Capital Markets Day

29 October 2020

Copenhagen (& virtual), Denmark

We are the bigger picture

Patients have given consent to provide images

Speakers

Rachel Curtis
Moderator

Sören Tulstrup
CEO & President

Donato Spota
SVP & CFO

Christian Kjellman
SVP & CSO & COO

Vincenza Nigro
VP, Head of Medical Affairs

Prof. Nizam Mamode, M.D
Professor of Transplant Surgery, Guy's and St Thomas' Hospital, London

Henk D. van Troostwijk
SVP & CCO

Prof. Achim Kaufhold,M.D
SVP & CMO

Prof. Mårten Segelmark,M.D
Professor of Nephrology at Lund University and Linköping University

Elisabeth Sonesson
Director & Head of Clinical Development

Emanuel Björne
VP & Head of Business Development

Lena Winstedt
Head of Science

Agenda

Hansa Biopharma Capital Markets Day 2020

Time	Length (min)	Topic	Presenter
13:30 – 13:35	00:05	Introduction	Klaus Sindahl, Head of IR and Rachel Curtis, Moderator
13:35 – 13:55	00:20	Our strategy and vision for the future	Søren Tulstrup, President and CEO
13:55 – 14:05	00:10	Our financial priorities	Donato Spota, SVP and CFO
14:05 – 14:30	00:25	Our scientific vision	Christian Kjellman, SVP CSO and COO
14:30 – 14:40	**00:10**	**Break**	
14:40 – 14:45	00:05	"Melissa" a patient's perspective on the long wait for a kidney	Patient video
14:45 – 15:00	00:15	Building awareness around a new transformative therapy	Vincenza Nigro, VP and Head of Medical Affairs
15:00 – 15:30	00:30	Clinical perspectives on desensitization in kidney transplantation	Prof. Nizam Mamode, M.D. Clinician, Guy's and St Thomas Hospital
15:30 – 15:50	00:20	Our European launch strategy	Henk Doude van Troostwijk, SVP and CCO
15:50 – 16:00	**00:10**	**Break**	
16:00 – 16:20	00:20	Opportunities beyond kidney transplantation	Prof. Achim Kaufhold, M.D. SVP and CMO
16:20 – 16:40	00:20	Anti-GBM disease and phase 2 data read-out	Prof. Mårten Segelmark M.D. Lunds & Linköpings University Elisabeth Sonesson, Director and Head of Clinical Operations
16:40 – 17:00	00:20	Imlifidase in gene therapy	Emanuel Björne, VP and Head of Business Development Lena Winstedt Head of Science
17:00 – 17:15	00:15	Questions from the audience	Rachel Curtis, Moderator
17:15 – 17:20	00:05	Closing remarks	Sören Tulstrup, President and CEO

Our strategy and vision for the future

Søren Tulstrup
President & CEO

Forward-looking statement

This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "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 statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma'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.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

Hansa Biopharma expressly disclaims any obligation to update or revise any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or otherwise, and disclaims any express or implied representations or warranties that may arise from any forward-looking statements. You should not rely upon these forward-looking statements after the date of this presentation.

We are building a global leader in rare diseases

Today

We are launching our first commercially approved product for kidney transplantation in Europe

Stock images

We are building a global leader in rare diseases

Tomorrow

We envision a world where patients with rare immunologic diseases can lead long and healthy lives

Stock images

Hansa Biopharma today

Successful track record...

Strong momentum...

Promising future...

A validated technology

VALIDATION ACROSS THREE AREAS

- Approval in kidney transplantations
- PoC in autoimmune diseases
- Partnership in gene therapy

Idefirix® our first approved drug in EU

EU KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

Established a high-performance organization

NEW COMPETENCIES ADDED

Staff tripled in 5 years

Highly qualified team with 20 years on average in lifescience

Strong R&D driven organization

PURPOSE DRIVEN ORGANISATION

Innovative

Agile

Dedicated

Well capitalized

FINANCED INTO 2023

SEK1.5bn in cash

Raised SEK 1.1bn in Q3 2020

Created value for shareholders

MARKET CAP SEK10bn

10x vs cost of development 13 years

Idefirix approved in EU under conditional approval

Our strategic priorities

Building tomorrow's Hansa Biopharma

Advance platform in new indications and therapeutic areas

Build new franchises to capture full value of technology platform

- Transplantation
- Autoimmunity
- Gene therapy
- Oncology

Commercialize Idefirix® in first markets and indications

Successfully launch Idefirix® in EU

Generate positive first experiences in key clinics and expand to targeted clinics with a patient focus

Geographical expansion

- Explore opportunities to commercialize Idefirix® beyond core markets

Secure FDA approval and launch Idefirix in the US

- Complete Randomized Control Trial (RCT) and submit BLA under the accelerated approval pathway (2023)

Build organizational capabilities and expand technology platform

Build a first-class commercial organization

Build commercial team and competences in transplantation and autoimmune diseases

Expand R&D capabilities

Pursue innovation, further strengthen scientific expertise and capabilities in rare diseases

Create partnerships

Initially focused around gene therapy and potentially oncology

Idefirix approved in EU under conditional approval

We envision a world where...

...patients with rare immunologic diseases can lead long and healthy lives…

Developing new therapies

- Desensitization in kidney transplant patients*
- Acute treatment in anti-GBM**
- Acute treatment in GBS**
- Acute treatment in AMR**

Extending and improving human lives

Transplantation leads to dramatically better quality of life and life expectancy than dialysis

77% of transplanted patients are alive after 8 years vs 44% of patients on dialysis[1]

Delivering value to society

Transplantation is a cost-effective intervention vs. dialysis

Help reduce the significant cost associated with the treatment of chronic kidney disease and ESRD

USD 115bn, equivalent to 20% of the US Medicare budget, relates to kidney diseases[2]

* Idefirix approved in EU under conditional approval
** Imlifidase under investigation

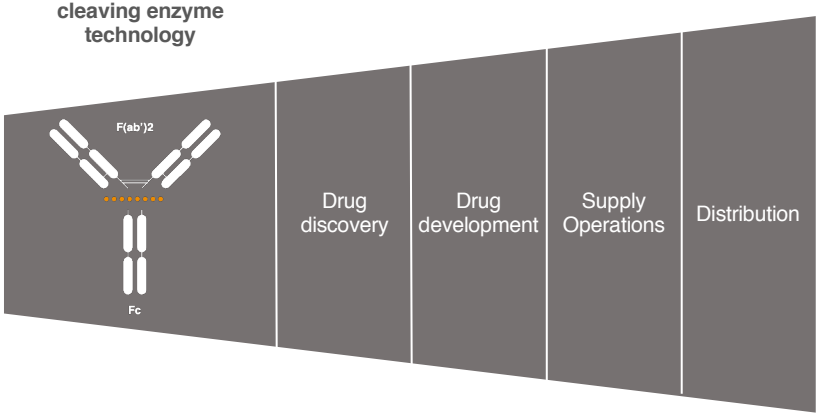
[1] Orandi et al. N Engl J Med 2016;374:940-50
[2] https://www.hhs.gov/about/news/2019/07/10

Leveraging our technology platform

Developing new therapies targeting rare diseases with unmet medical need across a range of indications

Growth engine

Leveraging our proprietary antibody cleaving enzyme technology



Value chain

We are controlling the full value chain

Drug discovery

Drug development

Supply Operations

Distribution

Commercialization

Build-up of franchises	Indications and therapies	Multiple income streams
Own commercial infrastructure	**Transplantation**	Revenue / sales
	Autoimmune diseases	Upfront payments
Partnership strategy	**Gene therapy**	Milestone payments
	Oncology	Royalties

Evolution into a fully integrated biopharmaceutical company

Our culture is driven by people passionate about making changes

Purpose driven culture

Helping patients with rare diseases serves as a **strong purpose** for our colleagues to **go the extra mile**

Diverse and international

35%
Internationals across 14 nationalities

50/50
Gender split in the leadership team

Skilled and experienced team

35%
With relevant PhD

~20 years
of life science experience on average from Big Pharma, Biotech and Academia

Motivated workforce

95%
identifies Hansa as a **"Great Place to Work"**

Great Place To Work. Certified 2020 SWEDEN

Becoming a fully integrated commercial stage biopharma company

While expanding our technology and global footprint

We are here!

