Leading Developer of Disease Modifying Therapies for Autoimmune Diabetes



Diango Medical

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Targeting Autoimmune and Insulin deficient Diabetes



Leading clinical stage pipeline

- First-in-class disease modifying therapies Diamyd[®] and Remygen[®]
- Upcoming pivotal program with a precision medicine approach
- 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 with a precision medicine approach
- Excellent safety profile and simple procedure support successful commercialization



Strong growth opportunity

- Phase IIa results (Remygen[®]) and start of pivotal program (Diamyd[®]) during 2021
- Strong financials with a cash-position of SEK 173 M (Nov 30, 2020). Market Cap ~SEK 1 800 M (Feb 8, 2021)



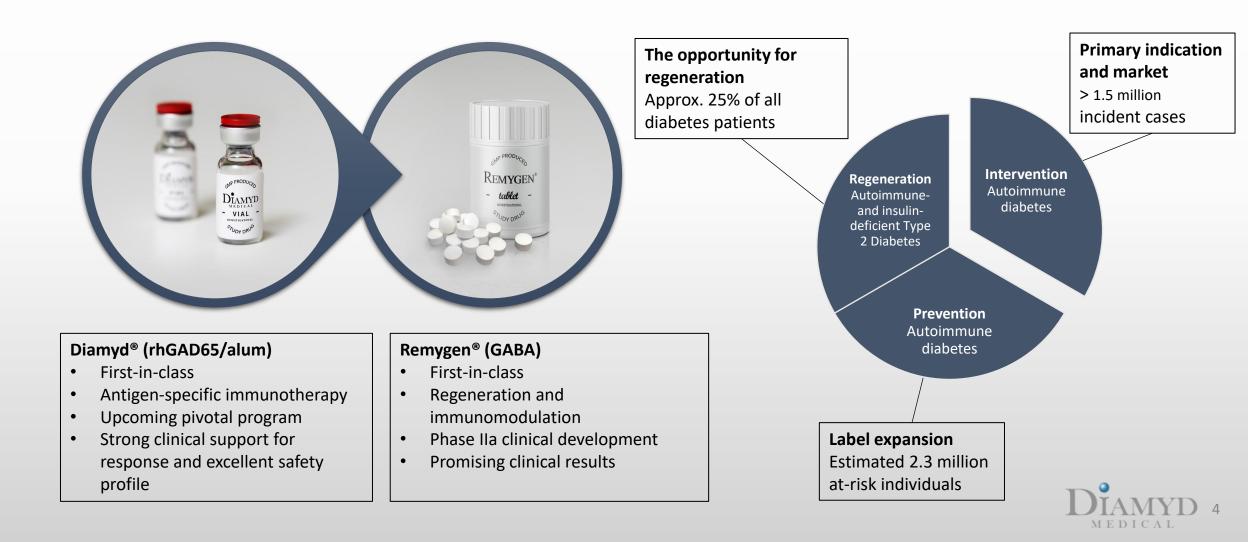
Experienced team

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



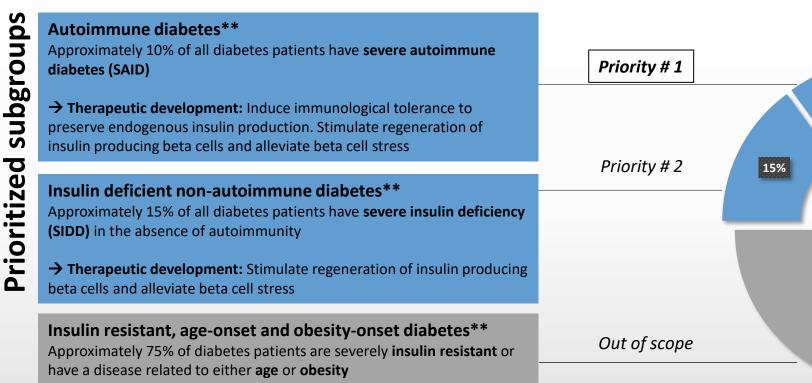
Clinical stage disease modifying therapies

