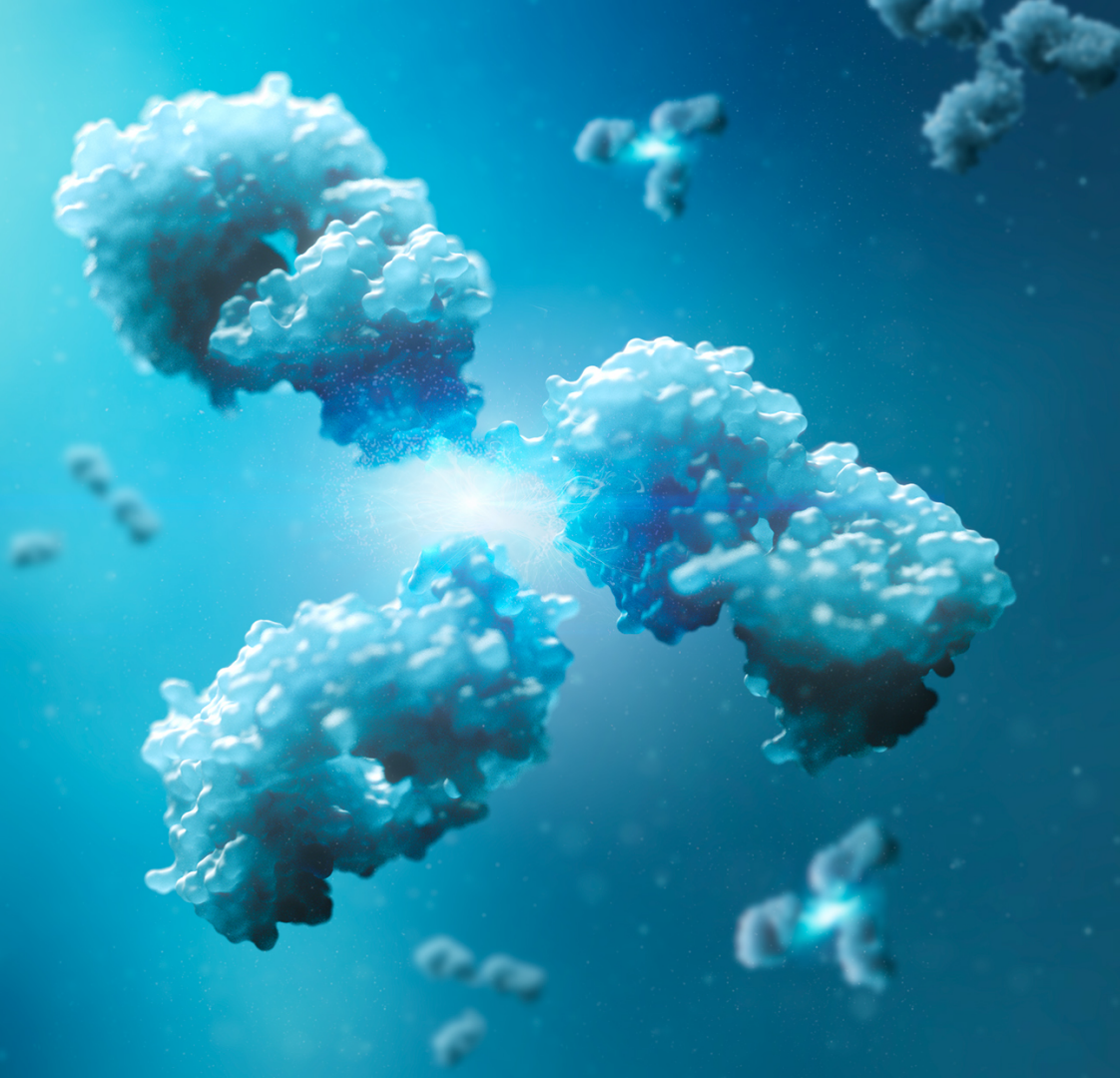
Hansa Medical

October 3-4, 2017
Capital Markets Days
Stockholm and London



Forward-looking statements

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Hansa Medical's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of Hansa Medical's strategy and its ability to further grow, risks associated with the development and/or approval of Hansa Medical's products candidates, ongoing clinical trials and expected trial results, the ability to commercialize IdeS, technology changes and new products in Hansa Medical's potential market and industry, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

No assurance can be given that such expectations will prove to have been correct. Hansa Medical disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Agenda

12:00	Welcome	
	Introduction Hansa Medical	CEO Göran Arvidson
	Overview to HMED pipeline	SVP Christian Kjellman
	The potential of IdeS as treatment of antibody-mediated disorders	Dr Stanley Jordan & Dr Tomas Lorant
	Q&A	
	Light lunch	
	IdeS – a potential game changer in transplantation	VP Lena Winstedt
	The path to approval	VP Sam Agus
	Transplantation market outlook	VP Emanuel Björne
	Commercialization strategy in transplantation	VP Henk Doude van Troostwijk
	IdeS beyond desensitization – Potentially an even greater opportunity	SVP Christian Kjellman
	Novel IgG-cleaving enzymes under development	SVP Christian Kjellman
	Q&A	
14:30	Closing remarks	CEO Göran Arvidson

Presenters

Göran Arvidson
President and CEO

Christian Kjellman
SVP, Research and Development

Stanley Jordan
Professor Cedars Sinai Medical Center, Los Angeles

Tomas Lorant
Associate Professor, Uppsala University

Lena Winstedt
VP, Project Management

Sam Agus
VP, Chief Medical Officer

Emanuel Björne
VP, Business Development and IR

Henk Doude van Troostwijk
VP, Commercial Operations

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Introduction

Göran Arvidson, President and CEO

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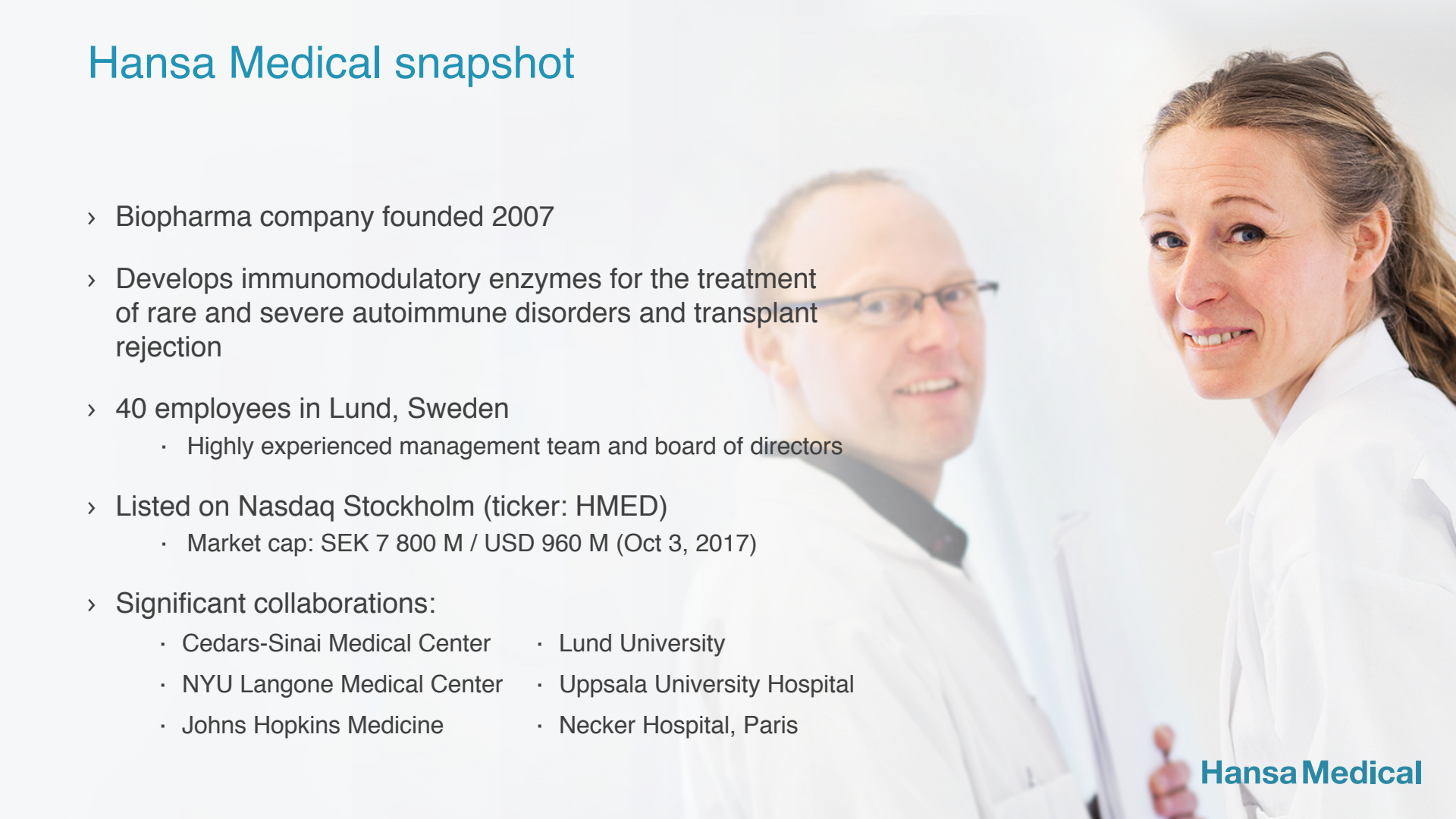
Hansa Medical snapshot



- Biopharma company founded 2007
- Develops immunomodulatory enzymes for the treatment of rare and severe autoimmune disorders and transplant rejection
- 40 employees in Lund, Sweden
  - Highly experienced management team and board of directors
- Listed on Nasdaq Stockholm (ticker: HMED)
  - Market cap: SEK 7 800 M / USD 960 M (Oct 3, 2017)
- Significant collaborations:
  - Cedars-Sinai Medical Center
  - NYU Langone Medical Center
  - Johns Hopkins Medicine
  - Lund University
  - Uppsala University Hospital
  - Necker Hospital, Paris

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Where are we today?

Investment to date:
~600 MSEK

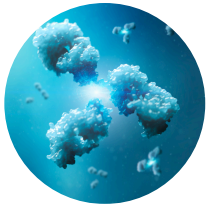
Cash today[1]:
SEK 131 m

- **Clinical success** with transplantation indications in several clinical and non-clinical studies, with **42 patients** treated prior to actual transplantation
- 5 anti-GBM patients treated
- Positive **pre-clinical results in autoimmune indications** (anti-GBM and GBS) as well as for EnzE
- Built up and established the **company organization** with systematic approach to R&D, Regulatory, Medical, Marketing, IP governance and IR – **39 co-workers**

Share price:
+ ~560%
since Capital Market Day 2015

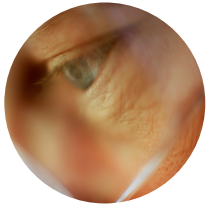
1) Cash position and short-term investments

Breakthrough therapy for rapid inactivation of IgG antibodies



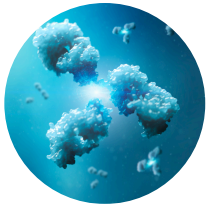
IgG-modulating enzymes – A novel mode-of-action

Significant unmet need



Clinical proof-of-concept demonstrated in several clinical studies

Breakthrough therapy for rapid inactivation of IgG antibodies

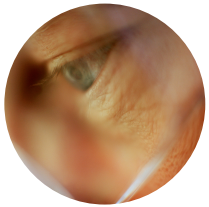


IgG-modulating enzymes – A novel mode-of-action

› IgG antibody modulating enzymes – IdeS, NiceR and EndoS
› Lead candidate IdeS in Phase II
› Strong IP protection, Orphan Drug Designation and PRIME

Significant unmet need

› Unmet medical need across a number of acute IgG-mediated autoimmune diseases
› Initial focus on inactivating antibodies prior to transplantation



Clinical proof-of-concept demonstrated in several clinical studies

› Two Phase II finalized and a third investigator sponsored study is ongoing in the US
› Phase II data published in The New England Journal of Medicine, August 3, 2017
› Highdes multicenter study ongoing – Potential filing 2018

Hansa Medical roadmap

Approval for pre-treatment of sensitized patients and immediate go-to-market

Proof of concept for related indications – short-term focus on a few indications, while expectation is broad applicability

Development of improved endopeptidases
(Novel immunoglobulin-cleaving enzymes for repeat dosing, NiceR)

Overview to HMED pipeline

Christian Kjellman, Senior Vice President,
Research and Development

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Pipeline with blockbuster potential

Candidate / Method / Project	Indication	Research / Preclinical	Phase I [1]	Phase I/II	Phase II	Pivotal	Registration
THERAPEUTICS							
IdeS	Kidney transplantation in sensitized patients [2]						
	Other kidney transplant indications (ABMR, ABOi) [3]						
	Anti-GBM antibody disease						
	Other acute autoimmune diseases [4]						
NiceR	Recurring treatment in autoimmune disease						
EndoS	Autoimmune disease						
EnzE	Cancer immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD)	Prediction of severe sepsis [5]						

Note: 1) Present and future IdeS Phase II studies to be based on the same Phase I study. Results from the Phase I study have been published, Winstedt el al. (2015) PLOS ONE 10(7). 2) Two separate Phase II studies with IdeS in sensitized patients are currently ongoing. 3) Phase II studies in antibody mediated rejection (ABMR) post kidney transplantation and blood-group incompatible (ABOi) kidney transplantation are being planned. 4) Phase II studies in rare autoimmune conditions like GBS are being planned. 5) Out-licensed to Axis-Shield Diagnostics Ltd

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A novel approach to rapidly eliminate pathogenic IgG

IdeS is an immunomodulatory, bacterial enzyme of Streptococcus pyogenes that specifically cleaves IgG[1]

- IdeS cleaves all forms of IgG: free, bound to antigen and membrane bound
- IdeS has no activity on IgM, IgD, IgE, nor IgA
- IdeS has selective species specificity
- Cleaves IgG below the hinge region
  - Glu-Leu-Leu-Gly236↓Gly-Pro
- Generates one F(ab')2 and one dimeric Fc fragment