Pre-clinical / Early-stage clinic	Late-stage clinic	Commercial stage
1	2	3
Creating a scientific platform	Preparing the company for commercial success	Building and capturing value in new indications and markets
• Advanced imlifidase from preclinial models through to approval • Initiated clinical studies in transplantation in EU and the US • Built the R&D organization • Validated through peer-reviewed publications (e.g. NEJM and AJT)	• Completion of four phase 2 studies in transplantation • Development of GMP process • Expanded the pipeline to post-transplantation and autoimmunity • Established corporate and medical functions • Expanding the footprint in EU and US	• First drug approval in kidney transplantation in EU* • EU commercial launch Q4 2020 • Expanding commercial teams and adding territory management • Securing supply chain management • Advancing our technology footprint

* Idefirix approved in EU under conditional approval

Targeting global leadership in rare diseases

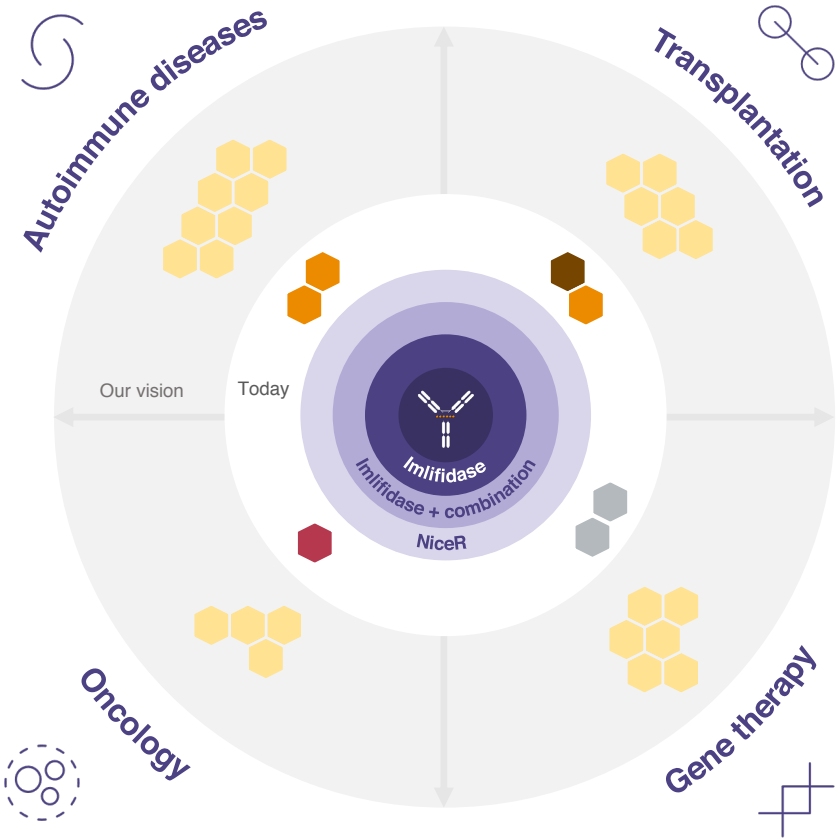
How our unique antibody cleaving enzyme platform has the potential to transform Hansa Biopharma

Expanding our technology platform

- Enzyme platform
- Imlifidase
- Imflidase plus combination
- New enzymes for repeat dosing “NiceR”

Expanding our commercial franchises

- Regulatory approval
- Clinical development
- Partnership (preclinical development)
- Preclinical development
- Opportunity



* Idefirix approved in EU under conditional approval

An exciting journey ahead!

This is just the beginning!

- Clinical validation
- External validation
- Regulatory validation
- Validated manufacturing
- Strong IPR
- Exciting pipeline
- Strong team

Key milestones to be achieved

- Expand Idefirix® label in transplantation and in other solid organs
- Obtain regulatory approval in anti-GBM, GBS and AMR
- Demonstrate PoC in our next gen enzymes (NiceR)
- Expand partnerships in gene therapy and oncology
- Advance clinical studies with imlifidase as pre-treatment in Limb-Girdle and Duchenne therapies with Sarepta
- Show PoC in new indications such as oncology

Idefirix approved in EU under conditional approval

Our future

Hansa Biopharma is a recognized global leader in rare diseases across multiple broad therapeutic areas with several market leading products and a highly valuable pipeline of late stage drug candidates