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

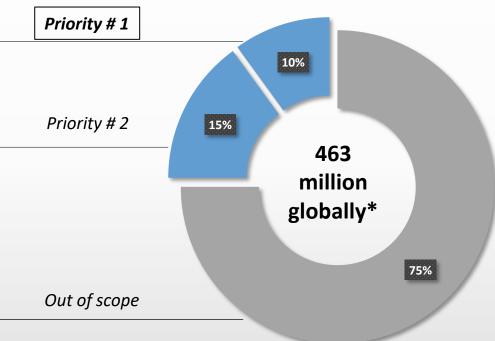


Prioritizing unmet medical need

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



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





*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

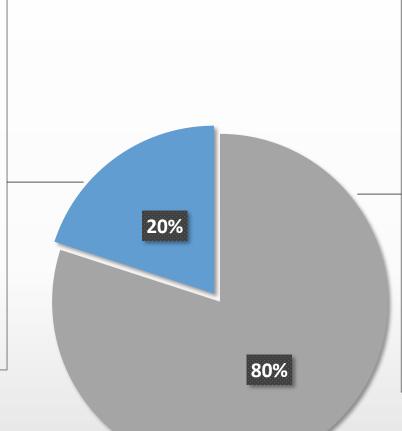
Priority #1 - Autoimmune diabetes

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 lifeexpectancy, 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 lifeexpectancy, decreased quality of life and significant health economic costs.

* Incidence for children and adolescents from IDF 2019 Atlas

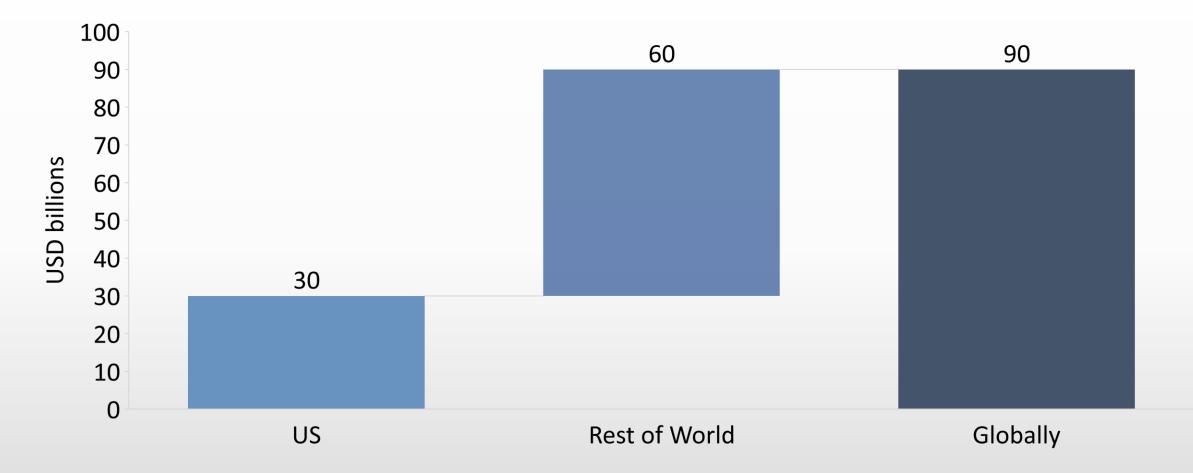
* Incidence for adult type 1 diabetes estimated from Thomas et al. Frequency and phenotype of type 1 diabetes in the first six decades of life: a cross-sectional, genetically stratified survival analysis from UK Biobank, The Lancet 2018

** 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 (T1D)



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

DIAMYD MEDICAL

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

Leading pipeline in autoimmune diabetes

Product	Indication	Trial	Participants	Sponsor	Clinical Trials Preclinical I IIa I	lib III	Status
Diamyd [®]	T1D, intervention	DIAGNODE-2	109	Diamyd Medical			Results available
Diamyd [®]	T1D, intervention	DIAGNODE-1	12	Linköping University			Results available
Diamyd®	LADA, intervention	GADinLADA	15	NTNU, Trondheim			Recruiting
Remygen®	T1D, T2D	ReGenerate-1	36	Uppsala University			Recruiting / Stage 1 results available
							Completed



Ongoing

Diamyd®



Recombinant GAD65 Formulated in Alum (rhGAD65/alum)