Single cleaved IgG (scIgG)

Note: 1) Winstedt el al. (2015) PLOS ONE 10(7)

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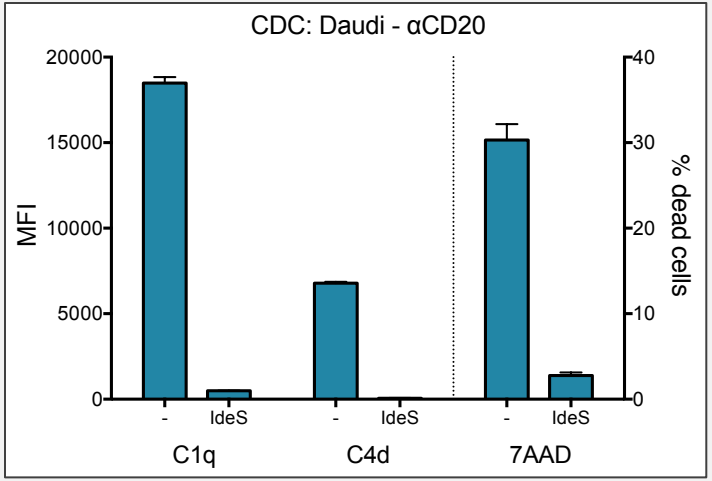
IdeS deletes all Fc-mediated functions of IgG[1]

Mechanism of action

› IdeS treatment inhibits Fc-mediated activities i.e.:
  - ›IgG-dependent complement deposition
  - ›IgG-mediated antibody-dependent cell cytotoxicity (ADCC)
  - ›IgG-mediated phagocytosis



Note: 1) Winstedt el al. (2015) PLOS ONE 10(7)

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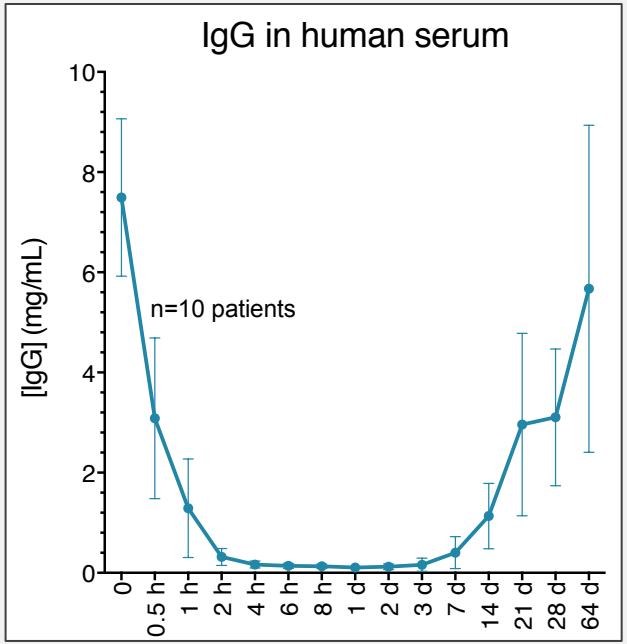
IdeS effectively and rapidly degrades IgG[1]

Proposed value proposition

For targeted indications

- Very effective inactivation of IgG
  - Pathogenic as well as non-pathogenic
  - Circulating as well as bound IgG
- Rapid onset
- An antibody-free window for approximately a week
- Ease of use and availability – administered as a single dose, off-the-shelf therapy



Note: 1) Winstedt el al. (2015) PLOS ONE 10(7)

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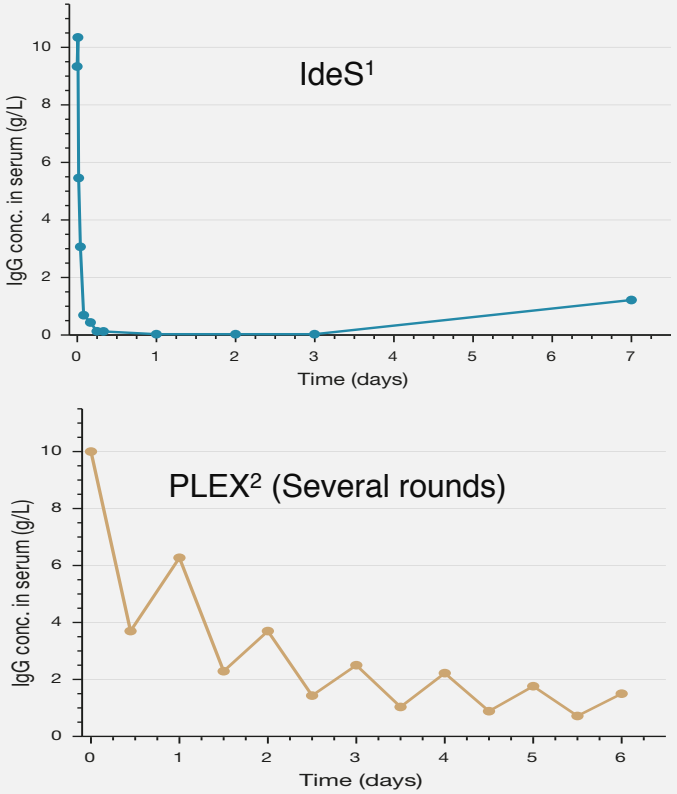
Advantages with IdeS over plasma exchange

- One dose of IdeS rapidly inactivates IgG
- Plasma exchange requires repeated cycles, usually one round per 1 or 2 days
- IdeS extraordinary effectiveness and speed constitutes a new treatment opportunity in several transplant situations and acute autoimmune diseases today treated with plasma exchange



Note: 1) Winstedt et al. PLOS One 2015. 2) Adopted from Ismail et al., Plasmapheresis in Handbook of dialysis. Philadelphia: Lippincott Williams Wilkins. Pp. 231-262

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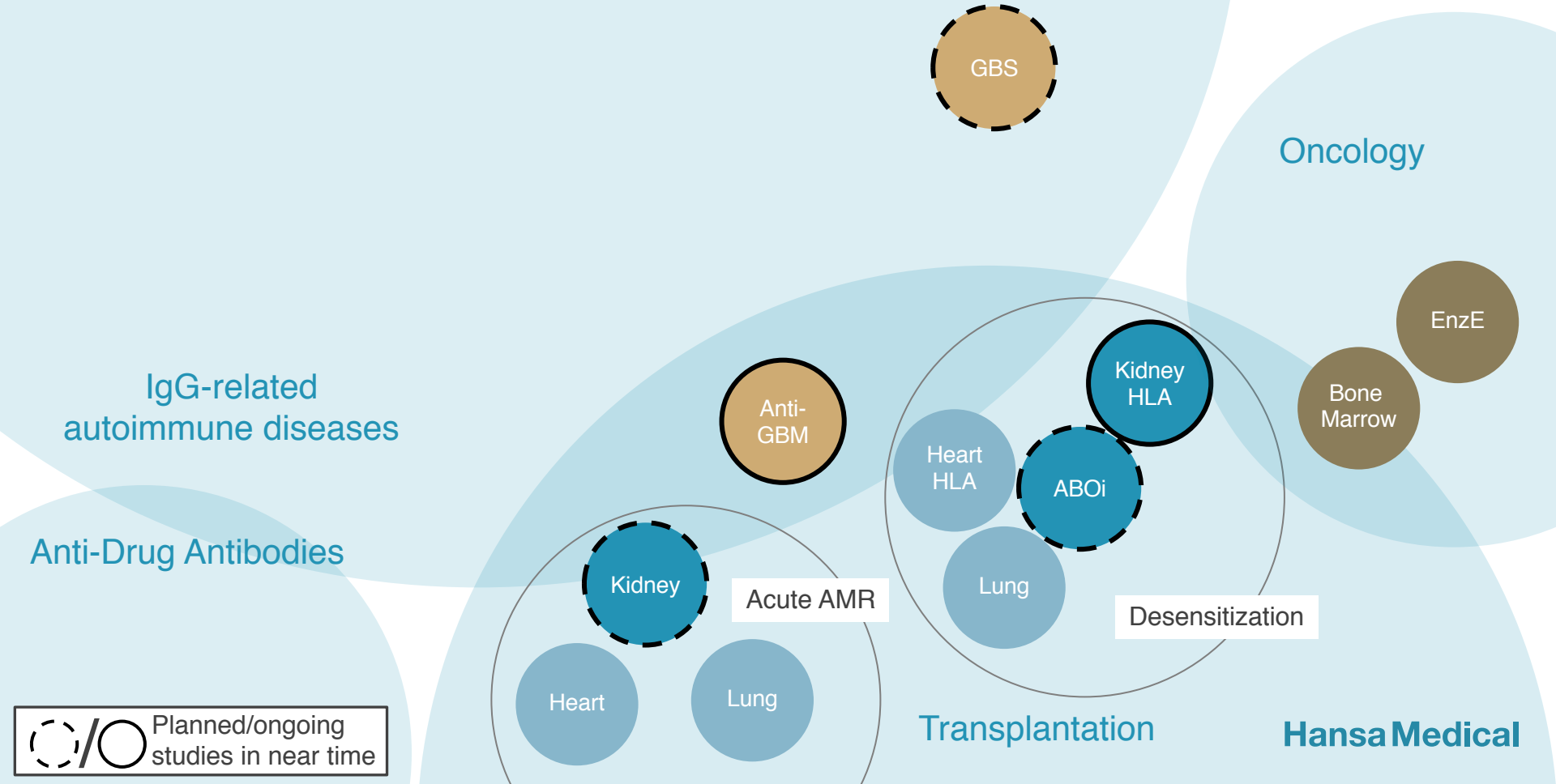
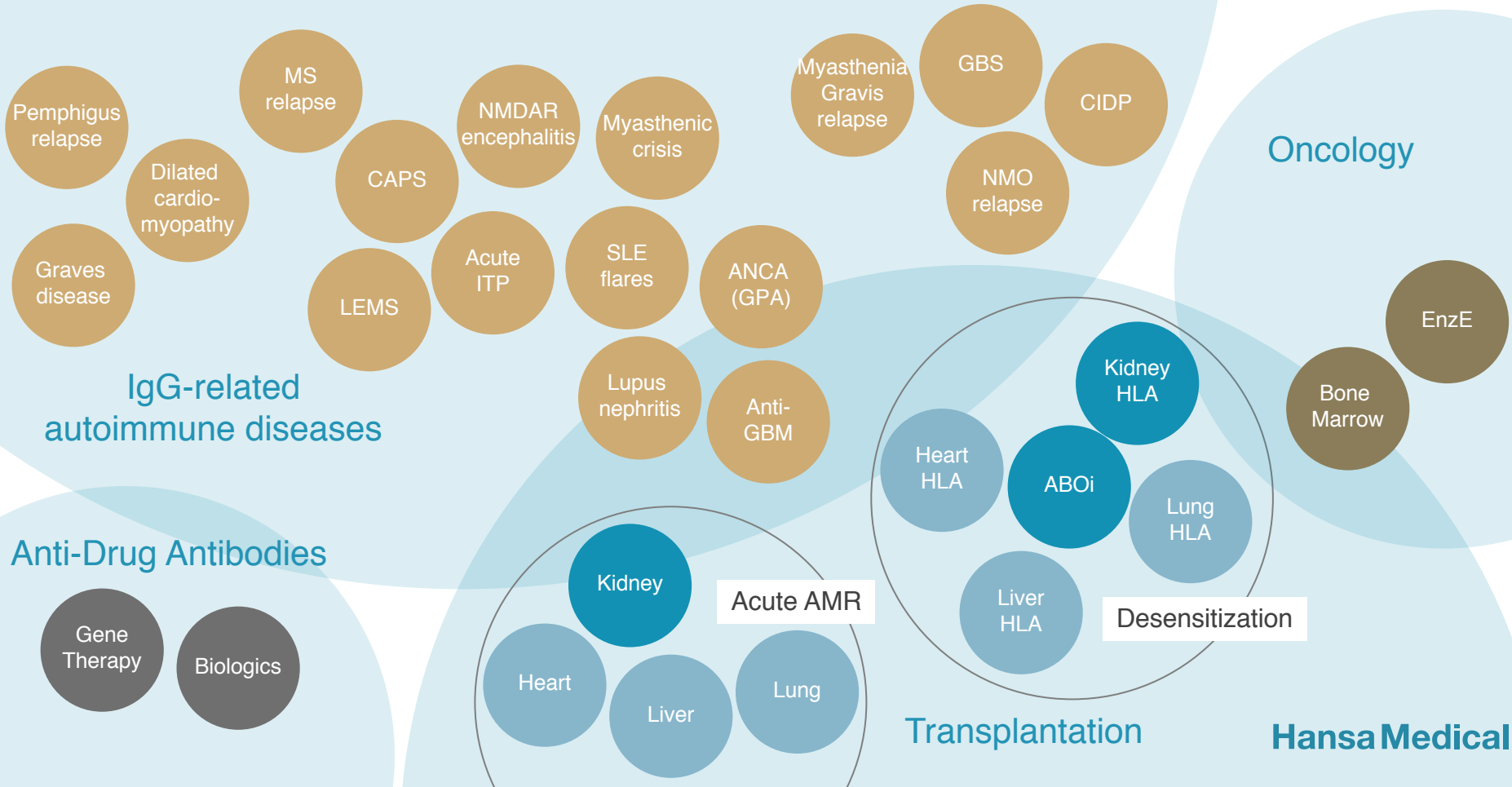
Near term focus



Potential to revolutionize acute care



The potential of IdeS as treatment of antibody-mediated disorders

Guest speakers: Dr Stanley Jordan & Dr Tomas Lorant

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Q & A

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IdeS – a potential game changer in transplantation

Lena Winstedt, Vice President
Project Management

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IdeS – a potential game changer in transplantation

Enabling transplantation for sensitized patients

› Patients with anti-HLA antibodies are called sensitized patients

› Presence of donor specific anti-HLA antibodies is a contraindication for transplantation