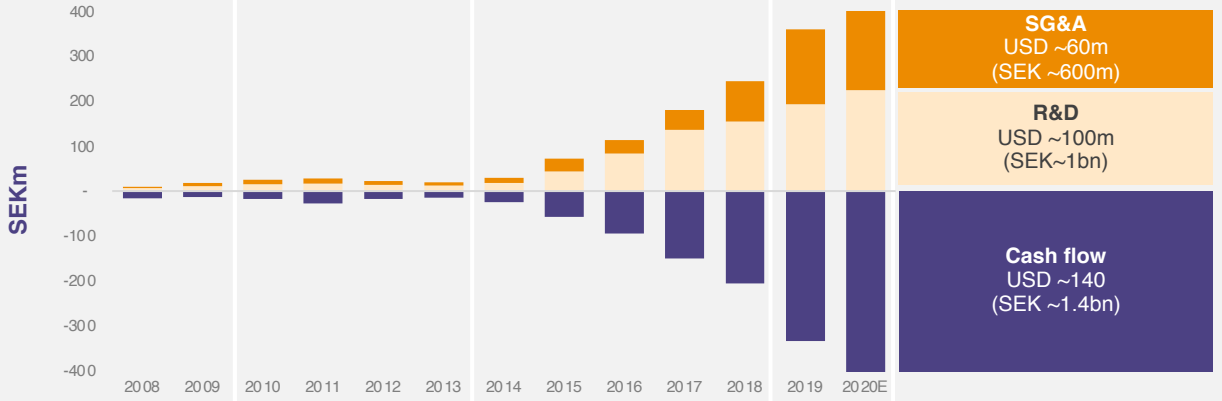
Stock images

Our financial priorities

Donato Spota
SVP & CFO

13 years of value creation from the labs to the market

Current Market Cap suggests ~10x return vs accumulated R&D investments



Market Cap
USD 1bn (SEK 10bn)
10x vs R&D investment

Discovery

Pre-Clinical/Clinical Development phase 1

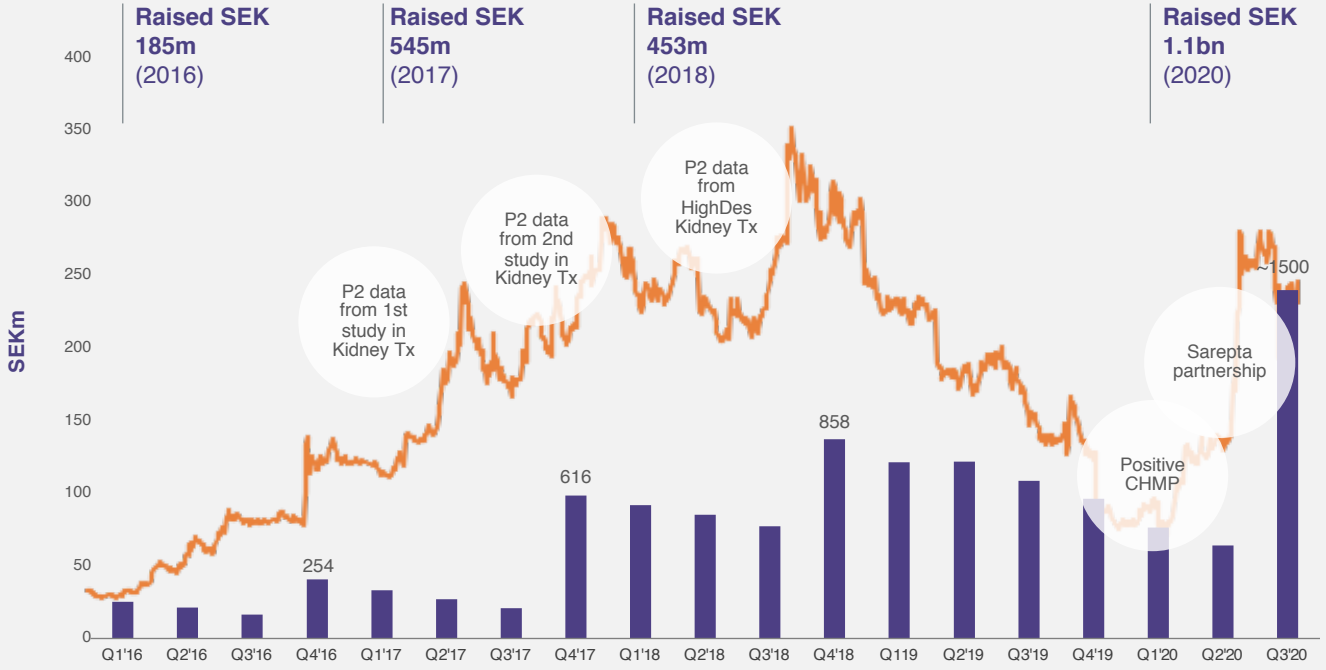
Clinical development Initiation of phase 2

Approval (EU)

Acc. investments

Strong value generation from our lead asset

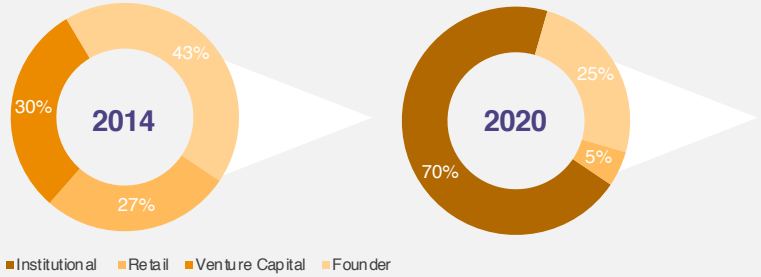
Meeting significant value inflection points



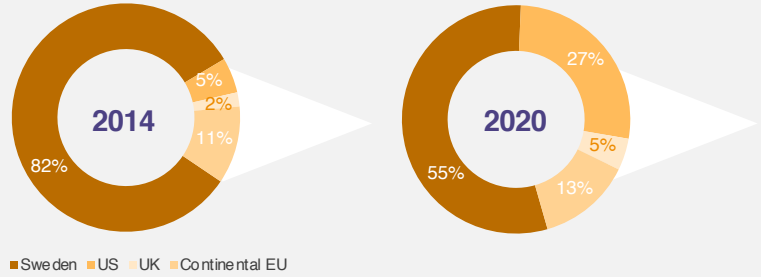
USD 270m (SEK 2.7bn) raised since 2007

Securing a strong, international shareholder base

allowing for continued support to exploit our highly investable platform

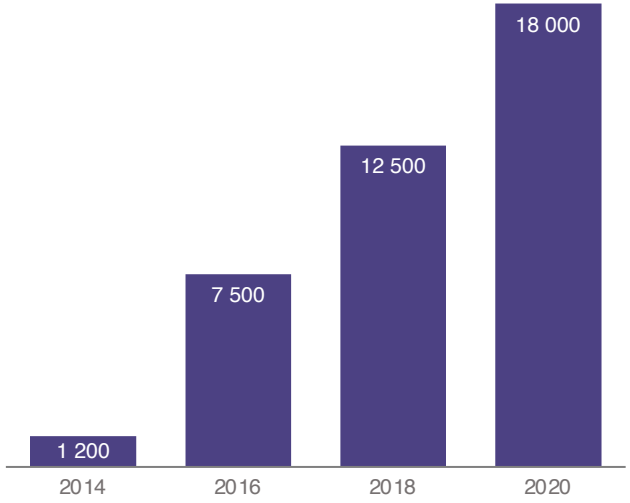


Share of institutional investors have increased to 70% as the Company has advanced towards commercialization



We have been able to attract some of the leading international life science specialist funds as owners, helping us to diversify our shareholder base

Since 2014 no. of shareholders has increased by 15x



Source: Q4 Inc Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

Our mid term financial priorities

Fund a broad exploitation of our platform technology while securing a successful EU launch

2020

From 2021+

- Fund commercial expansion across Europe, targeting mid-term product profitability
- Continue investments in kidney transplantation to approach US market
- Continue progressing in new therapeutic areas incl. auto-immunity, gene-therapy, cancer
- Develop next generation enzymes for repeat dosing

USD 150m (SEK 1.5bn) Cash position and short-term investments (Sept 2020)

Our scientific vision

Christian Kjellman
SVP CSO and COO

Idefirix® obtains conditional approval in EU

Let's start with our greatest achievement so far

idefirix®
imlifidase

Therapeutic Indication

Idefirix is indicated for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of Idefirix should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.

Patient*

This is a break-through for the patients who need but can't access kidney transplantation.

*Actual patient has given consent to provide images

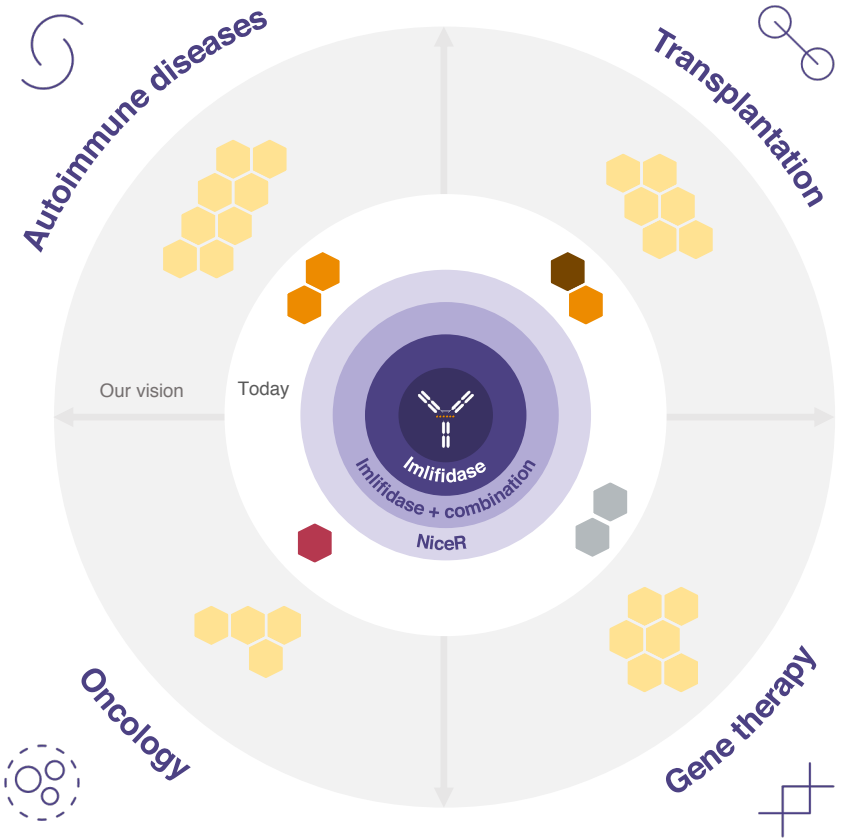
HANSA BIOPHARMA

Hansa

Validation of our technology and capabilities as an organisation and team.