Primary Indication *New-onset type 1 Diabetes with HLA type DR3-DQ2*

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*

MEDICA

Mode of Administration *Three intranodal injections one month apart*

Development Status *Phase III planning*

Licensing Status *Global rights available*

Acknowledged Precision Medicine approach

Highlights

Diabetes Care Volume 43, January 2020

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

Introducing the Endotype Concept to Address the Challenge of Disease Heterogeneity in Type 1 Diabetes

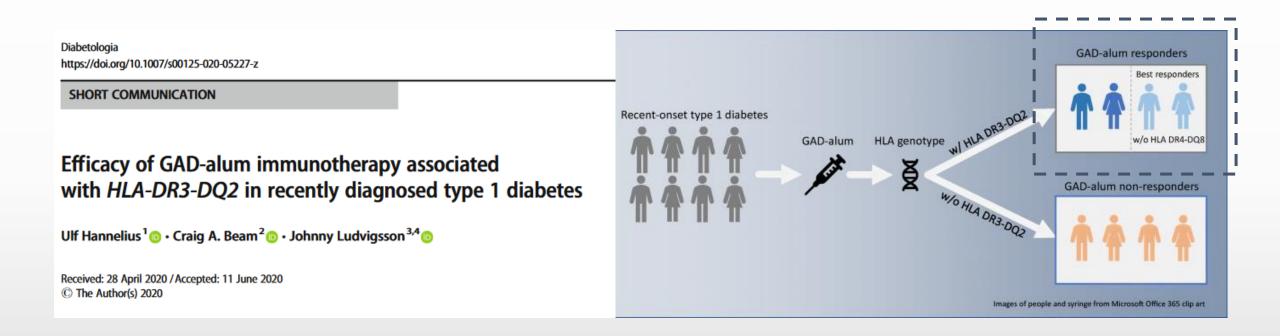
Diabetes Care 2020;43:5-12 | https://doi.org/10.2337/dc19-0880

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}





Responders to Diamyd[®] treatment identified



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 topline results demonstrate significant treatment effect of Diamyd[®] in genetically predefined group of individuals recently diagnosed with T1D

