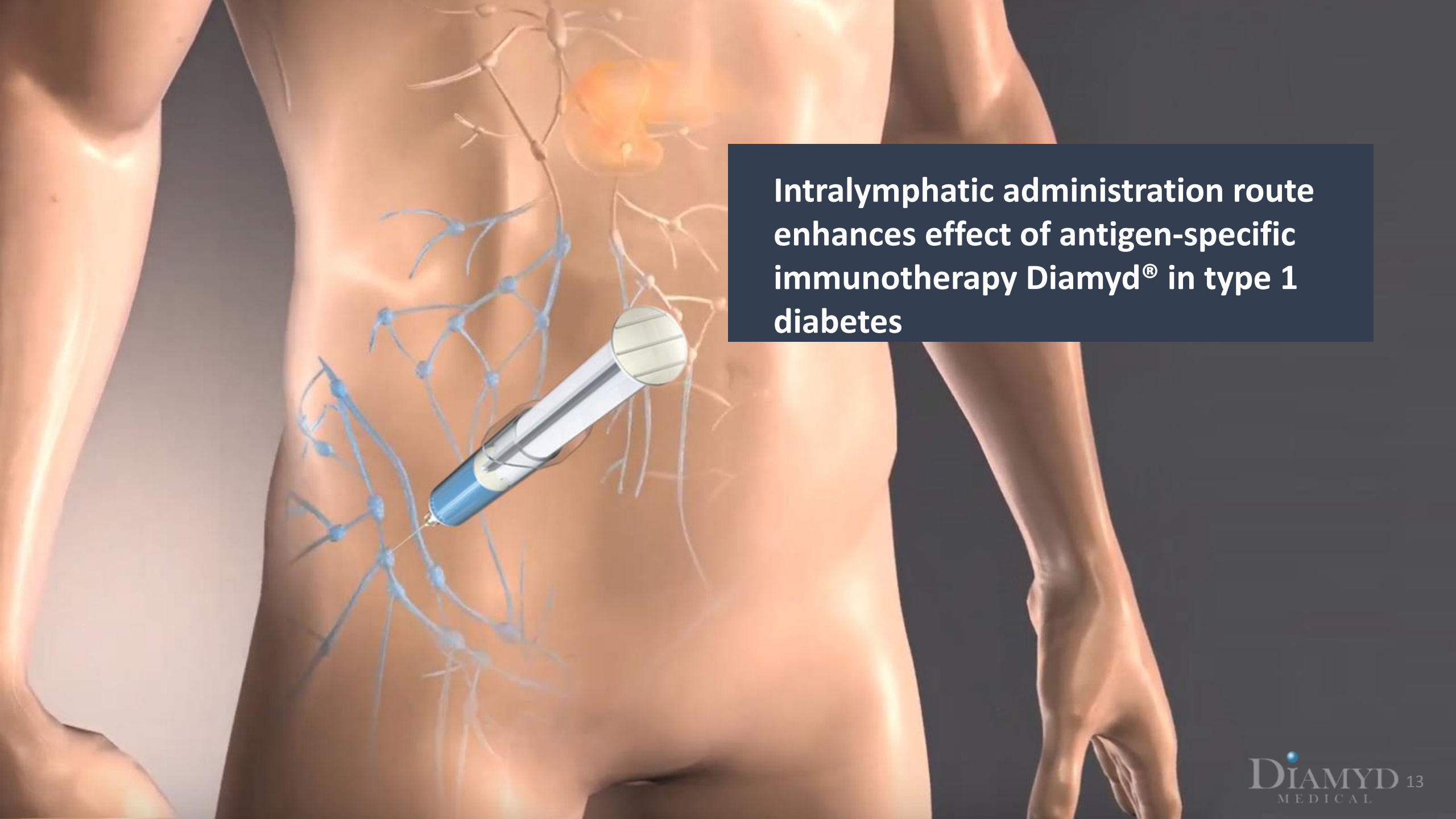
Agardh, C.D., et al., Clinical evidence for the safety of GAD65 immunomodulation in adult-onset autoimmune diabetes. J Diabetes Complications, 2005. 19(4): p. 238-46.
Ludvigsson, J., et al., GAD treatment and insulin secretion in recent-onset type 1 diabetes. N Engl J Med, 2008. 359(18): p. 1909-20.
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.