Our unique antibody cleaving enzyme technology can transform Hansa Biopharma

New therapies targeting rare diseases across a range of indications

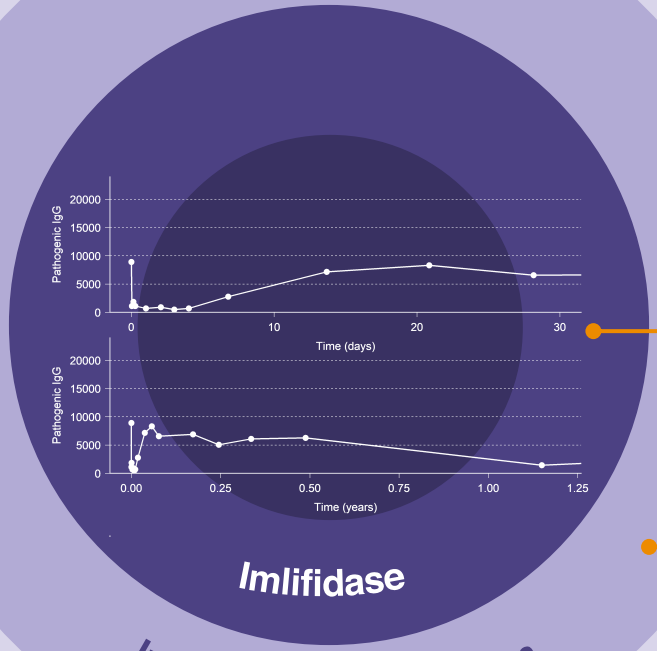


Expanding our commercial franchises

- Regulatory approval
- Clinical development
- Partnership (preclinical development)
- Preclinical development
- Opportunity

The technology platform is the primary basis for our evolution

Evolve our technology and combine



Two opportunities:

- Reduce immune response to enzyme, i.e. allow **repeated treatment**
- **Combination therapy**, i.e. induction and maintenance therapy

- Indication selection
- Advance patient management

Targets:

- IgG
- Complement
- Immune cells

- Genetic modification

Idefirix approved in EU under conditional approval

Transplantation

The first patients can access Idefirix® – to enable a life changing transplantation

Shaping a new standard for desensitization

Expanding our commercial franchises

- Regulatory approval
- Clinical development
- Partnership (preclinical development)
- Preclinical development
- Opportunity

Expanding our technology platform

- Imlifidase
- Imflidase plus combination
- New enzymes for repeat dosing "NiceR"

Idefirix approved in EU under conditional approval

Anti-GBM paves the way for further development in auto(allo)immunity

To meet a unmet need in IgG driven disease

Expanding our commercial franchises
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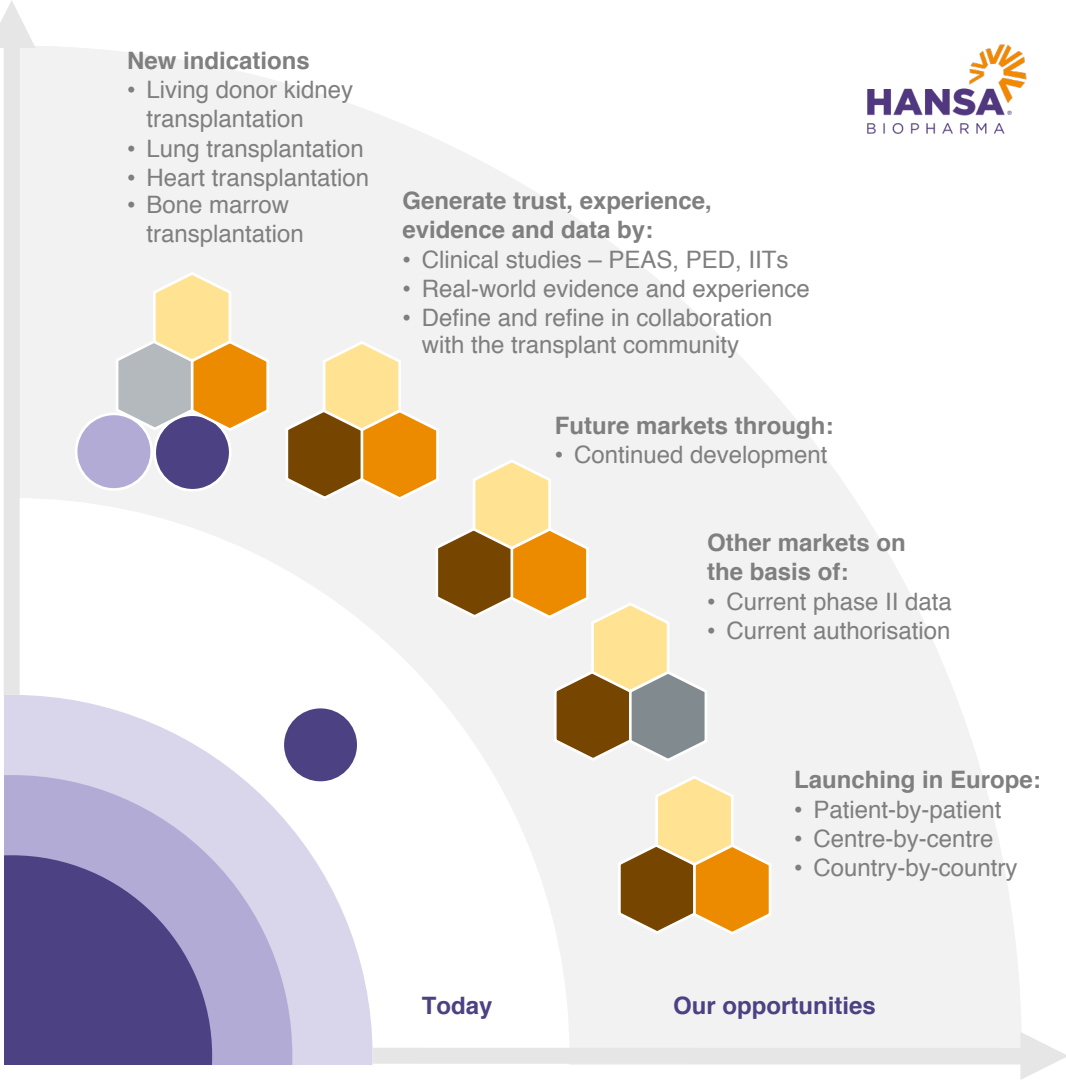