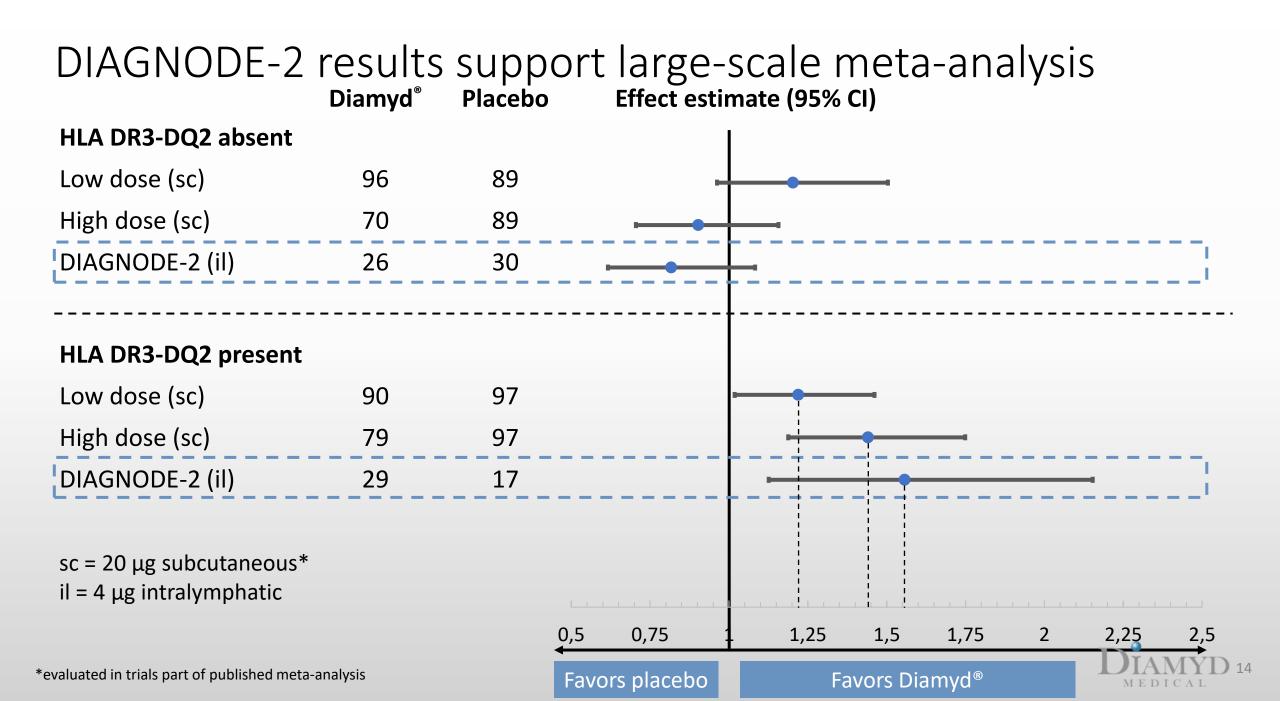


Topline results – significant treatment effect of Diamyd[®] in genetically predefined group

- Phase IIb verified meta-analysis effect of Diamyd[®] was seen in HLA DR3-DQ2 positive individuals. No
 observed effect in individuals negative for HLA DR3-DQ2
- More than 50% greater preservation (p < 0.01) of endogenous insulin production compared to placebo in genetically predefined group
- **Positive trends in important secondary endpoints** (change in HbA1c, insulin dose and insulin-adjusted HbA1c) in genetically predefined group
- No safety concerns
- → Fewer short and long-term complications, easier disease management, improved quality of life

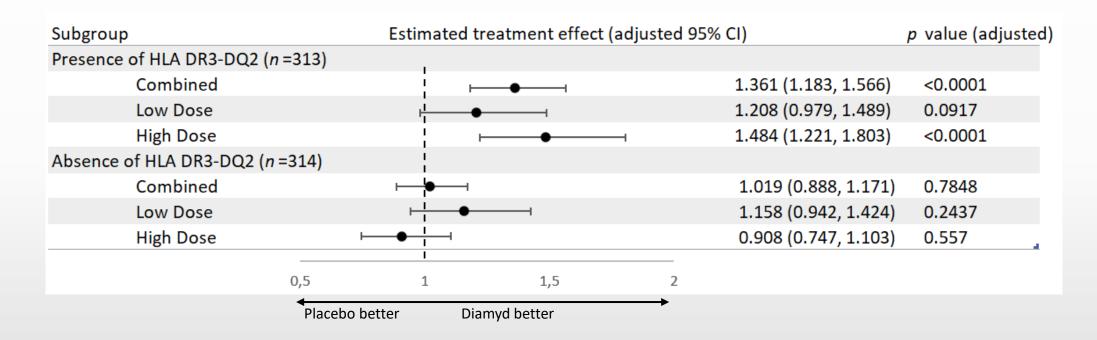
→ Potential to prevent, pathway to a cure





Combined analysis including DIAGNODE-2 further supports precision medicine approach

Meta-analysis based on more than 600 individuals from four placebo-controlled randomized intervention trials (Phase III Europe, Phase II Sweden, Phase II US, Phase IIb Europe)



Low dose = 2 injections; High dose = 3 or 4 injections Treatment effect estimate at 15 months from baseline based on MMRM Note: Preliminary unpublished results



Secondary endpoints in meta-analysis support effect on primary endpoint in DR3-DQ2 individuals

Subgroup	Estimated treatment effect (adjusted 9	Estimated treatment effect (adjusted 95% CI)			
Presence of HLA DR3-DQ2					
Combined	⊢I	-3.229 (-6.170, -0.289)	0.032	H	
Low Dose	⊢	-1.509 (-5.763, 2.746)	0.5268		
High Dose	⊢ 	-4.743 (-8.951, -0.534)	0.0044		
Absence of HLA DR3-DQ2					
Combined	⊢ ∔ _●(1.164 (-1.739, 4.067)	0.2130		
Low Dose	⊢ <u>↓</u>	2.219 (-1.881, 6.321)	0.0684		
High Dose	i −−−−− 1	-0.018 (-4.227, 4.192)	0.7157		

HbA1c (mmol/mol)