› At least 30% of patients on transplantation waitlists are sensitized

Enabling blood-group independent transplantation

› Blood group incompatible donor-recipient pairs can only be transplanted if antibodies against blood group antigens are removed prior to transplantation

Treatment of antibody mediated rejection post transplantation

› 10–15% of all transplanted patients experience an episode of acute AMR

IdeS development in transplantation is going according to plan

Study	Subjects	Status	Patients incl. in NEJM
Phase I (SWE)	29 healthy subjects	• Completed 2014	
Phase II (SWE)	8 sensitized patients	• Completed 2015	1 patient
Phase II (SWE)	10 sensitized patients	• Completed 2016	10 patients
Phase II (USA)	20 sensitized patients	• Ongoing: 18/20 patients included	14 patients
Multicenter Phase II	20 patients with positive cross match to donor	• Ongoing: 14/20 patients included	

The NEW ENGLAND JOURNAL of MEDICINE

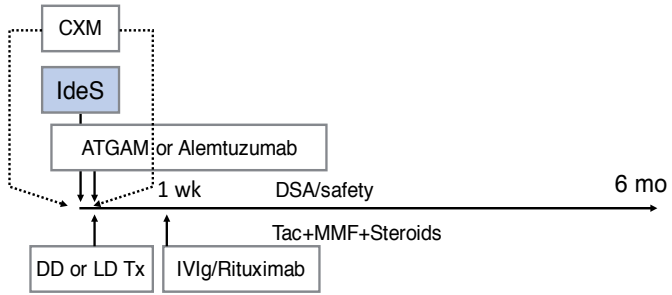
Study outline: Highdes 06-study (phase II) – Ongoing

Study outline

- Primary objective
  - IdeS efficacy in creating a negative crossmatch test
- Secondary objectives
  - DSA levels
  - Time to negative crossmatch
  - Safety parameters and kidney function
  - PD, PK, ADA
- 1(-2) doses
  - 0.25 (0.5) mg/kg
- Per-protocol medication
  - IVIg (d7)
  - Rituximab (d9)
  - ATGAM or Alemtuzumab induction
  - Loratadin (d1)
  - Corticosteroids (d1)
- 6 months follow up

Patient population

- 20 crossmatch positive patients with LD or DD. Patients have previously undergone desensitization unsuccessfully or effective desensitization will be highly unlikely
- Multicenter



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CMC overview

Status

- Drug substance (DS) / drug product (DP) currently used for clinical trial is a frozen 10 mg/mL solution
- The DS and DP processes have been developed and transferred to manufacturers suitable for commercialization
- The DP will be a lyophilized product

Ongoing and planned

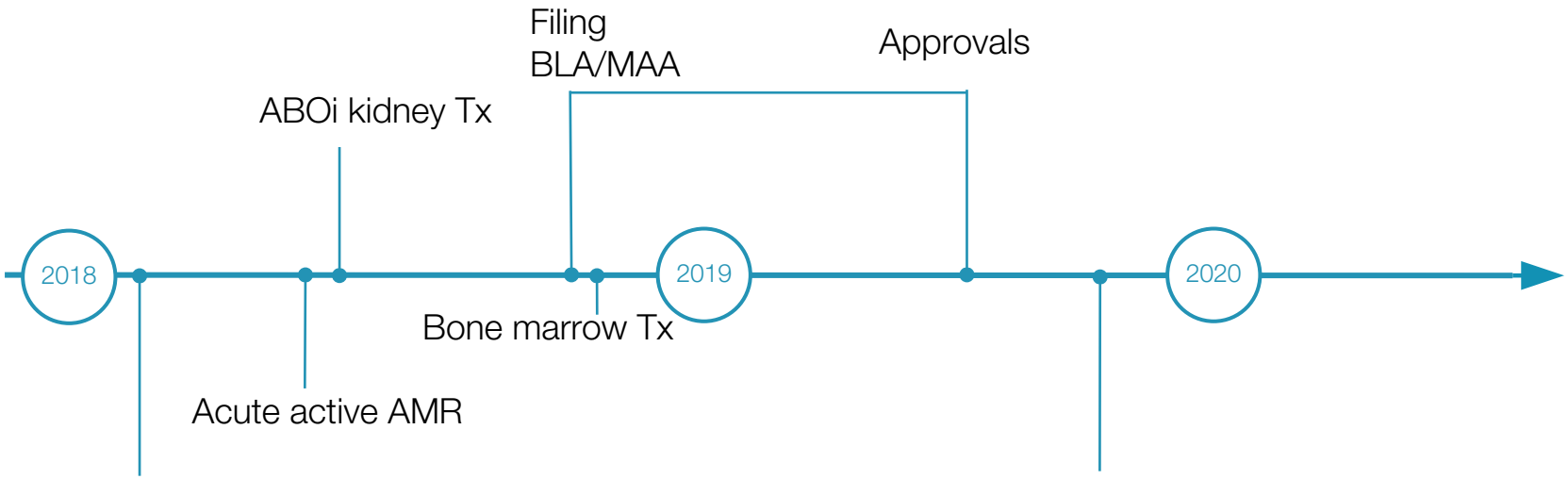
- First GMP batch for clinical trials and commercial supply to be produced in October 2017
- Process characterization and validation for commercial is scheduled to be completed in Q3 2018

Promising results for transplantation

- 42 patients treated with IdeS prior to kidney transplantation[1] in 02-, 03-, 04- and 06- studies
- IdeS has made all highly sensitized patients eligible for transplantation
  - Allows desensitization for transplants from deceased donors
  - Inactivates DSA
  - Converts positive crossmatches to negative
  - IdeS has been safe and well tolerated
- Good kidney function after follow up period
- Several recent regulatory milestones achieved:
  - Granted EU SME designation Q1 2017
  - Obtained orphan drug status in EU Q1 2017
  - Granted access to EMA PRIME scheme Q2 2017

Note: 1) Additional patients have been treated with IdeS but without subsequent transplantation

Getting closer to approval for transplantation



Observational study

› Follow-up study to understand long-term outcome
› ~60 pat. (previously treated)

The path to approval

Sam Agus, Chief Medical Officer

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Pre-transplant treatment to make patients with donor-specific IgG eligible for transplantation

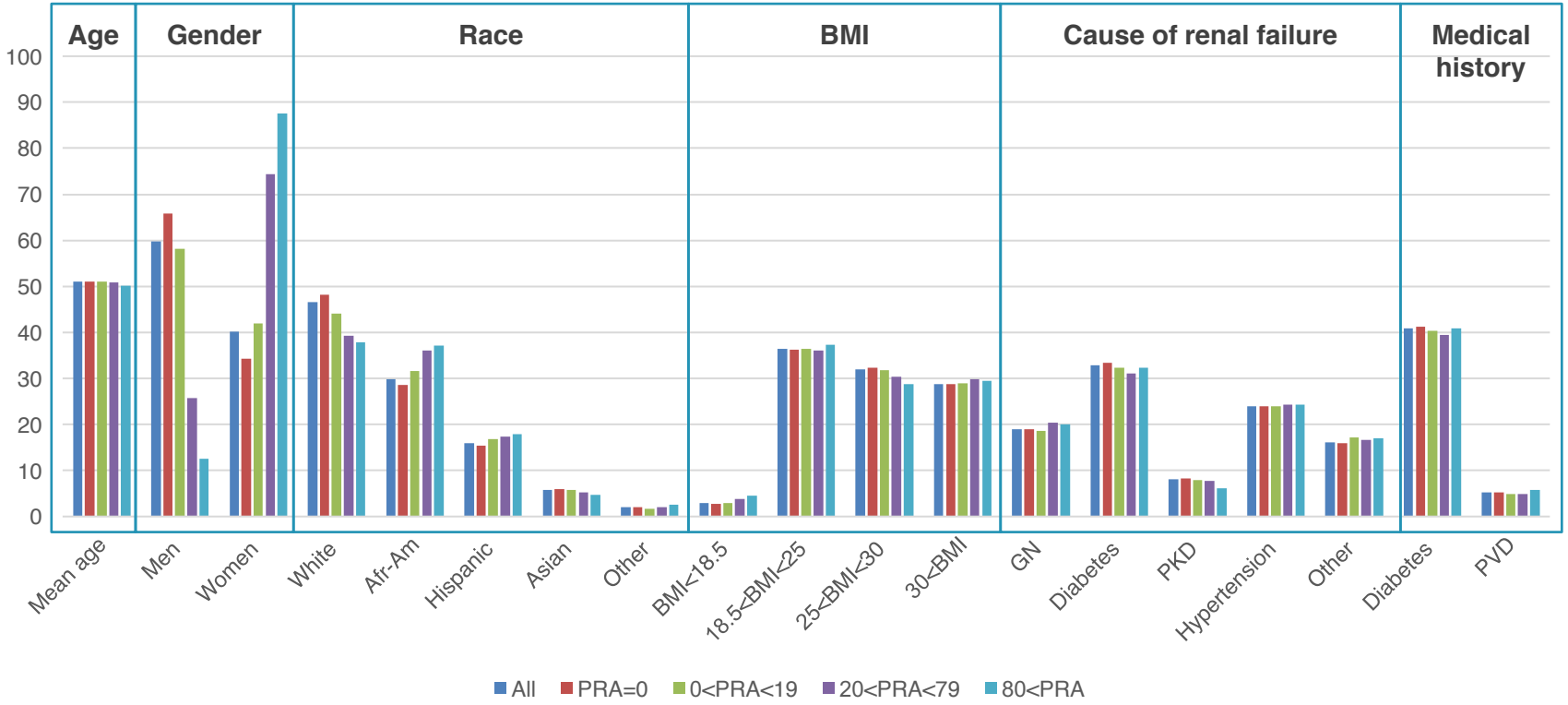
The current situation is:

- Guidelines and standards exist – but interpretation and implementation depend on clinical judgement, which is highly variable
- Measurements are service dependent – they depend on the experience and expertise of that service and reflect the approach of the service towards a given treatment paradigm

The unmet need is:

- Be able to manage the patients who are sensitized – individually
- This need could be addressed by an easy to use and robust de-sensitization method – combined with robust data collection that enables assessment and management of risk for the patient and in the system

Who is the highly sensitized patient?



Note: UNOS data 2000-2009, based on: Sapir-Pichhadze et al., J Am Soc Nephrol 27: 570–578, 2016

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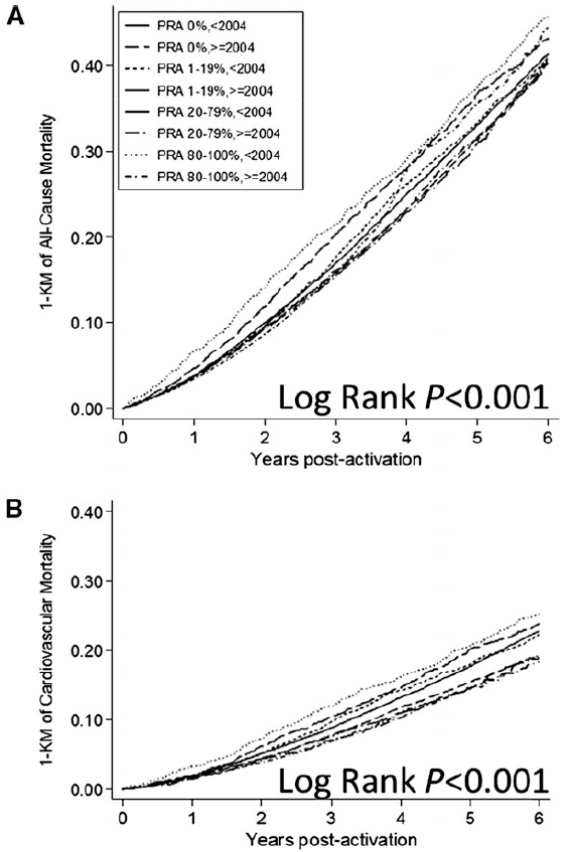
The implication of being with a highly-sensitized state

Table 4. Estimated number of match runs needed to have a 95% probability of finding an acceptable donor based on candidate cPRA

cPRA, %	Theoretical number of match runs to have a 95% chance of finding an acceptable donor
10	2
20	2
30	3
40	4
50	5
60	6
70	9
80	14
85	19
90	29
95	59
99	300
99.5	600
99.9	3000
99.99	30,000
99.999	300,000

cPRA, calculated panel-reactive antibody.