Position Diamyd® to maximize Efficacy, Safety and 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.

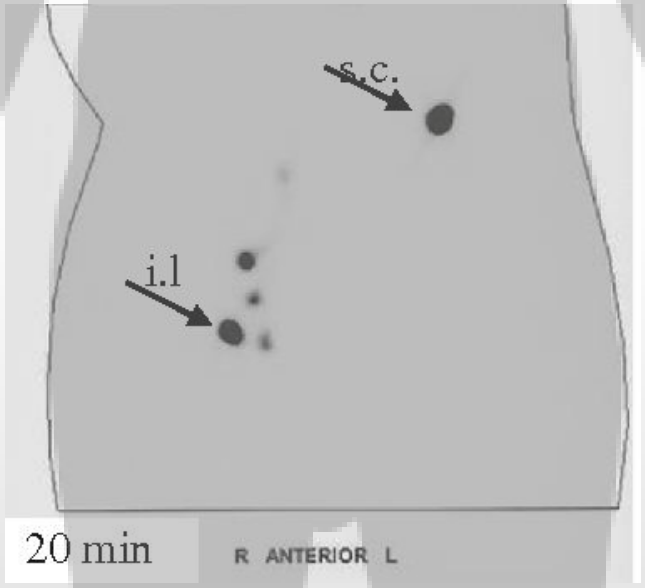
The current **standard treatment** for type 1 diabetes is life-sustaining, subcutaneous deliveries of insulin by injection or pump therapy, combined with continuous glucose monitoring (CGM). In addition to non-insulin anti-diabetic drugs and aids, such as artificial pancreases and smart insulin pens to help patients manage their condition, therapies targeting the underlying causes of the disease are also being developed.

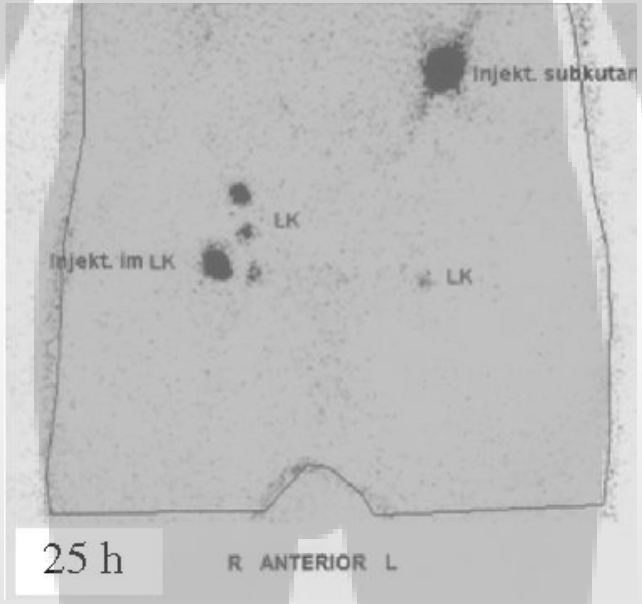


Intralymphatic administration route enhances effect of antigen-specific immunotherapy Diamyd® in type 1 diabetes