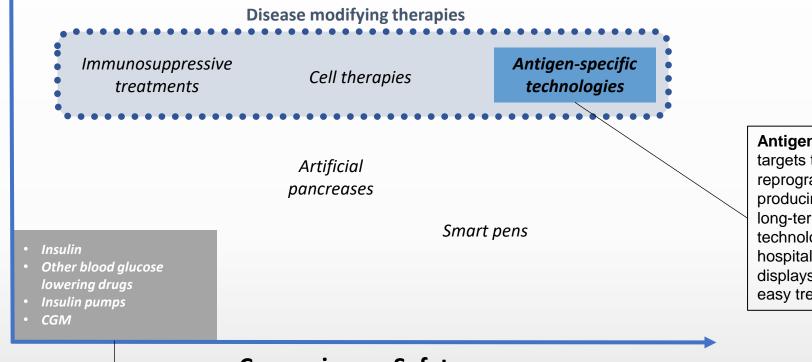
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DICAL

Subgroup	Estimated treatm	ent effect (adjustec	I % CI)	p value (adjusted)	
Presence of HLA DR3-DQ2		:			
Combined	⊢ ●		-0.062 (-0.119, -0.006)	0.03	= + + + + + + + +
Low Dose	⊢ ●	÷	-0.071 (-0.153, -0.010)	0.07	Insulin dose (IU/kg/24h)
High Dose	⊢ ●		-0.054 (-0.134, -0.026)	0.2858	
Absence of HLA DR3-DQ2		1			
Combined		i	0.049 (-0.004, 0.104)	0.0705	
Low Dose			0.023 <mark>(</mark> -0.055, 0.101)	0.8571	
High Dose		•	0.077 (-0.002, 0.156)	0.0576	
		1			
	-0,2 -0,1	0 0,1	0,2		
Subgroup	Estimated tr	eatment effect (adj	usted 95% CI)	p value (adjusted)	
Presence of HLA DR3-DQ2					
Combined	⊢●	ii	-0.453 (-0.851, -0.056)	0.0254	
Low Dose	⊢ ●		-0.369 (-0.944, -0.207)	0.3312	
High Dose	⊢ ●	-1	-0.528 (-1.093, 0.037)	0.0751	IDAAC1
Absence of HLA DR3-DQ2					
Combined		• · · · ·	0.365 (-0.017, 0.746)	0.061	Noto, Drolinsinor,
Low Dose	F	• •	0.392 (-0.157, 0.941)	0.2413	Note: Preliminary
High Dose	H		0.342 (-0.211, 0.894)	0.3624	unpublished results
	-1,5 -1 -0,5	0 0,5 1	1,5		DIAN
	Diamvd better	Placeho hetter	→		MEDIO

Diamyd better Placebo better

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 insulinproducing 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.

Convenience, Safety

Added value compared to standard of care

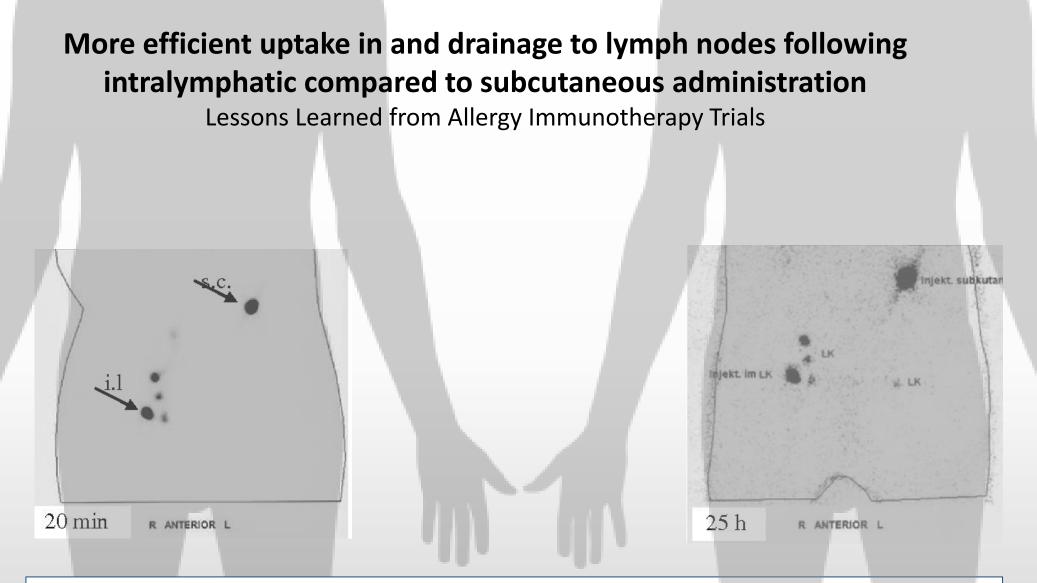
The current **standard treatment** for type 1 diabetes is life-sustaining, subcutaneous deliveries of insulin by injection or pump therapy, combined with continuous glucose monitoring (CGM). In addition to non-insulin anti-diabetic drugs and aids, such as artificial pancreases and smart insulin pens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