Source: Keith and Vranic, Clin J Am Soc Nephrol 11: 684–693, 2016; Sapir-Pichhadze et al., J Am Soc Nephrol 27: 570–578, 2016

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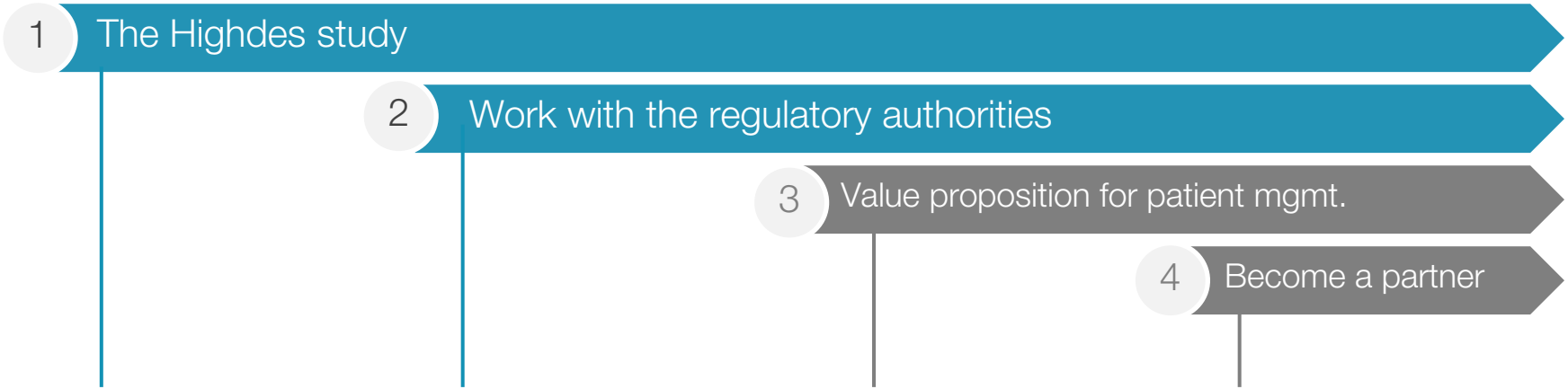
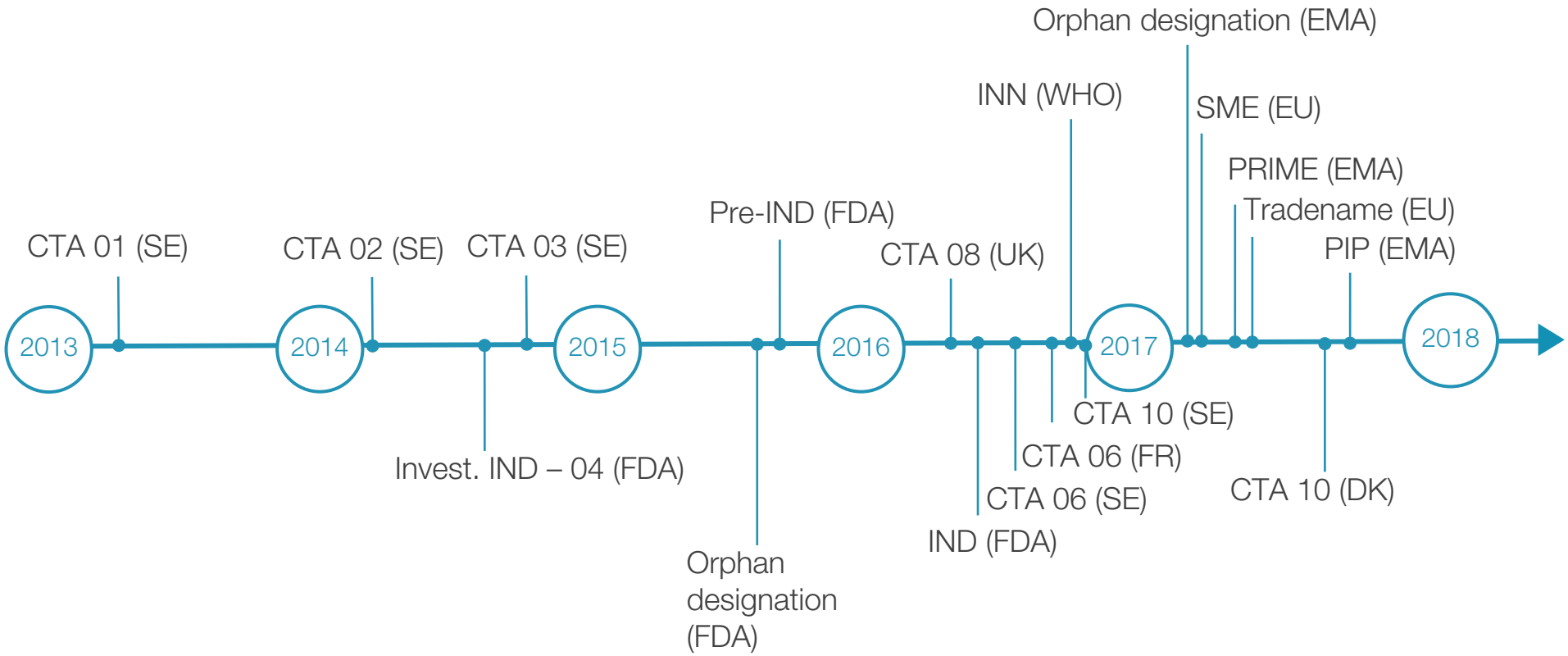
Our approach



Overview of regulatory interactions



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Regulatory interactions

Transplantation market outlook

Emanuel Björne, Vice President Business Development and IR

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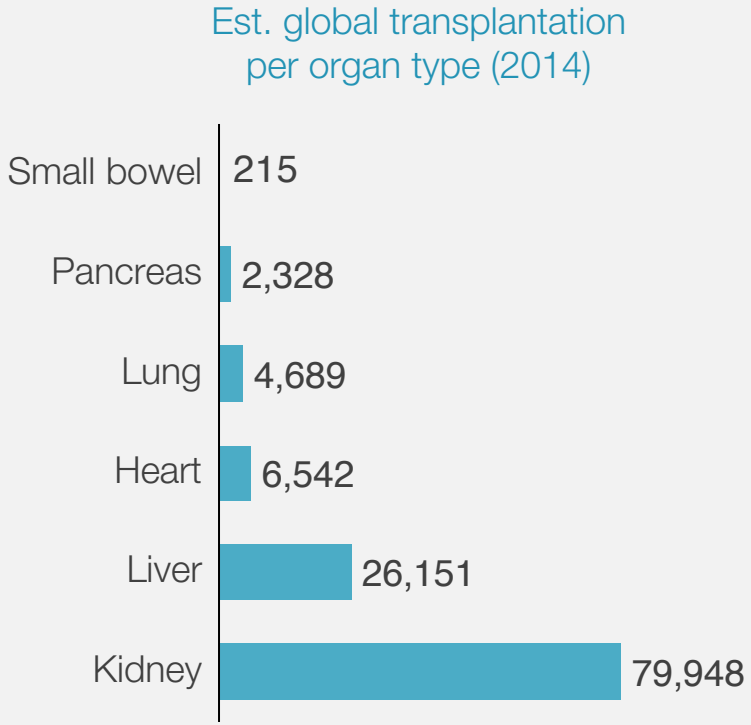
High unmet need for solid organ transplants

- c.120,000 solid organs were transplanted globally in 2014, annual increase of 1.8%
- Chronic Kidney Disease 9th leading cause of death in the US
- Less than 10% of global need is met
- Transplant rates vary globally, while there is a widespread shortage of deceased donors



Source: Organ Procurement and Transplantation Network (OPTN), Organ Donation and Transplantation Activities 2014, Global Observatory on Donation and Transplantation, National Vital Statistics Reports Vol. 65 No. 4

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HLA Sensitized Patients

Meaning

› anti-HLA antibodies to potential donors

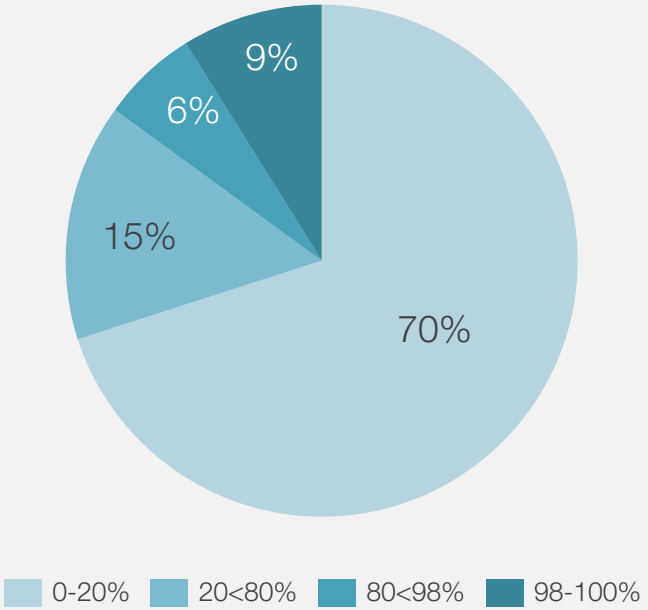
› anti-HLA antibodies due to pregnancy, earlier transplant or blood transfusion

Prevalence

› 30% of patients on transplant waitlists are sensitized[1,2]

PRA levels on kidney transplant wait-list

Panel Reactive Antibodies, 0-100%, a measure of broadness of sensitization



Note: 1) Jordan et al. British Medical Bulletin, 2015, 114:113-125
2) Orandi et al. NEJM, 2016;374:940-50

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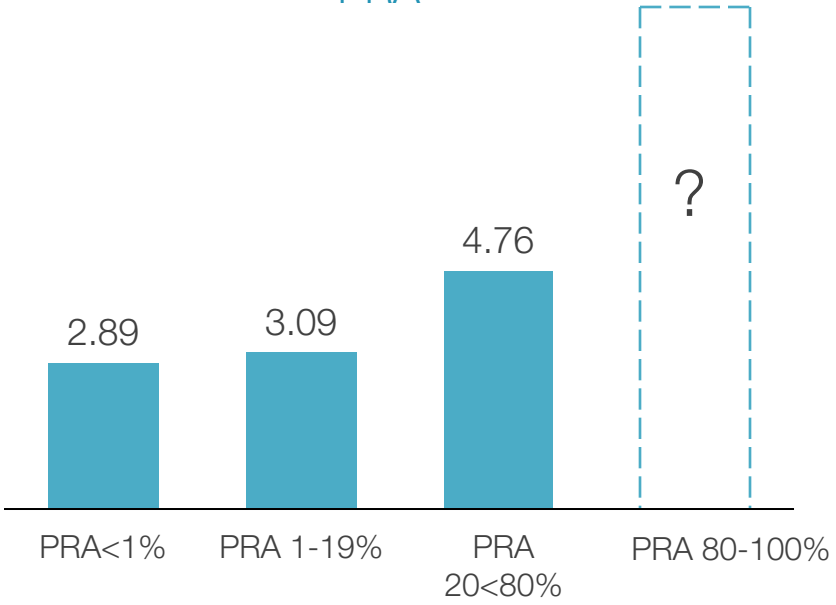
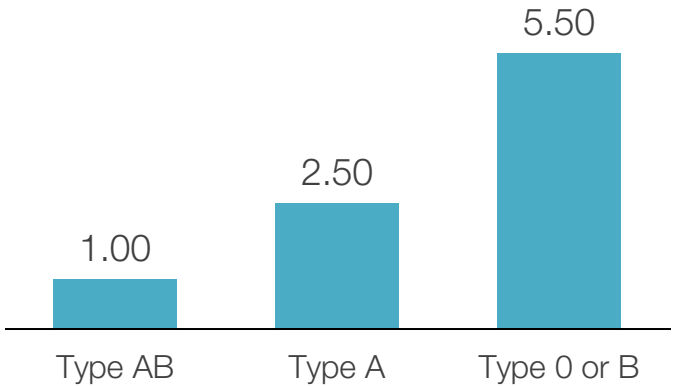
Median years on kidney transplant waitlist (US)

HLA-sensitized patients by PRA[1,2]



By blood type[2]



Note: 1) US OPTN /SRTR 2012, 2011 Annual Data. 2) Primary research

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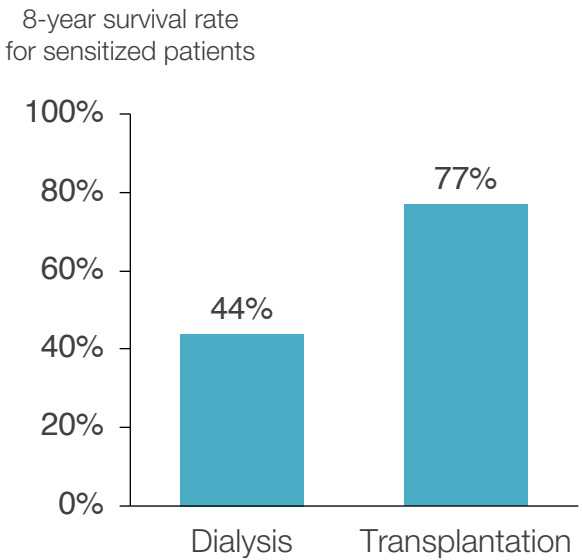
The importance of desensitization

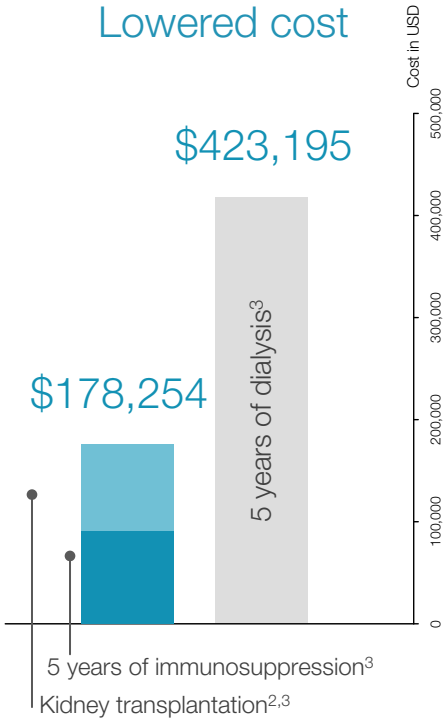
Avoiding complications

› Long-term dialysis results in cardiovascular complications

Increased survival rate[1]



Lowered cost



Note: 1) Orandi et al, NEJM, 374;10, March 10, 2016. 2) www.usrds.org. 3) Shehata et al., Transfus Med Rev. 2010;24 Suppl 1: S7–S27