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

Lessons Learned from Allergy Immunotherapy trials



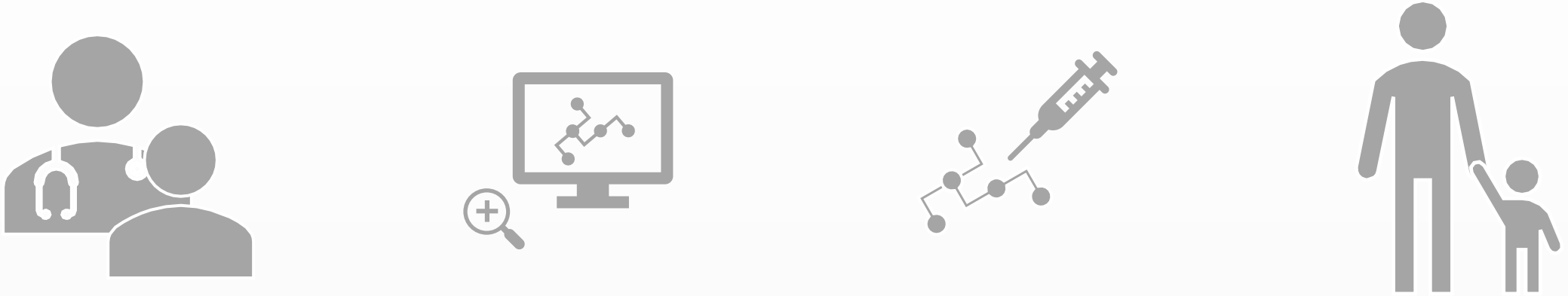


Subcutaneously (S.C.) injected large molecules including proteins do not effectively spread to the draining lymphnodes. Intranodal (I.L.) injections lead to immediate spreading to deeper lymphnodes. The image depicts radio tracing of labeled IgG at 20 minutes and 25 hours after subcutaneous and intranodal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

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

Simple outpatient procedure enhances value proposition for Diamyd®

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



Appointment → Ultrasound (minutes) → Intralymphatic administration (seconds) → Treated patient

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

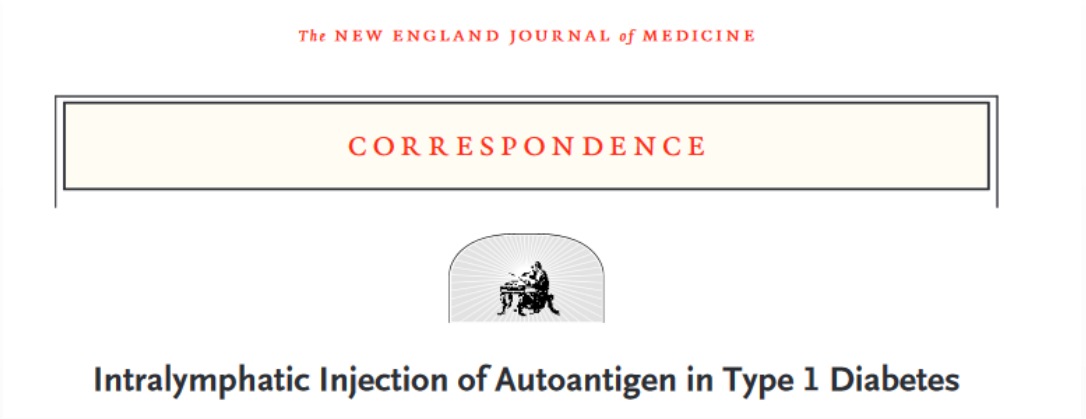
- 3 intralymphatic injections (outpatient procedure) of 4µg Diamyd® one month apart
- Oral supplementation of Vitamin D

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


The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Intralymphatic Injection of Autoantigen in Type 1 Diabetes


Hindawi
Journal of Diabetes Research
Volume 2018, Article ID 9391845, 11 pages
https://doi.org/10.1155/2018/9391845

Hindawi

Research Article

Intralymphatic Glutamic Acid Decarboxylase-Alum Administration Induced Th2-Like-Specific Immunomodulation in Responder Patients: A Pilot Clinical Trial in Type 1 Diabetes