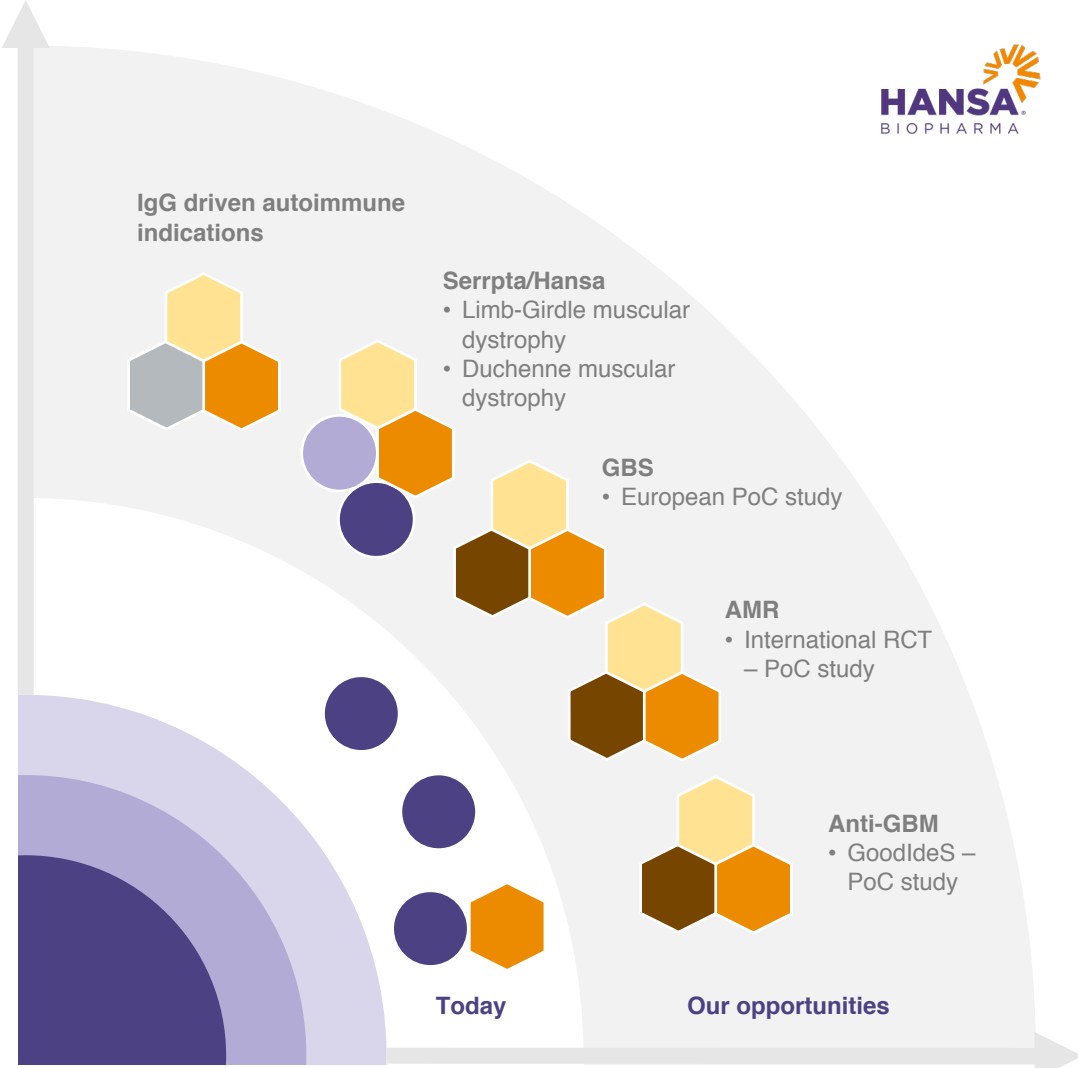
Idefirix approved in EU under conditional approval

Oncology

Can IgG cleaving enzymes enable or even potentiate cancer therapy?

EnzE

Cell therapy



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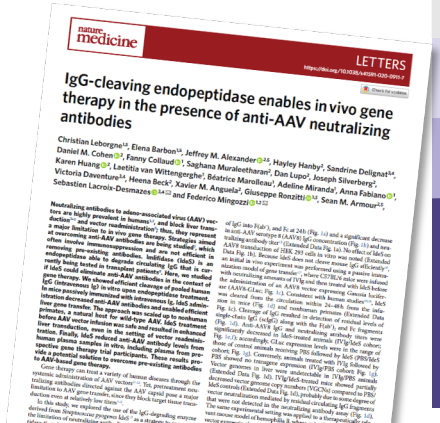
Exploring opportunities in gene therapy

Neutralizing antibodies (Nabs) are immunological barriers in gene therapy



Expanding our commercial franchises
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Idefirix approved in EU under conditional approval

Enzyme-based antibody Enhancement (EnzE)

Chimeric antigen receptor T cells
- Allogenic CAR-T

Allogenic stem cell (bone marrow) transplantation

Today

Our opportunities

The WHY of our people

the core of Hansa

Pride

This is so much more than just a job.

I am proud to tell others I work here

Teamwork

Everyone is working so hard for Hansa to be a success, always giving 200% and always as a team, always

Safe work place

When I come to work I always feel welcome, it's a warm nest

A higher purpose

I feel privileged to get the chance to possibly change the life of patients

Authenticity

I can be myself, and its ok to do mistakes

All in it together

I am surrounded by competent and great people.

Their enthusiasm and support makes my job even better, especially when I had a really long day.

We are all in it together

“Melissa B”*

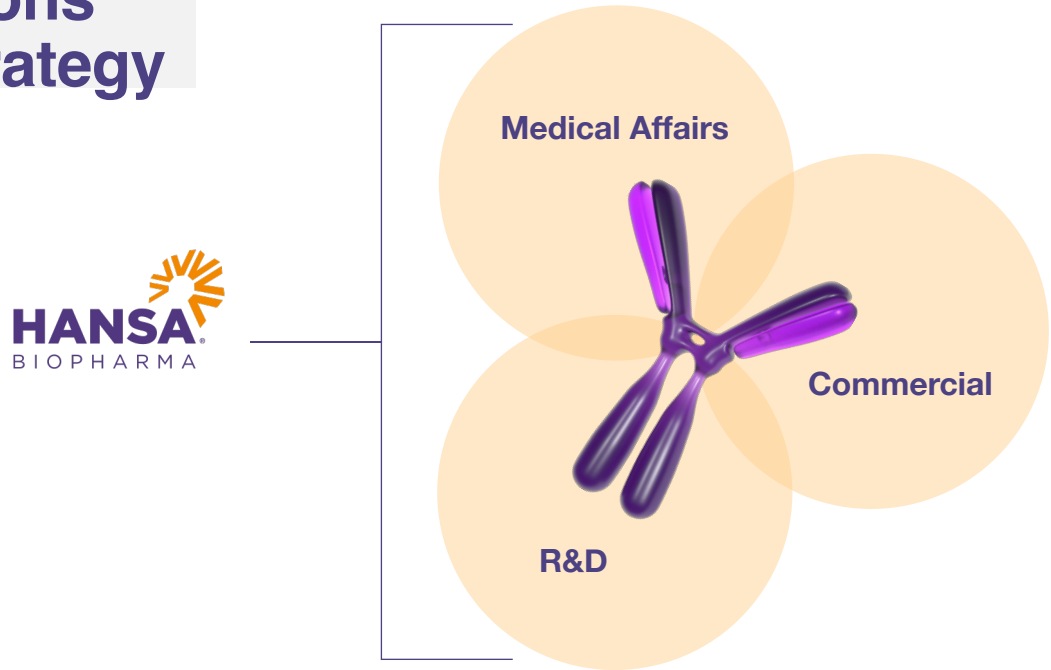
Patient video

*Actual patient has given consent to provide images

Building awareness around a new transformative therapy

Vincenza Nigro
VP Head of Global Medical Affairs

Our Global Medical Affairs is central to our integrated operations and our launch strategy