Effect, Benefit Added value compared to standard of care

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





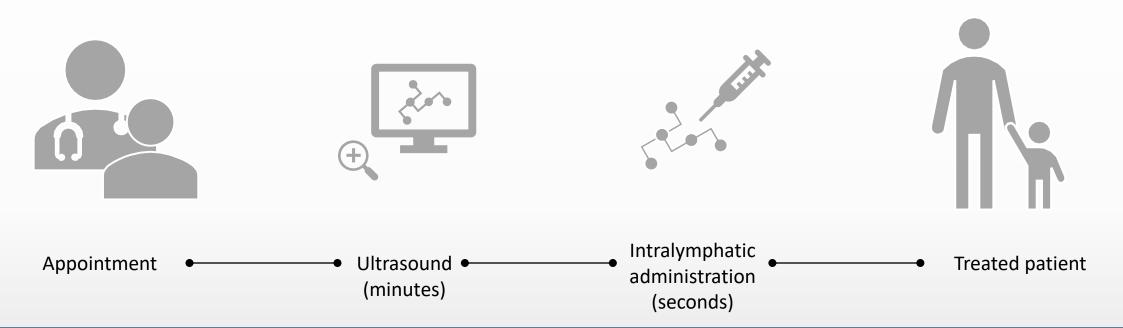
Subcutaneously (S.C.) injected large molecules including proteins do not effectively spread to the draining lymphnodes. Intranodal (I.L.) injections lead to immediate spreading to deeper lymphnodes. The image depicts radio tracing of labeled IgG at 20 minutes and 25 hours after subcutaneous and intranodal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



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



Dose-response relationship

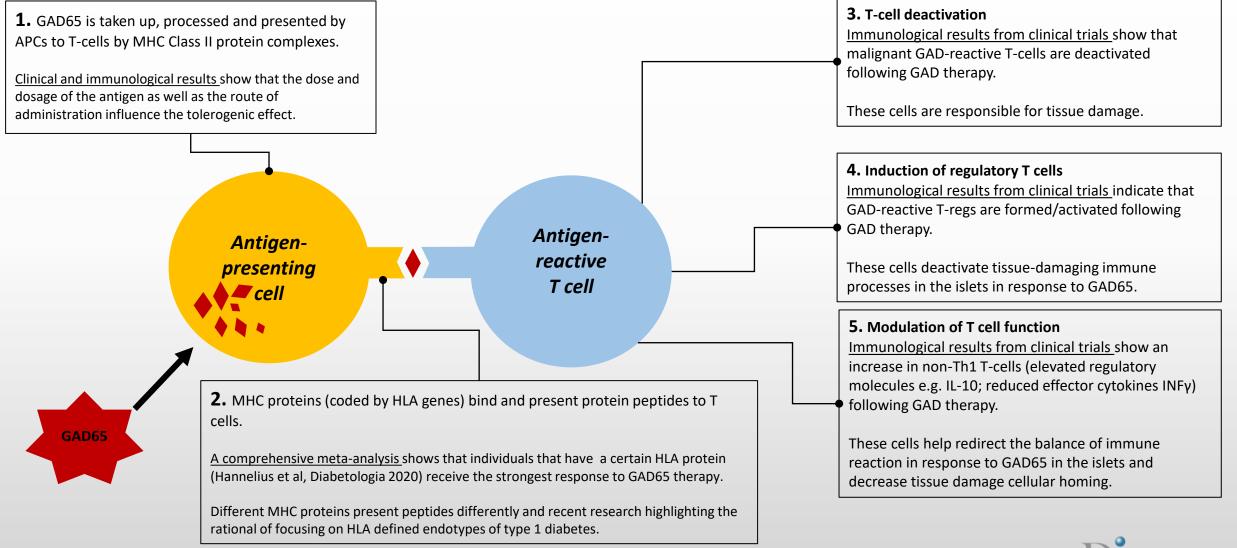
Intralymphatic injections are superior to subcutaneous injections