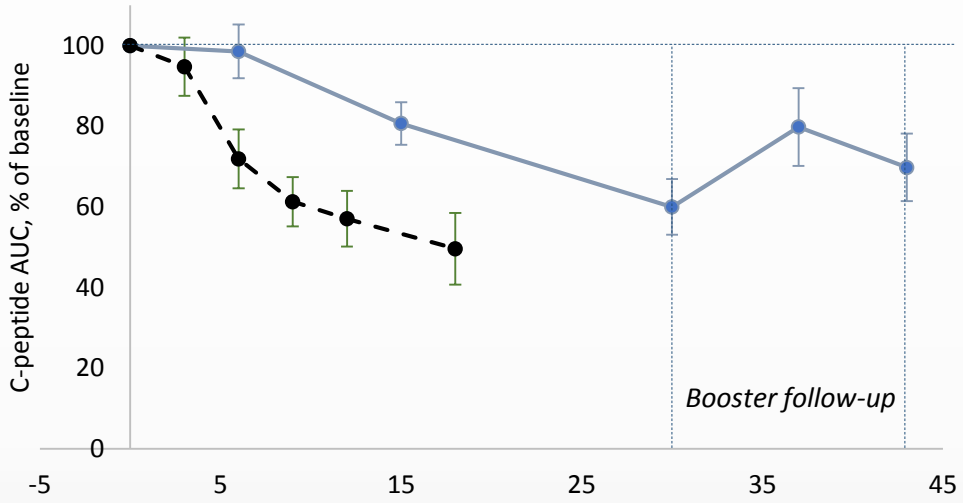
Beatriz Tavira,[1] Hugo Barcenilla,[1] Jeannette Wahlberg,[2] Peter Achenbach,[3] Johnny Ludvigsson,[1,4] and Rosaura Casas[1]

See also publications and company press releases for additional details

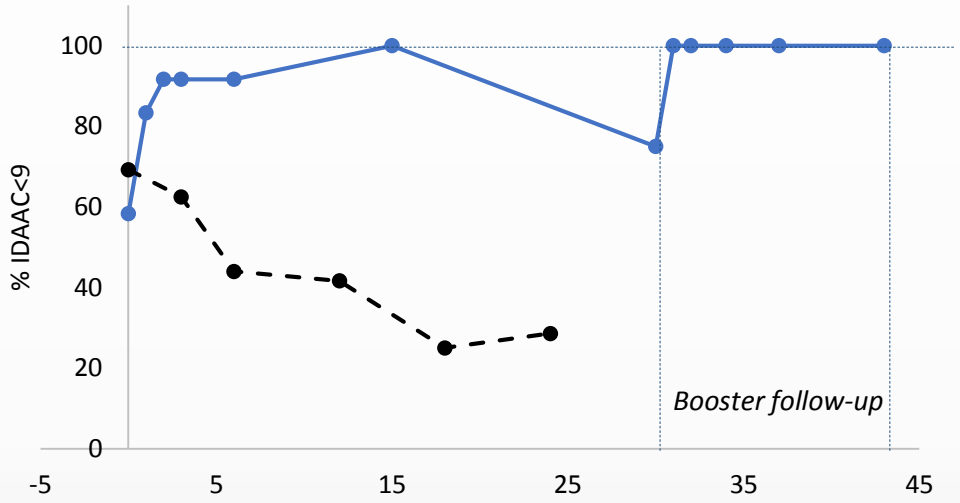
Clinical results support enhanced effect of intralymhatic Diamyd®

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

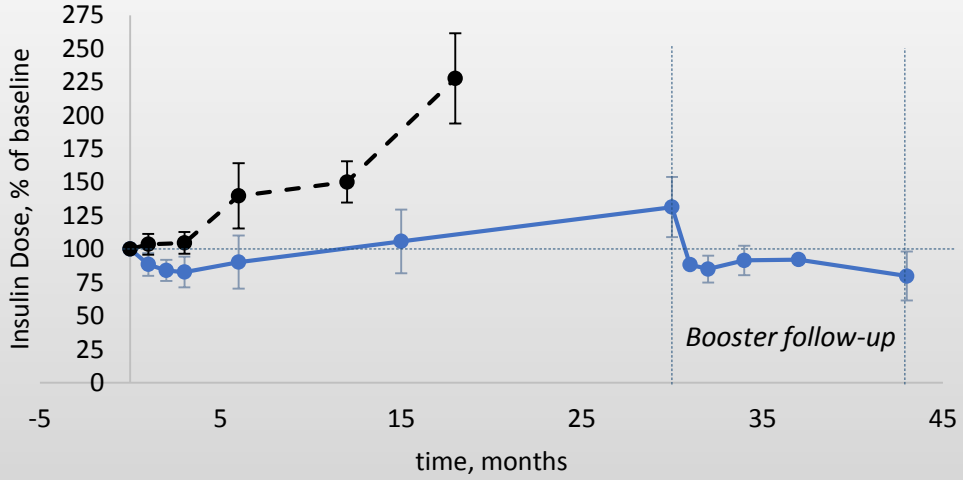
Preserved endogenous insulin production (C-peptide AUC)