A new path, a new way and a new journey

Clinic-by-Clinic and One Patient at a Time

- Awareness, Education and Readiness
- Build experience one-patient-at-a-time
- Gold standard for desensitization

…positive experiences and outcomes for patients and physicians

Focus on…

…shaping the area of desensitization with the global transplant community

- Best practice sharing
- Standardization of approaches
- Continued investment in research

Shaping desensitization within EU

Medical community engaged with Hansa

10
Abstracts/ Publications on imlifdase and unmet need

5
Hansa-sponsored symposia

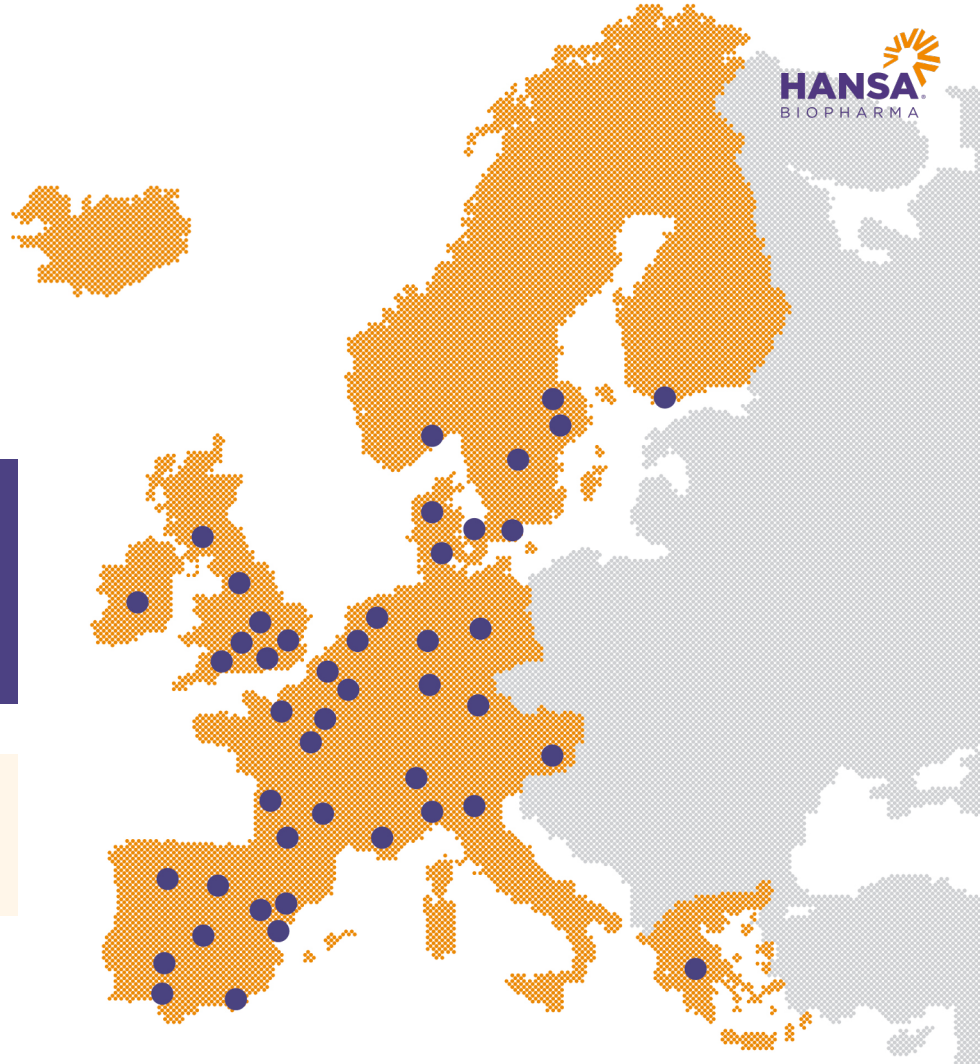
1
Acceptance of pivotal HighDeS trial in Transplantation Journal (In Press)

ESOT

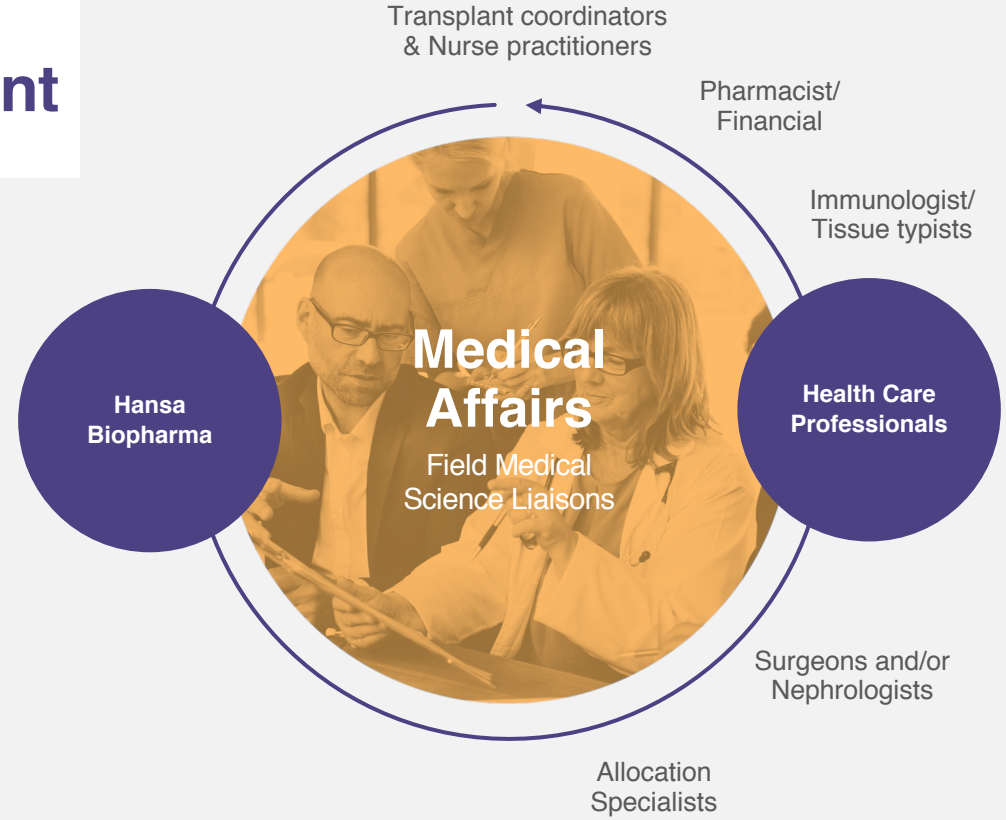
Partnership with ESOT TLJ 2.0

Workstream dedicated to desensitization

A unique collaboration to bring European consensus on kidney transplants for highly sensitised patients



Creating value across the kidney transplant ecosystem



Hansa Market research – Hibiscus ESKD Disease Burden, Unmet need testing & Message & concept testing

Identifying the right patient

Low complexity transplants ← → Higher complexity transplants

~70% of patients[1,2]	15-20% of patients[1,2]	10-15% of patients[1,2]
Non or less sensitized (cPRA < 20%)	Moderately sensitized (20% > cPRA < 80%)	Highly sensitized (cPRA > 80%)
		Highly sensitized patients that are likely to be transplanted with a compatible donor
		Highly sensitized patients unlikely to be transplanted under available KAS, including prioritization programs

Actual patient have given consent to provide images

Idefirix® is indicated for

desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.