Comparison of three SC injections vs three IL (Bayesian analysis)

- ightarrow 99% probability that IL is superior to SC regarding C-peptide retention
- \rightarrow 98% probability that IL is superior to SC regarding reduction of HbA1c
- \rightarrow 77% probability that IL is superior to SC regarding reduction of insulin dose
- \rightarrow 97% probability that IL is superior to SC regarding reduction of insulin dose adjusted HbA1c

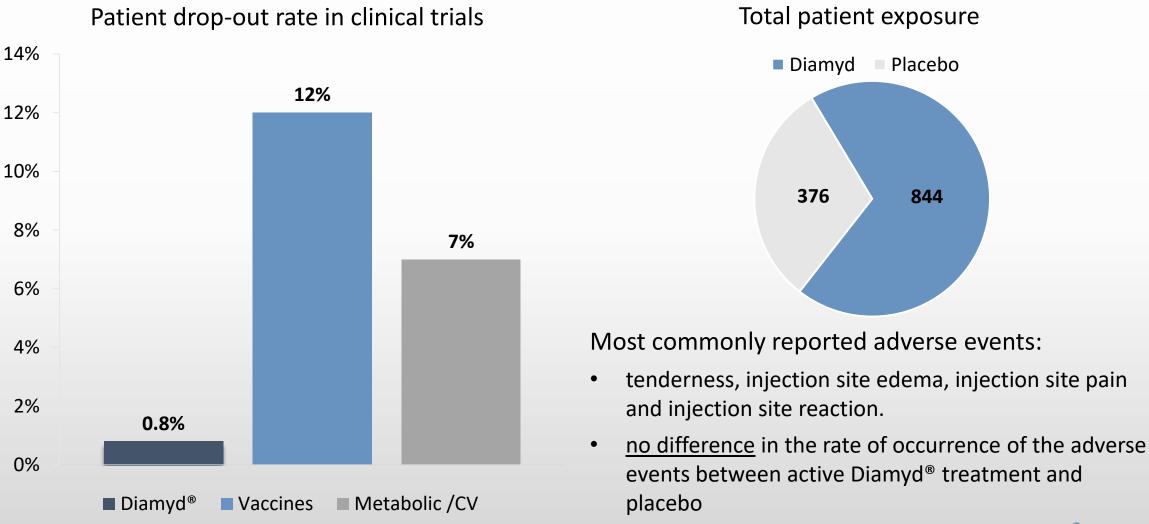


Clinical and immunological results from Diamyd[®] trials support the mechanistic rational for antigen-specific reprogramming of the immune response





Superior safety profile





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

Vaccine Manufacturing – Control and Predictability

- 10,000 square feet site comprising clean rooms, laboratory facilities and office space
- Transferring manufacturing of recombinant GAD65 (active pharmaceutical ingredient in the diabetes vaccine Diamyd[®]) to own facility
- Making Diamyd Medical independent of third parties



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



Comprehensive knowledge ahead of Phase III



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



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 shortand long-term complications
- Prevention of hypoglycemia