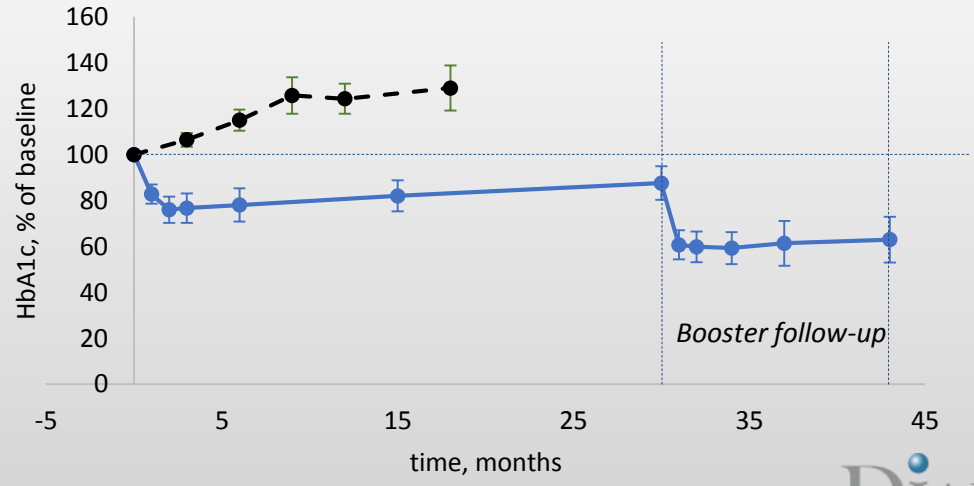
Partial remission (IDAAC≤9)



Lower requirements for exogenous insulin



Lower blood glucose (HbA1c)



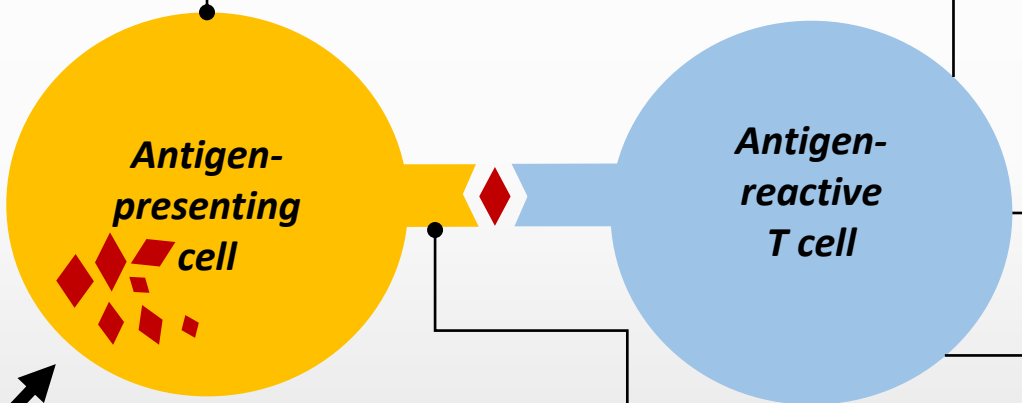
DIAGNODE-1 (12-25) TrialNet Placebo (12-25)

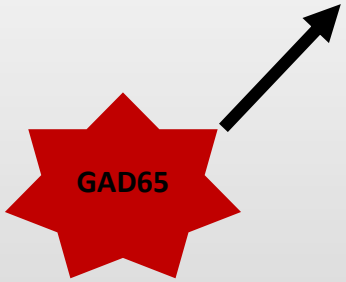
DIAGNODE-1 (12-25) TrialNet Placebo (12-25)

Clinical and immunological results from Diamyd® trials support the mechanistic 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 (submitted for publication) 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.

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.