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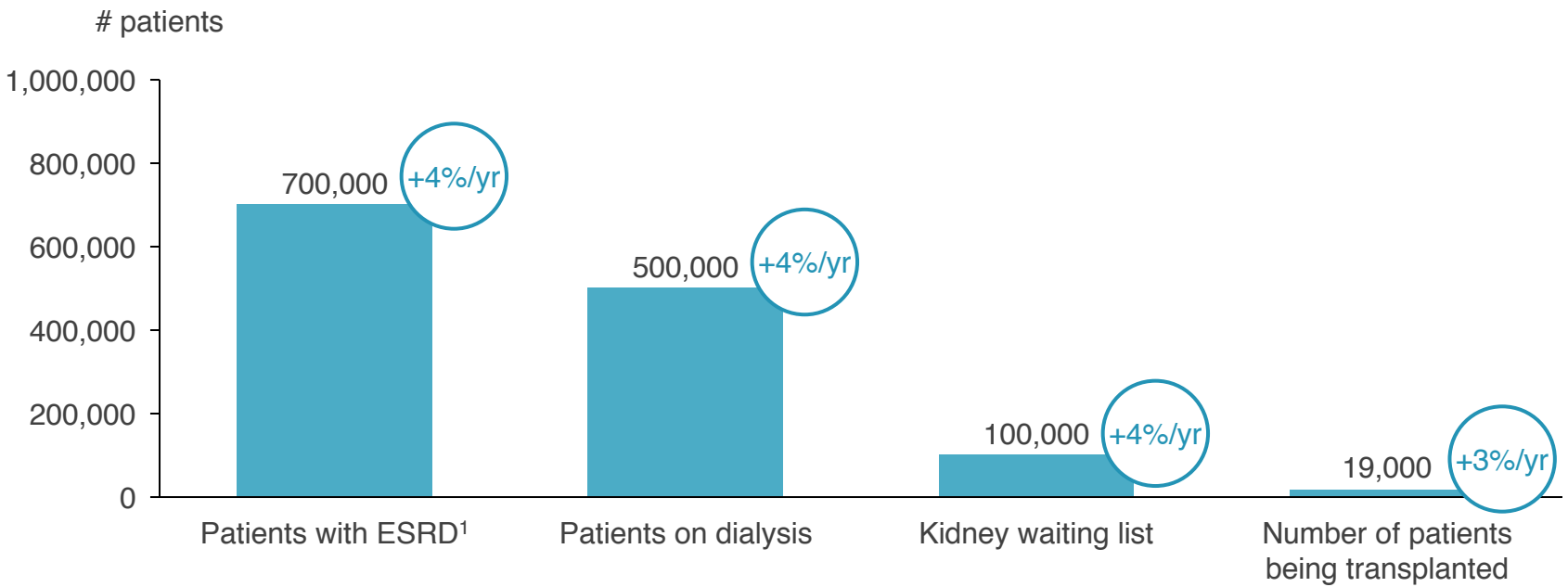
High medical need for IdeS

Build up of patients in need of kidney transplantation in the US



Source: USRDS Annual Data Report 2016, US HHS Organ Procurement and Transplantation Network
Note: 5-year CAGRs (until 2016 for waiting list and transplantations; 2014 for rest). 1) End stage renal disease

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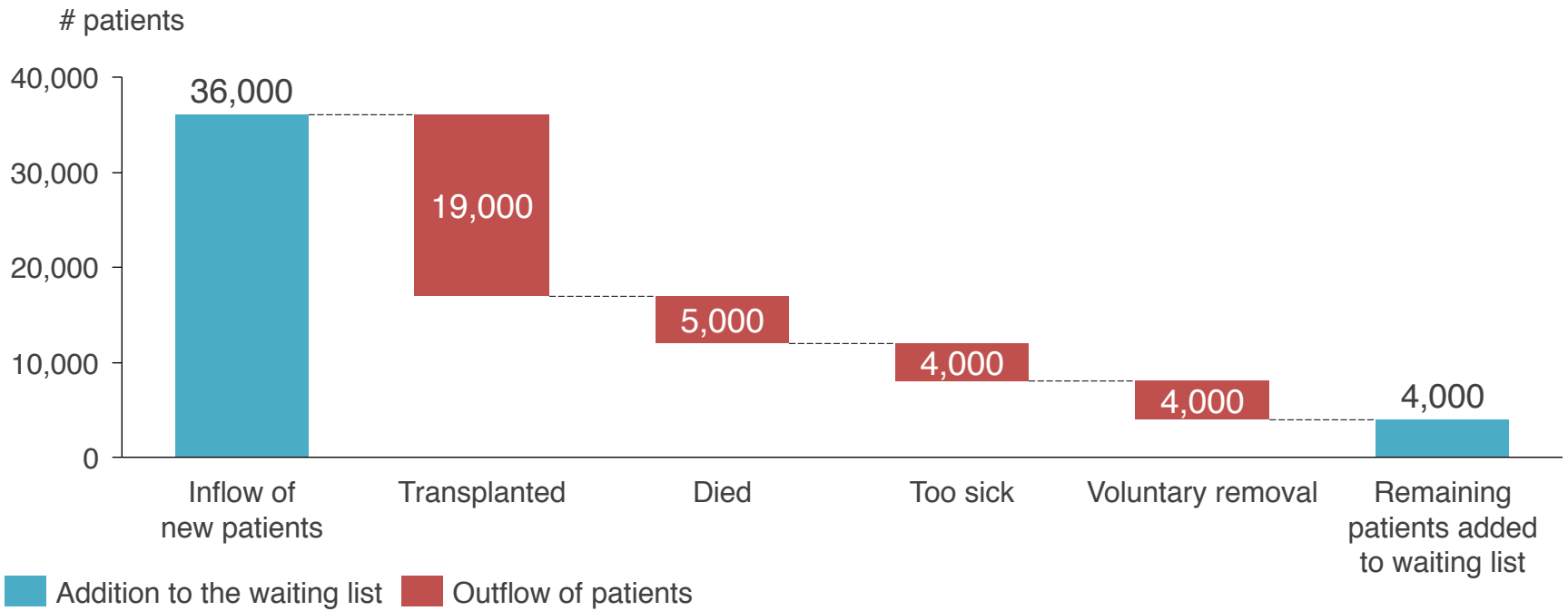
High medical need for IdeS

Dynamics of patients on waiting list for a kidney transplantation in the US[1]



Source: US HHS Organ Procurement and Transplantation Network. Note: 1) 5-year mean numbers, 2011-2016

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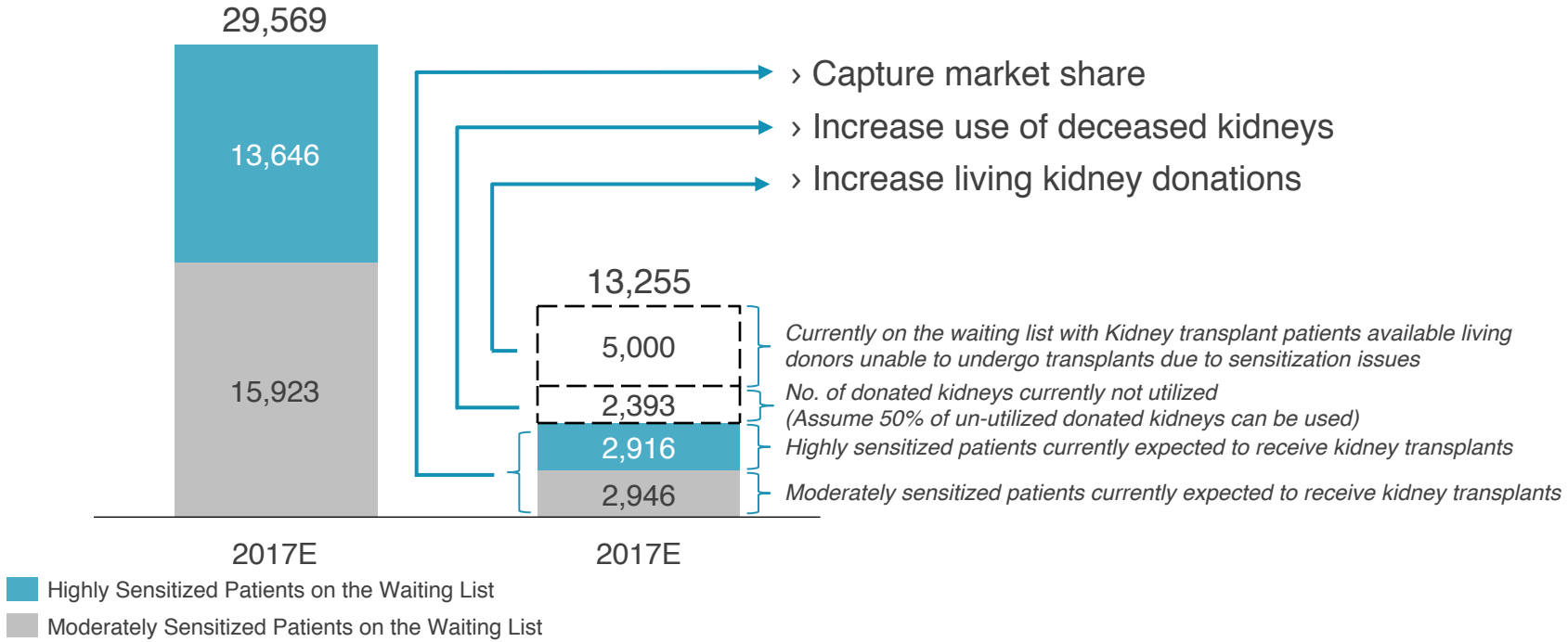
Potential target market for IdeS amongst patients awaiting kidney transplants

Breakdown of sensitized patients awaiting kidney transplants in the US (2017)



Source: Organ Procurement and Transplantation Network (OPTN), Hansa estimates (company research)
Note: Lowly sensitized = CPRA score 0-19; Moderately sensitized = CPRA score 20-79; Highly sensitized = CPRA score 80-100

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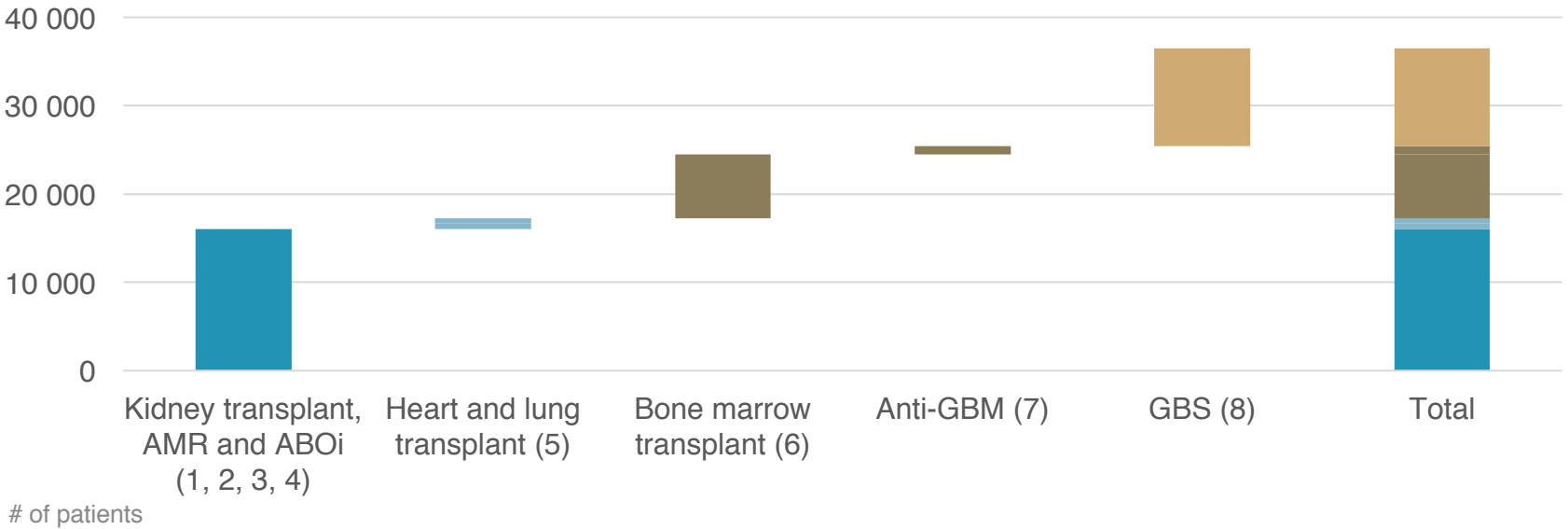
The addressable patient population for prioritized indications is ~36 000 in the seven major markets (7MM*)



1. Organ Procurement and Transplantation Network (OPTN); EDQM Council of Europe
2. Jordan et al. British Medical Bulletin, 2015, 114:113-125
3. http://www.irodat.org
4. Internal report
5. Kluth et al. J Am Soc Nephrol. 1999 Nov;10(11):2446-53
6. Bloodcell transplant HRSA 2014, Center for International Blood and Marrow Transplant Research® (CIBMTR) as of January 20, 2016, Gratwohl-2010, Passweg-2016, Zachary-2014
7. Chih et al. The Journal of Heart and Lung Transplantation, Vol 35, No 8, August 2016
8. McGrogan et al. Neuroepidemiology 2009;32(2):150-63

* US, Germany, UK, France, Spain, Italy, and Japan

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The first wave product launch of IdeS is guided by Hansa's ambition to be The Partner in kidney transplantation