Mode of Administration Oral

Development status *Phase Ib/IIa ongoing*

Licensing Status Global rights available

Remygen®





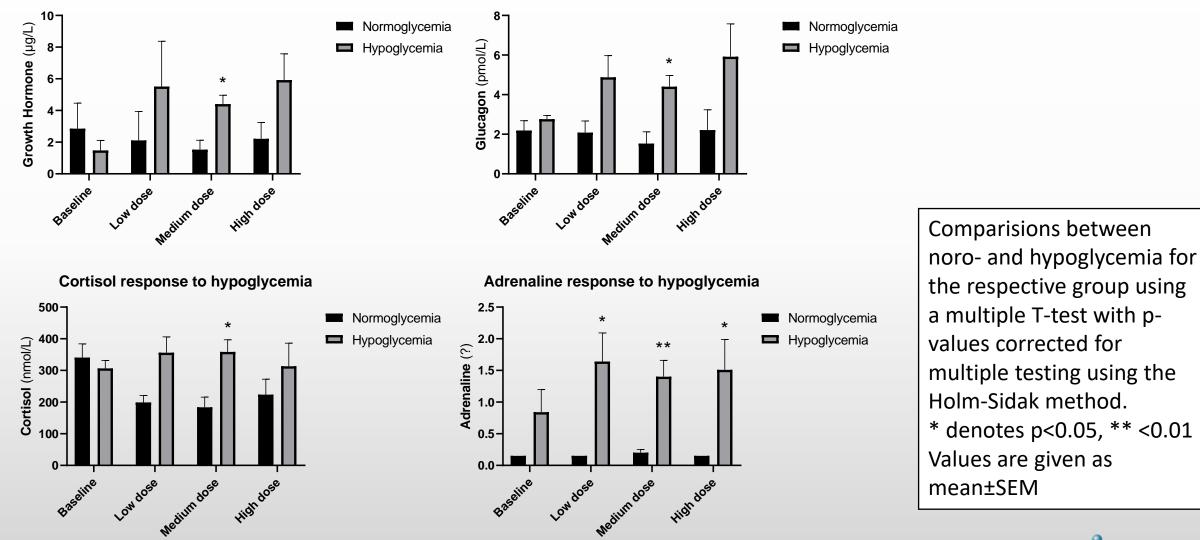
Clinical results with attractive path to market for Remygen®

- 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 longstanding type 1 diabetes patients
- <u>Clinical effects</u> (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*
- <u>Clinical effects of GABA shown on decreasing glucagon secretion in</u> 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



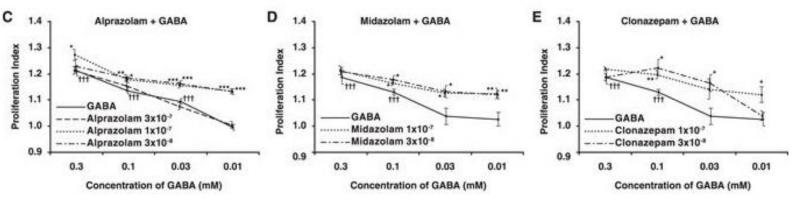
GABA treatment improves the hormonal response to hypoglycemia



Glucagon response to hypoglycemia

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

GH response to hypoglycemia

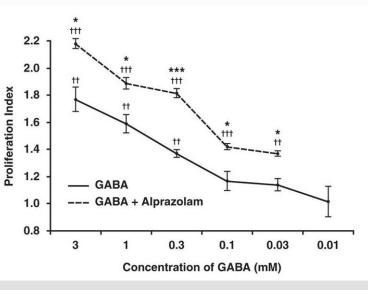


Positive allosteric modulators enhance GABA:s beta cell regenerative effects^{*}

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 ³H 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 < 0.001for 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





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



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, 2020: 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, 2020: 2 556 223 A-shares and 6 333 040 B-shares. 1 590 000 B-shares via an endowment insurance.



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, 2020: 263 998 Bshares.



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, 2020: -



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, 2020: 6 750 Bshares



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, 2020: 147 666 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, 2020: 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, 2020: -



Maja Johansson Facility Manager

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, 2020: -



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, 2020: -



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 alumformulation of GAD was

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 Feb 8, 2021 ~ MSEK 1 800
- Cash Nov 30, 2020: MSEK 173

INDICATIONS

- Diabetes
- Autoimmunity

PRODUCT CANDIDATES

- Diamyd[®] (Phase IIb)
- Remygen[®] (Phase lb/lla)

INVESTMENT

• Next Cell Pharma (Stockholm, Sweden)





Diamyd Medical www.diamyd.com