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, excellent safety profile
- Topline results expected Q3 2020

Diamyd® market exclusivity and manufacturing

Core Intellectual Property

- **Substance of matter** in the US until **2032**
- National phase patent applications covering intralymphatic administration, HLA subgroups and biomarkers with expiry **2035 and later**

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 as backup for phase III
- Transfer of drug substance (GAD) manufacturing process to new CMO to prepare for phase III and commercial readiness

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

Mode of Administration
Oral

Development status
Phase Ib/IIa ongoing

Licensing Status
Global rights available

Remygen®

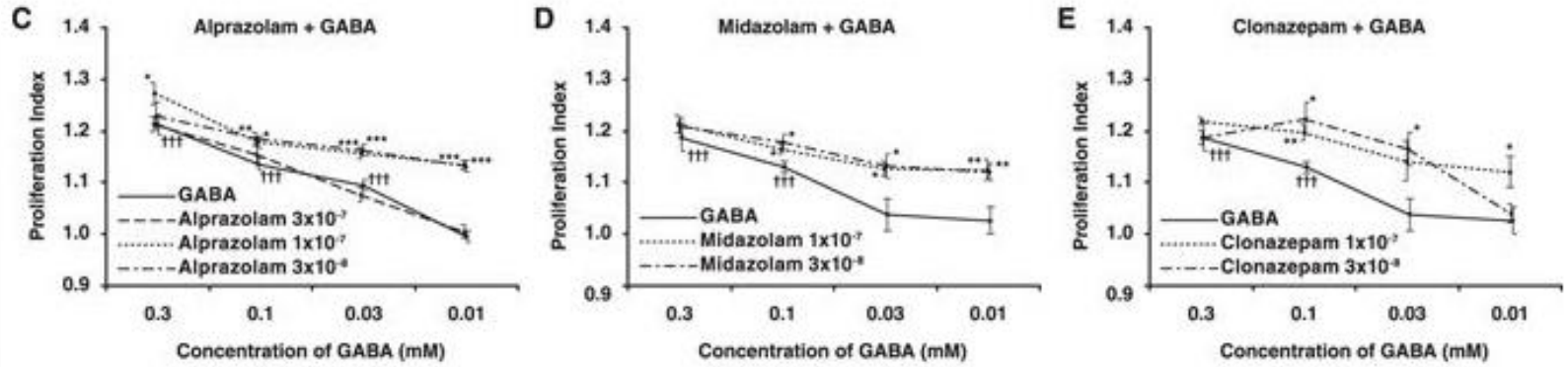
Ongoing clinical program with attractive path to market for Remygen®

- 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 results from stage 1 of trial pending
- 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 following dose-escalation communicated in November 2019

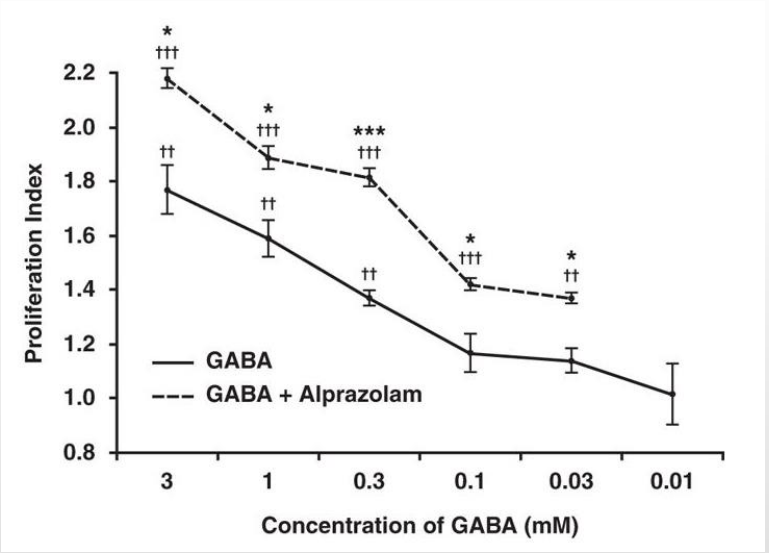
**Preliminary results presented at EASD 2019 by Professor Kenneth McCormick, University of Alabama

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®) 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

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 MSEK 776 (March 24th 2020)
- Burn rate / month ~ MSEK 3.0
- Cash February 29, 2020: MSEK 88

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

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