The use of Idefirix® should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients

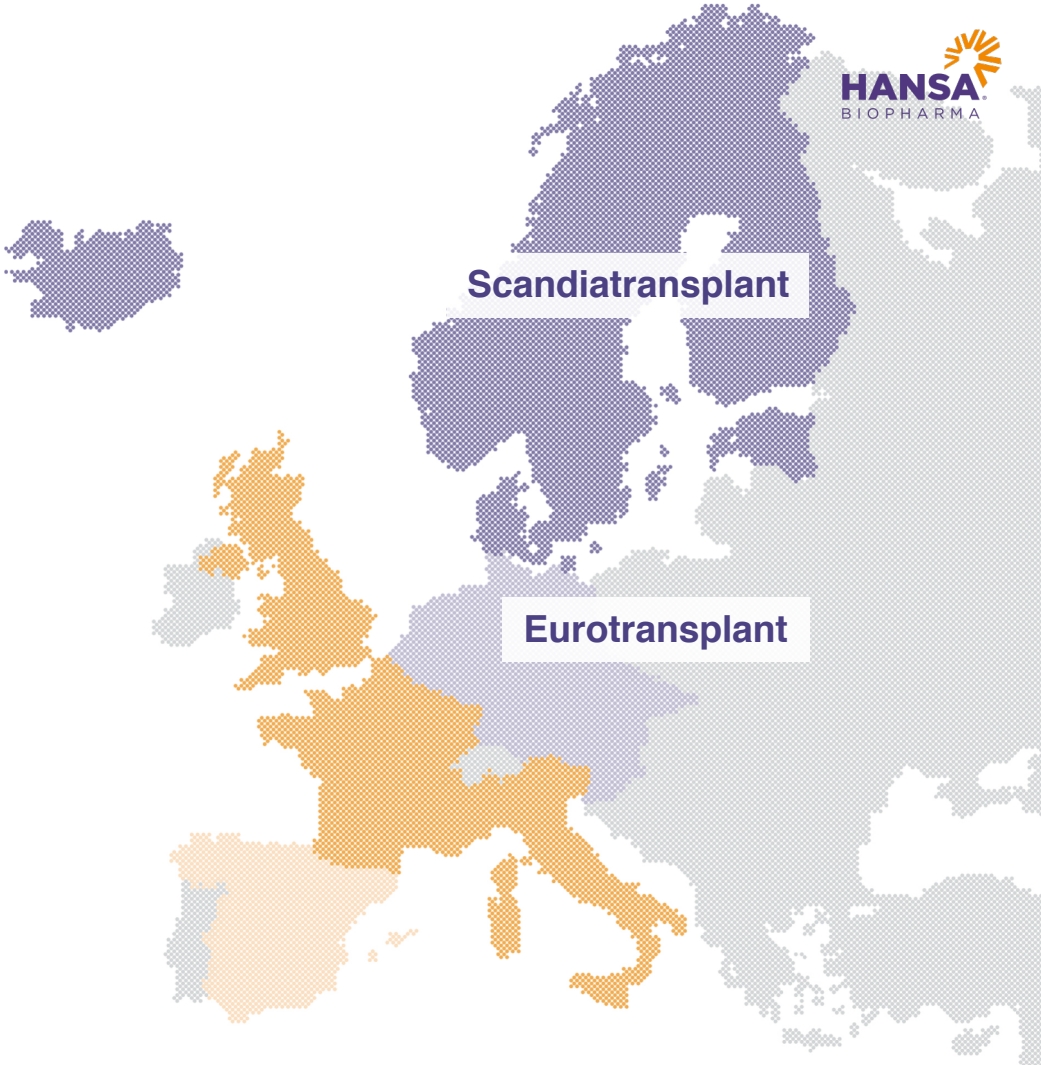
Potential patients

idefirix® imlifidase

[1] EDQM. (2020). International figures on donation and Transplantation 2019
[2] SRTR Database and individual assessments of allocation systems

Working with KOL's to harmonize approaches across Europe

In Europe there is not a single allocation system



- Regional systems
- National systems
- Scandiatransplant
- Eurotransplant

Clinical perspectives on desensitization in kidney transplantation

Professor Nizam Mamode M.D.
Professor of Transplant Surgery

Guy's and St Thomas' Hospital
London

Speaker disclosures

I have received honoraria and / or funding for studies from Alexion, CSL Behring, Hansa Biopharma and Shire

I have received a speaker fee and travel expenses from Hansa Biopharma to attend and speak at the present symposium

Key messages

Kidney failure is a major global health problem, and is rising

There is an increasing proportion of patients with antibodies who cannot be transplanted

Existing methods of treating these patients are inadequate

What can we transplant?

Heart
5 400 heart transplants

Liver
20 200 liver transplants (14.6% from living donors)

Lung
3 400 lung transplants

Kidney
69 400 are kidney transplants (46% from living donors)

Pancreas
2400 pancreas transplants

Small bowel

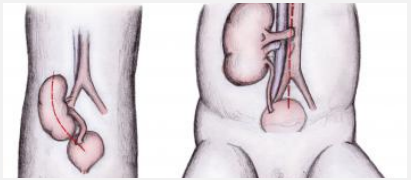
Hand

Face

Uterus

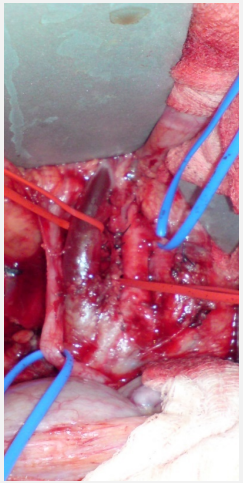
Based on activity data analysed from 2008 for 104 countries, representing nearly 90% of the worldwide population, it is shown that around 100, 800 solid organ transplants are performed every year worldwide. Although some countries do not provide complete data on deceased donation, information from around 22 400 deceased donors was also reported to the GODT

Source: WHO GKT1 Activity and Practices
https://www.who.int/transplantation/gkt/statistics/en/



698 million
cases chronic kidney disease
in 2017 globally- prevalence of 9.1%

1.2 million deaths
in 2017- best case scenario is 2.2 million in 2040



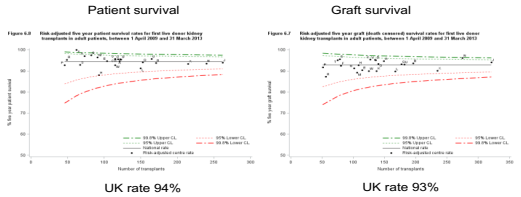
GBD Chronic Kidney Disease Collaboration Lancet 2020

The success of transplantation

Living donor kidney transplant - Five year survival

NHS Blood and Transplant

Excellent post transplant outcomes – no outlying centres with poor survival



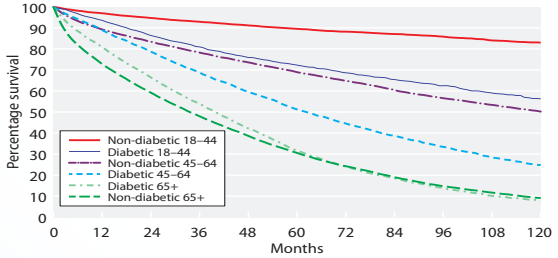
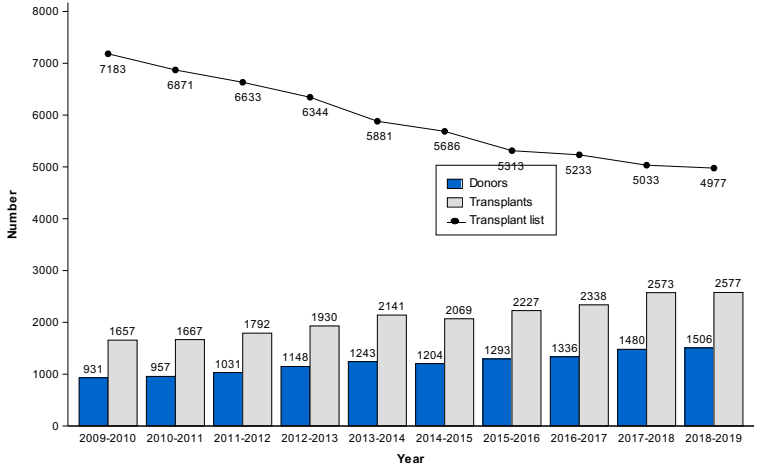


Fig. 5.19. Long term survival for incident RRT patients with and without diabetes by age group, 2003–2012 cohort, followed up for a minimum of three years

Source: NEPHRON 2017;137 (suppl1)
UK Renal Registry
19th Annual Report of the Renal Association

Deceased donor kidney programme in the UK, 1 April 2009 - 31 March 2019, Number of donors, transplants and patients on the active transplant list at 31 March



Source: Transplant activity in the UK, 2018-2019, NHS Blood and Transplant

HLA- why is it important?