Henk Doude van Troostwijk, Vice President
Commercial Operations

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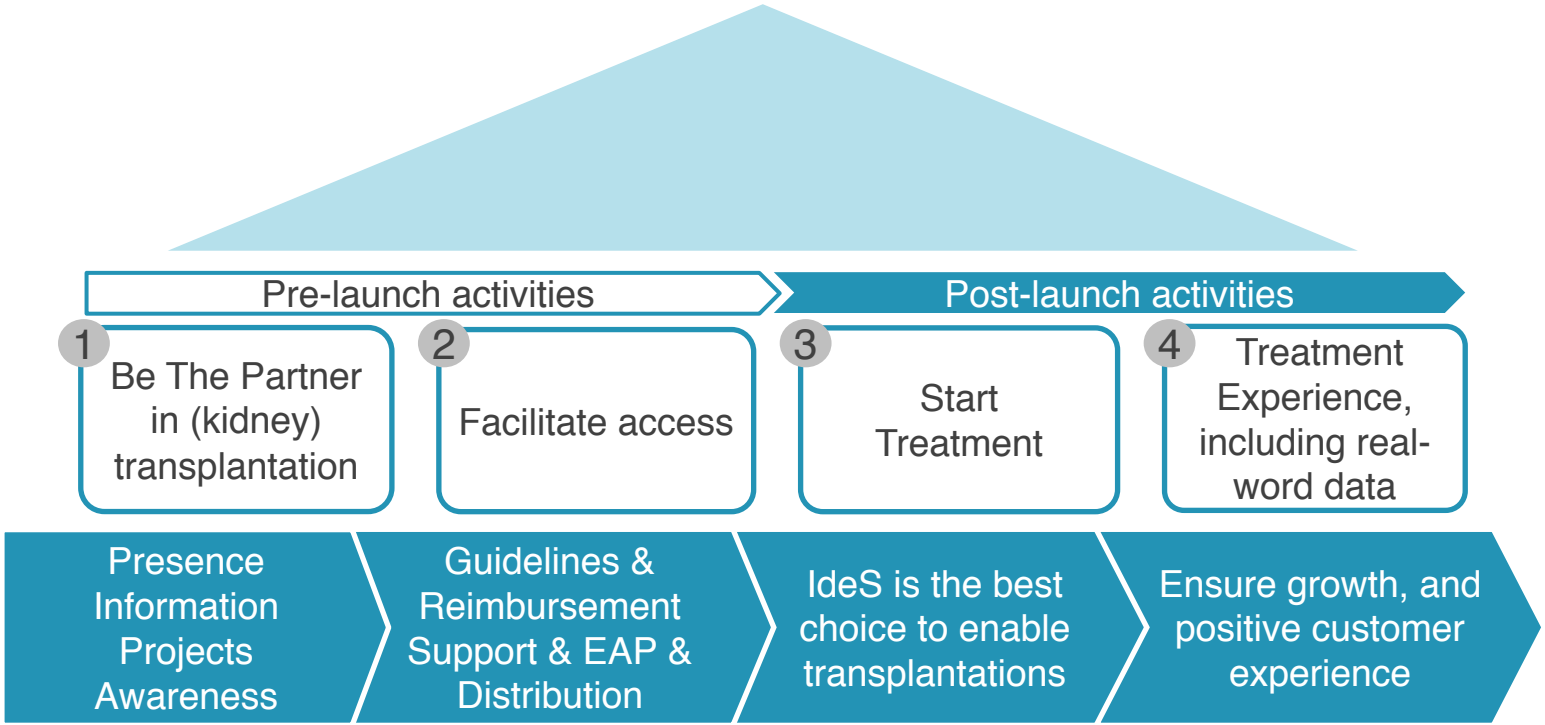
Establish IdeS as the therapeutic option



Roll-out of IdeS in transplantation will start in the US, followed by step-wise expansion to Europe and RoW

Stage 1

- US

Stage 2

- Germany
- France
- UK
- Nordics
- Benelux

Stage 3

- Rest of Europe
  - South cluster

Stage 4

Access by partnering

- Rest of World (RoW)

Organizational launch preparations

Approximate FTE numbers

Today

2020

Start ~12-24 months prior to launch

- Market access, reimbursement strategy, etc.
- Initiate and build awareness with patient foundations in a compliant manner
- Strengthen relationships with KOLs and TAEs (therapeutic area experts)
- Payer education

+10 FTEs

Start ~6-12 months prior to launch

- Sales force preparation
- Education and assistance of patient foundations and physicians
- Negotiate with payers
- Marketing materials etc.
- Pricing preparations

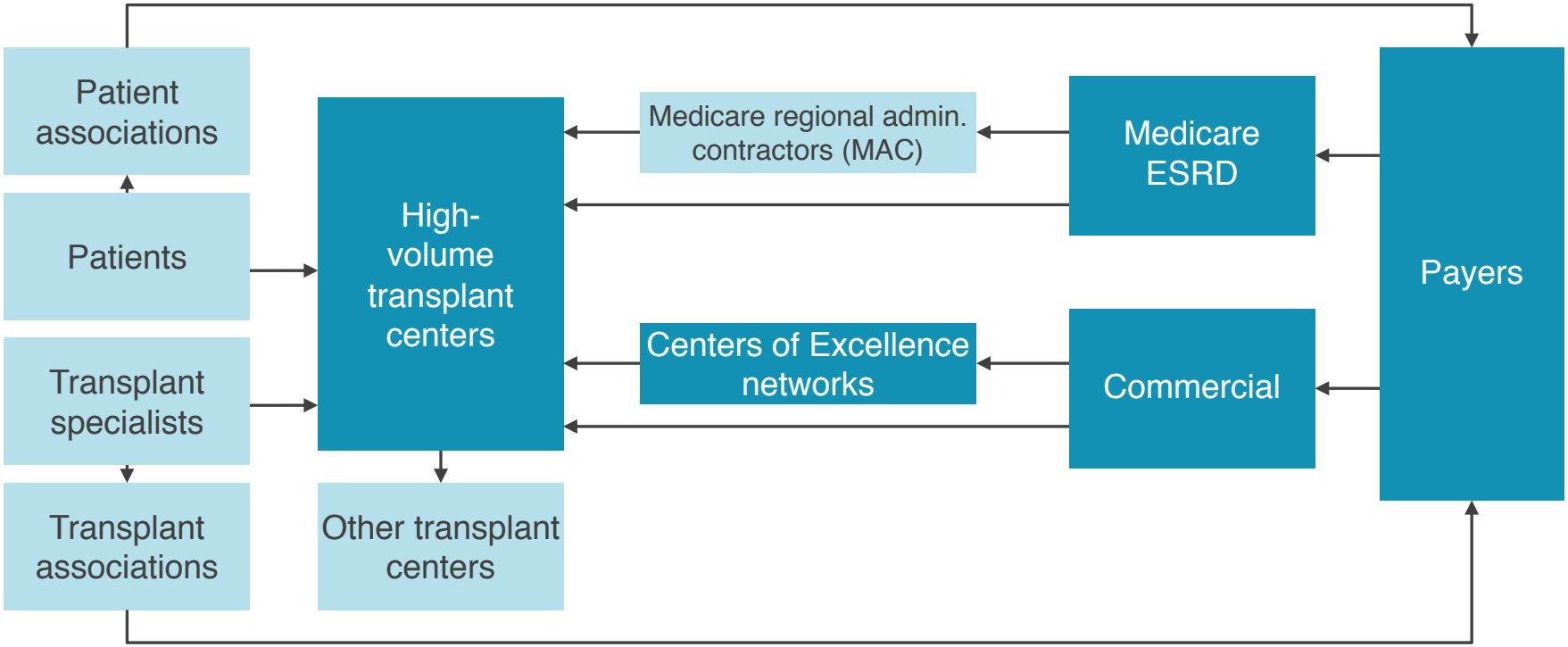
+10 FTEs

Start ~6 months prior to launch

- Finalizing pricing
- Launch activities
- Supporting patients
- Manage supplier network, logistical program etc.

+40 FTEs

Key stakeholders



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Factors supporting orphan drug pricing

- IdeS has a high clinical and economical value
- Low availability of alternative treatments
- IdeS is not a chronic treatment, in contrast to other ODs
- Kidney transplantation is a limited patient pool, implying a limited impact on budgets

IdeS pricing considerations

Reimbursement systems

- P&R system per country
- In Hospital and Out Hospital Reimbursement
- Availability of Alternatives

Willingness to pay

- Clinical and Economic Value
- Population Size
- R&D Investment
- Situation Optics (patient, dosage form, other)

Hansa-specific considerations

- IdeS Franchise Protection
- Reimbursement Timing & Success
- Corporate Philosophy

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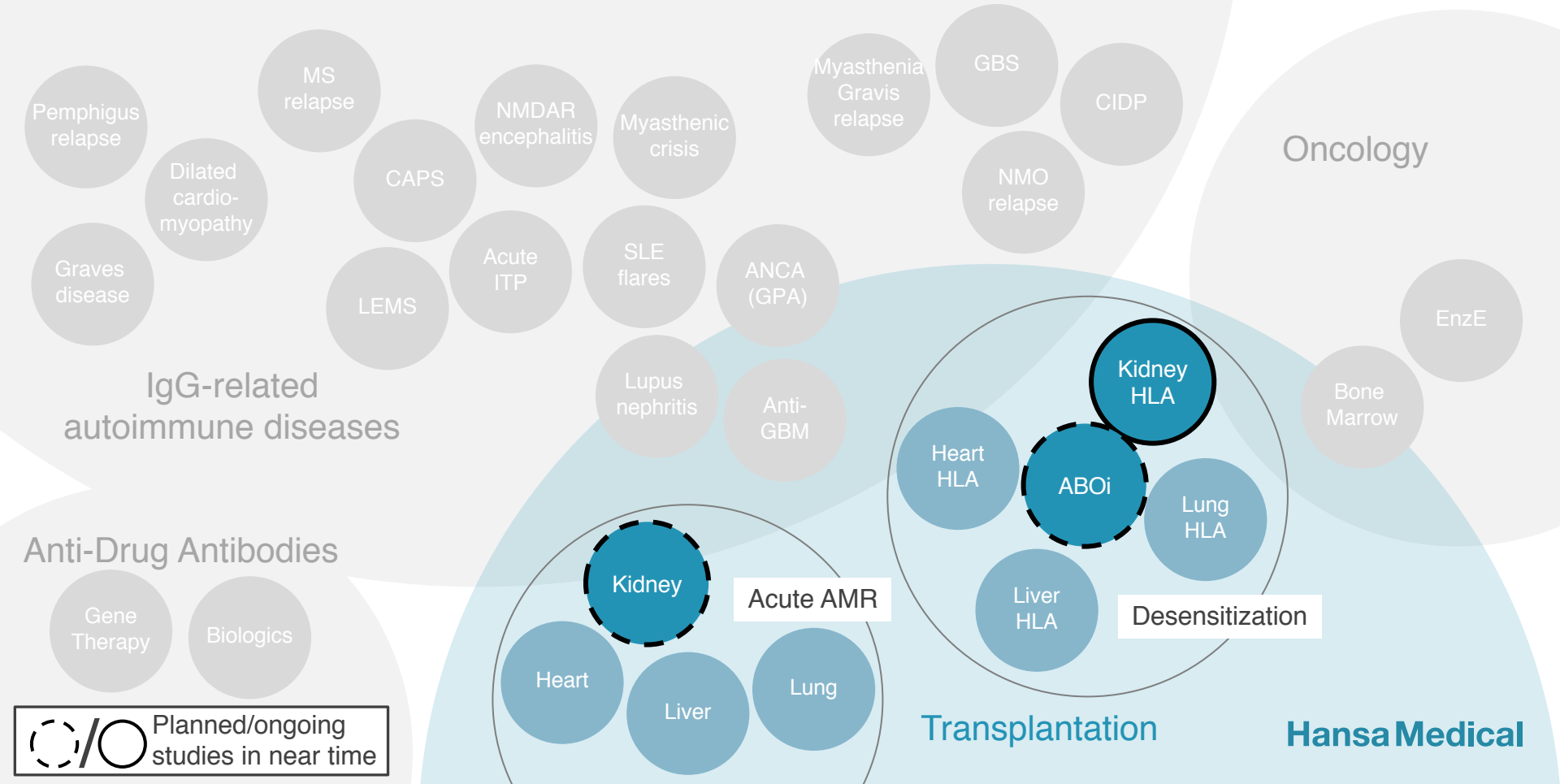
IdeS beyond desensitization – Potentially an even greater opportunity

Christian Kjellman, Senior Vice President
Research and Development

Hansa Medical

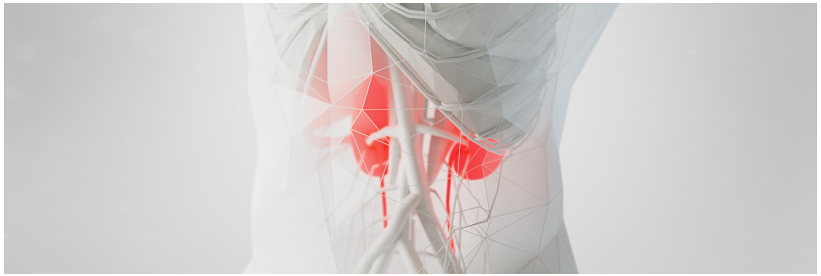
IdeS in additional transplantation indications



Acute kidney AMR

Indication overview

- Acute antibody mediated rejection after transplantation is a significant challenge to long term graft survival
- Occurring in ~10-15% of kidney transplants[1]
- Addressable population of 3,200[2,3] in 7MM[4]



Treatment options

- There are no approved drugs for treatment of AMR; PE and steroids are primarily used today
- AMR patients not treated successfully risk graft failure, dialysis and return to transplantation waitlist

IdeS opportunity

- IdeS treatment of AMR is a quick and effective method to inactivate donor specific antibodies and we expect this to translate into a clinical benefit for the patient

Source: 1) Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724. 2) Jordan et al., British Medical Bulletin, 2015, 114:113-125. 3) http://www.irodat.org. Note: 4) Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

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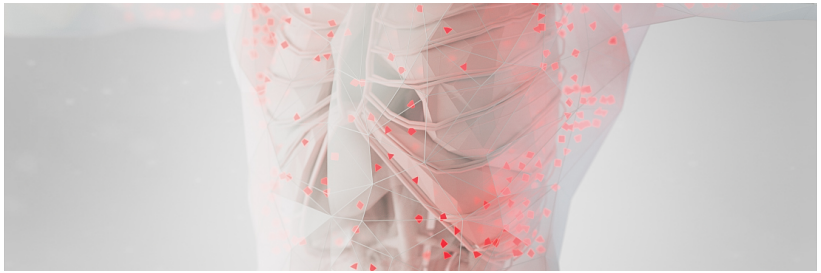
ABOi kidney transplantation

Indication overview

- Desensitization protocols are used in ABO incompatible transplant to lower antibodies to blood group antigens
- ABOi transplantation increases the donor pool
- Addressable population of >2,600[1] per year in 7MM[3]



Treatment options

- SoC: combinations of antibody removal by PE or IA, rituximab and standard triple immunosuppression[2]
- Current protocols are often cumbersome, time consuming and not suitable for deceased donor transplantation

IdeS opportunity

- Strong scientific rationale due to an significant role of IgG
- Strong clinical rationale with high likelihood of success

Source: 1) Internal report. 2) Lipshutz, McGuire, Zhu et al., Arch Surg. 2011 Apr;146(4):453-8. Note: 3) Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

Planned additional studies in transplantation

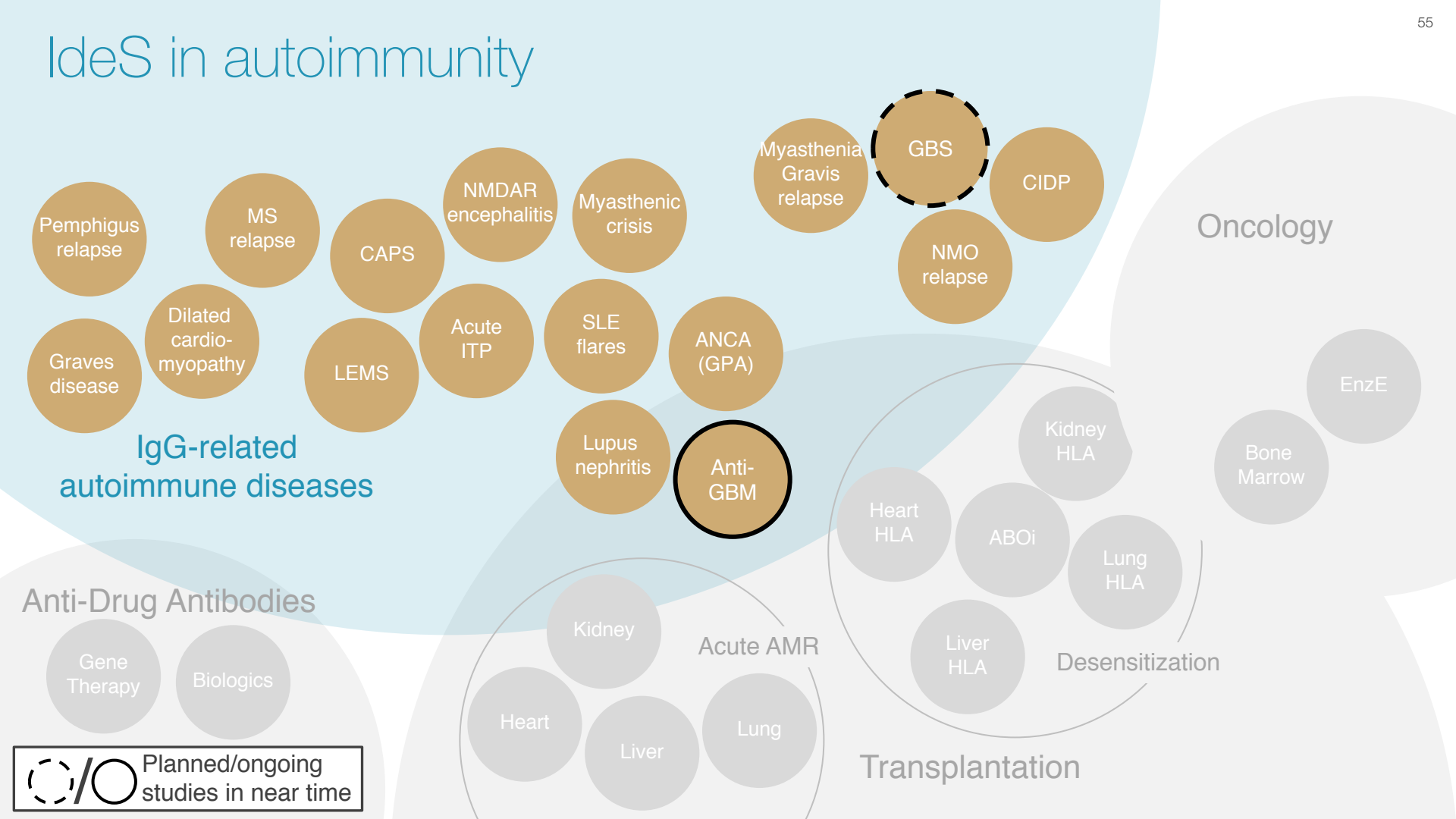
Treatment of AMR in kidney Tx patients

- Phase II study
- 10-15 patients
- Start early 2018, duration 18 months
- The aim is to demonstrate inactivation of DSA and improved kidney function after IdeS treatment
- Main inclusion criteria:
  - Biopsy proven acute active AMR

Tx with ABO incompatible live donor

- Phase II study
- 10 patients
- The aim is to demonstrate inactivation of anti-A/B IgG and successful kidney transplantation after IdeS treatment
- Main inclusion criteria:
  - Available ABO-incompatible live donor
  - Unacceptable anti-A/B IgG levels for transplantation

IdeS in autoimmunity



Anti-GBM antibody disease

Indication overview

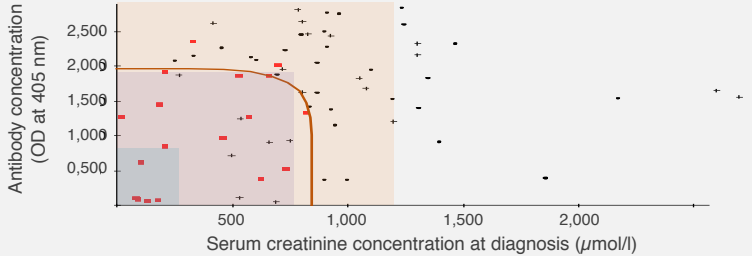
- Antibodies are directed against an antigen to the glomerular basement membrane (GBM)
- Cause acute injury of kidney and/or lung
  - Renal survival rate: 15-58%
  - 6-12 month survival rate: 67-94%
- Addressable population of 900[1] per year in 7MM[2]

Treatment options

- There are no FDA/EMA-approved methods for treatment of anti-GBM
- Standard of care in the acute phase: plasmapheresis, steroids and cyclophosphamide

Anti-GBM creatinine and antibody concentration

Both creatinine and levels of antibodies predict outcome



IdeS opportunity

- Both creatinine and levels of antibodies predict outcome
- IdeS is assumed to rapidly and effectively reduce anti-GBM antibodies to non-toxic levels leading to better treatment outcome

Note: 1) Chih et al. The Journal of Heart and Lung Transplantation, Vol 35, No 8, August 2016. 2) Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

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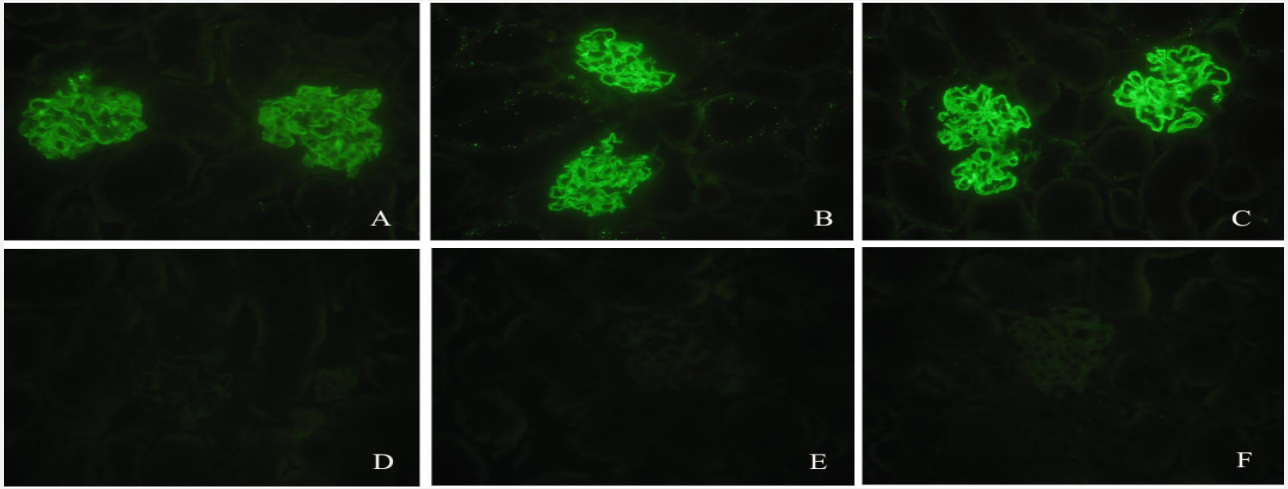
IdeS cleaves IgG bound to mouse kidneys

› **Favorable pre-clinical studies:** “IdeS degrades IgG bound to the GBM *in vivo*, thereby preventing renal damage in this animal model”[1]

Mouse anti-rabbit IgG (Fc-specific)



Placebo

IdeS

Note: 1) Yang et al. Nephrology Dialysis Transplantation, Vol. 25, Issue 8, 2479-2486, March 2010

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A study for IdeS in anti-GBM is underway

Current study to investigate safety, tolerability and efficacy of IdeS:

- Anti-GBM **investigator initiated** study under Dr Mårten Segelmark, Linköping
- Multi-center, multi-country study in collaboration with the EUVAS (European Vasculitis study group)
- 15 patients diagnosed with anti-GBM with decreased eGFR (<15 ml/min/1.73 m^2)
- According to published data less than 10 % will have a functional kidney at 6-12 months – used for power calculations
- Single arm study comparing the outcome following IdeS treatment to historical controls

Status

- 2 patients included in Sweden – both responded favorably
- 3 patients treated under named patient in Sweden prior to site initiation
- No concerning safety findings so far

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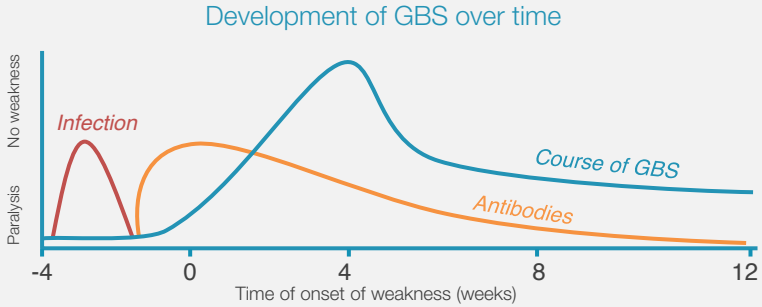
Guillain-Barré syndrome (GBS)

Indication overview

- GBS is an autoimmune attack on the peripheral nervous system, which rapidly and progressively weakens extremities
  - 40% lose strength and have pain; 3-7% mortality
- Can affect anyone, at any age
- Addressable population of 11,000[1] per year in 7MM[2]



Treatment options

- Current SOC is treatment with IVIG or PE
- Only parts of the patients fully recover from GBS, thus a high unmet need for new treatments

IdeS opportunity

- Direct or indirect evidence supports a causative role of pathogenic antibodies in all GBS subtypes

Source: 1) McGrogan et al. Neuroepidemiology 2009;32(2):150-63. Note: 2) Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

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Non-clinical study results acknowledge the potential

An animal study published in May 2017 supports the potential of IdeS use for GBS

- Animal model with disease development following immunization (bovine ganglion)
- IdeS improves survival
- IdeS prevents disease progression
- IdeS reduces disease severity
- Number of IdeS doses correlates with better outcome

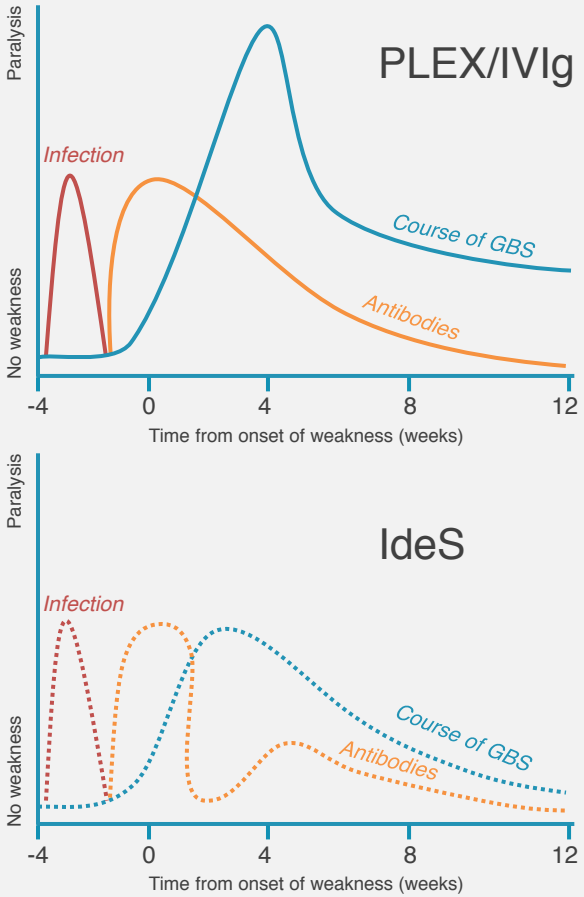
"Our data support that IdeS treatment is a promising therapeutic strategy for GBS"

– Wang et al., 2017

Source: Wang et al., IgG-degrading enzyme of Streptococcus pyogenes (IdeS) prevents disease progression and facilitates improvement in a rabbit model of Guillain-Barré syndrome, Experimental Neurology, Vol 291, 134-140, May 2017

Phase II PoC study for GBS is planned

- Phase **II PoC study** to investigate the **safety and efficacy** of IdeS in patients diagnosed with GBS
  - Improved long-term outcome and reduced long-term disability
  - Reduced time to recovery
  - Shorter time in ICU and hospital
- Multicenter study on 30 GBS patients
- Start Q1 2018



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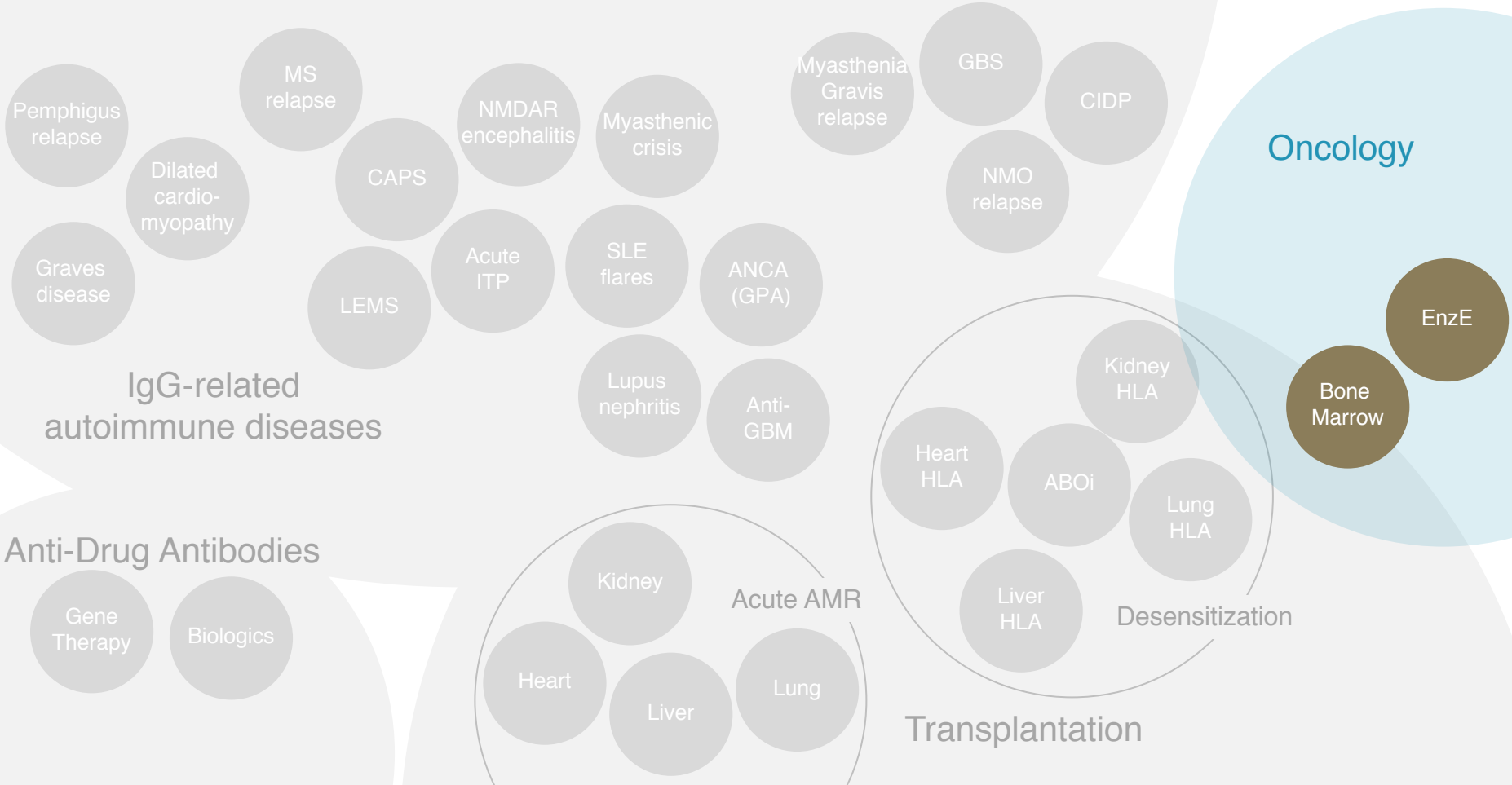
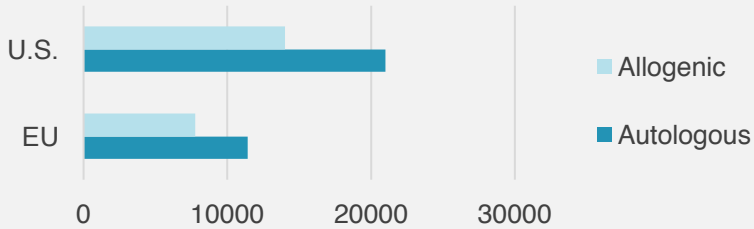
IdeS in oncology



Bone marrow transplantation

Indication overview

- Engraftment failure associated with antibodies to donor HLA limits options for sensitized bone marrow transplantation candidates
- Addressable population of 7,300[1] per year in 7MM[3] – more than 50,000 bone marrow transplants (BMT) are carried out per year



Treatment options

- No treatment – implies limited donor options, potentially while there is an urgent need to proceed to transplant
- Presence of donor specific HLA antibodies is associated with increased risk of engraftment failure, if carried out

IdeS opportunity

- Similarly to the currently ongoing studies for kidney transplantation, IdeS is assumed to enable bone marrow transplantation through specifically and effectively cleaving IgG

Note: 1) Bloodcell transplant HRSA 2014, Center for International Blood and Marrow Transplant Research® (CIBMTR) as of January 20, 2016, Gratwohl-2010, Passweg-2016, Zachary-2014, 2) Curr Opin Hematol. 2013 Nov;20(6):485-93. 3) Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

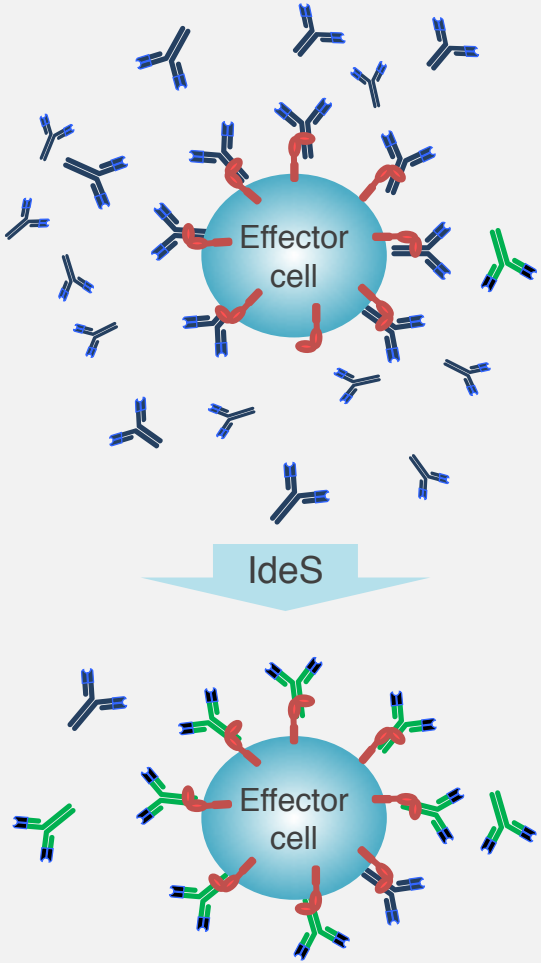
EnzE – novel IdeS use in oncology

Enzyme based antibody enhancement through pre-treatment

- The abundance of normal IgG in blood interferes with therapeutic monoclonal antibodies
- Pre-treatment with IdeS/NiceR has potential to potentiate antibody based cancer therapies
    - Growing market – targeted therapies are already increasingly replacing existing chemotherapies
- Currently in preclinical development

How it works – enhancing antibody-mediated effector functions

- Therapeutic antibody efficacy is severely impacted by the presence of endogenous IgG (by binding/blocking FcγRs) – but not by IdeS-generated fragments
- IdeS pre-treatment empties FcγRs and has the potential to improve treatment efficacy[1]



Source: 1) Sofia Järnum et al. Enzymatic Inactivation of Endogenous IgG by IdeS Enhances Therapeutic Antibody Efficacy. Mol Cancer Ther 2017;16:1887-1897

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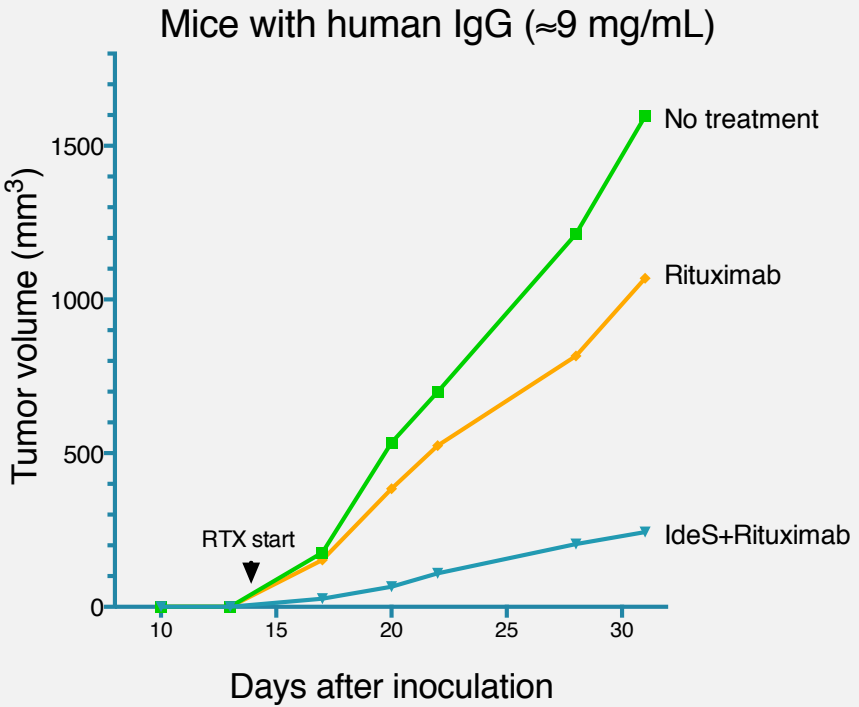
EnzE PoC has been demonstrated *in vivo* for mice

› Study design
- Mice (SCID) were injected intraperitoneally with either, IVIg or IVIg and 3x IdeS
- Rituximab (RTX) treatment was started on day 14 after tumor cell inoculation (palpable tumors), once a week

› Outcome
- The suppressive effect of IVIg on effector cell function is abrogated by IdeS
- IdeS can significantly improve the therapeutic effect of rituximab



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Novel IgG cleaving enzymes under development

Christian Kjellman, Senior Vice President
Research and Development

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NiceR – treating more indications by enabling repeat dosing

- Hansa is developing NiceR – novel IgG cleaving enzymes with lowered immunogenicity for repeat dosing
- NiceR broadens the indication space to reoccurring acute conditions, e.g. relapses in auto-immune diseases or reoccurring AMR

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Development of the two NiceR projects are run in parallel

› NICP
- Generate an IgG cysteine peptidase based on the amino acid sequence of IdeZ, a homolog to IdeS – already from start less immunogenic
- Currently developed to improve activity against IgG
- A production process is under development

› TRICP
- “Molecular stealth technology” to avoid the immune system
- Generate variants of IdeS molecules less immunogenic but with retained enzymatic activity compared to IdeS
- For TRICP, drug candidates are modified and evaluated

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Q & A

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Closing remarks

Göran Arvidson, President and CEO

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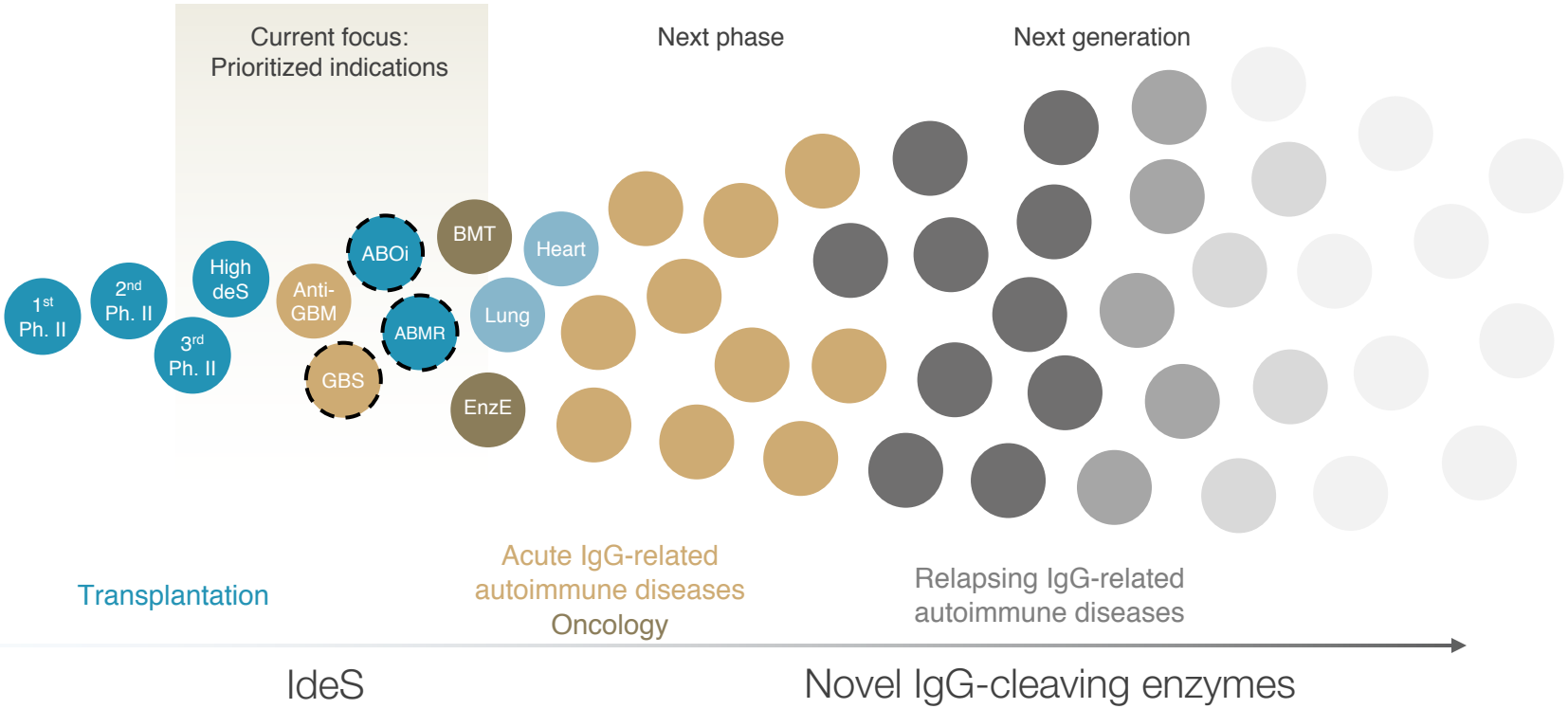
Hansa Medical roadmap

Approval for pre-treatment of sensitized patients and immediate go-to-market

Proof of concept for related indications – short-term focus on a few indications, while expectation is broad applicability

Development of improved endopeptidases
(Novel immunoglobulin-cleaving enzymes for repeat dosing, NiceR)

The world leading IgG-modulating company



Planned studies

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