Antigenic proteins on cell surface

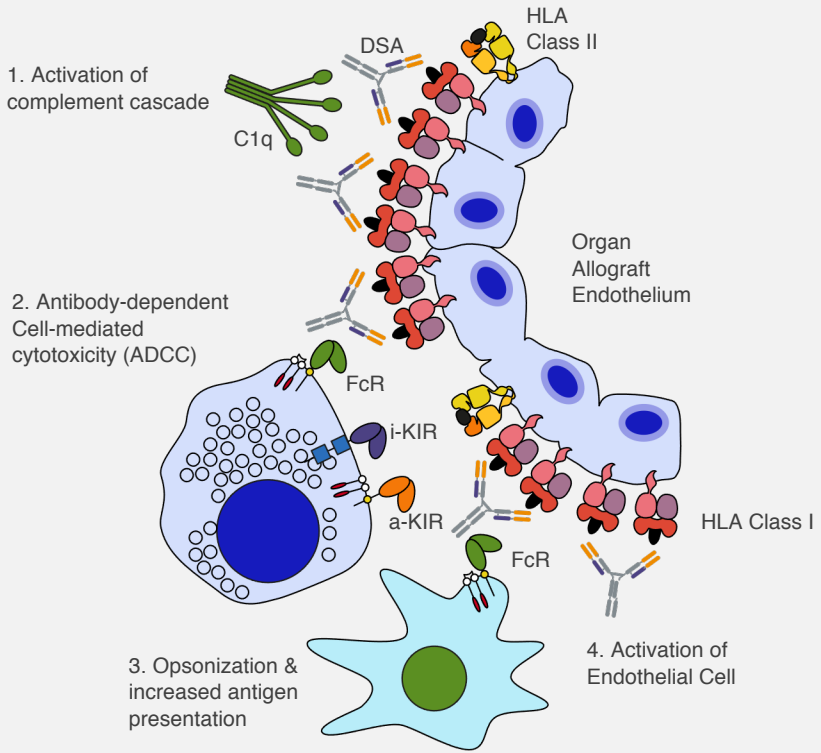
HLA loci determine the 'match'- 000 to 222

Anti-HLA antibodies in the recipient will bind to cell surface in the donated organ

This will result in cell lysis- i.e acute rejection of the transplant

Why do you have HLA Ab?

Previous transplant, blood transfusion, pregnancy

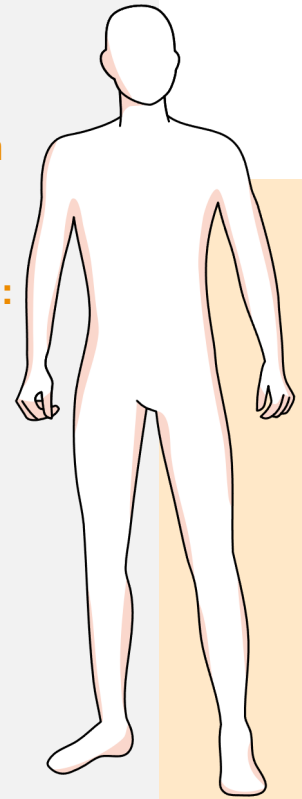


Soruce: Abdominal Organ Transplantation: State of the Art, Nizam Mamode Raja Kandaswamy
First published:23 December 2012
Print ISBN:9781444334326 IOnline ISBN:9781118483664 IDOI:10.1002/9781118483664

HLA Ab- why is it important?

We call patients with HLA Ab sensitised

In the UK, we use CRF to measure this: the % of the last 10,000 deceased donors to whom you have HLA Ab



You will not be offered a deceased donor organ if you have HLA Ab to it

A living donor transplant cannot go ahead if you have HLA Ab which causes a positive cross-match

Landscape of Highly Sensitized patients worldwide according to different immune assays

Courtesy Oriol Bestard

Stewart DE AJT AJT 2015
ONT, Official letter. December 2018
Heidt S et al Exp rev Clinc Immunol 2018
Manook M Lancet 2017

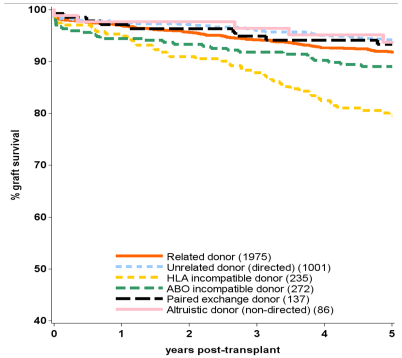
What is the unmet need for sensitised patients?

The most highly sensitised (cRF 95–100%) don't get an offer

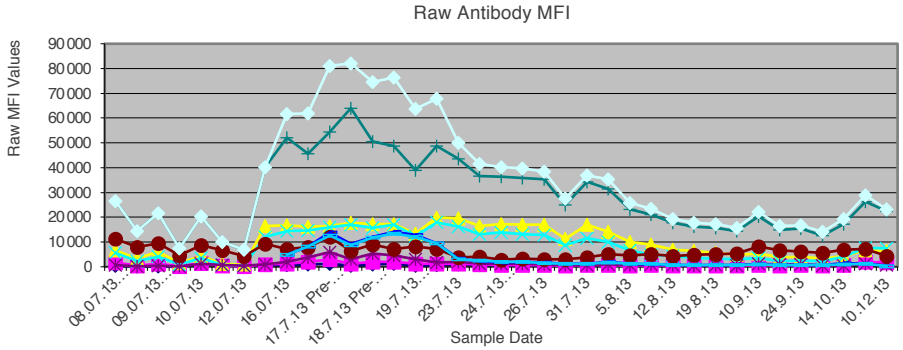
Early aggressive AMR related to a memory response

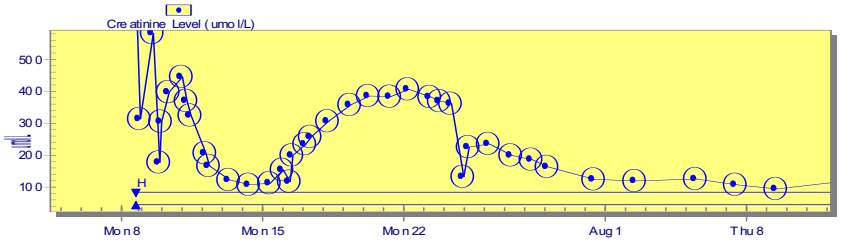
High rates of acute AMR – high graft loss and mortality

Worse long term graft survival – CAMR



NHSBT Annual Report 2017

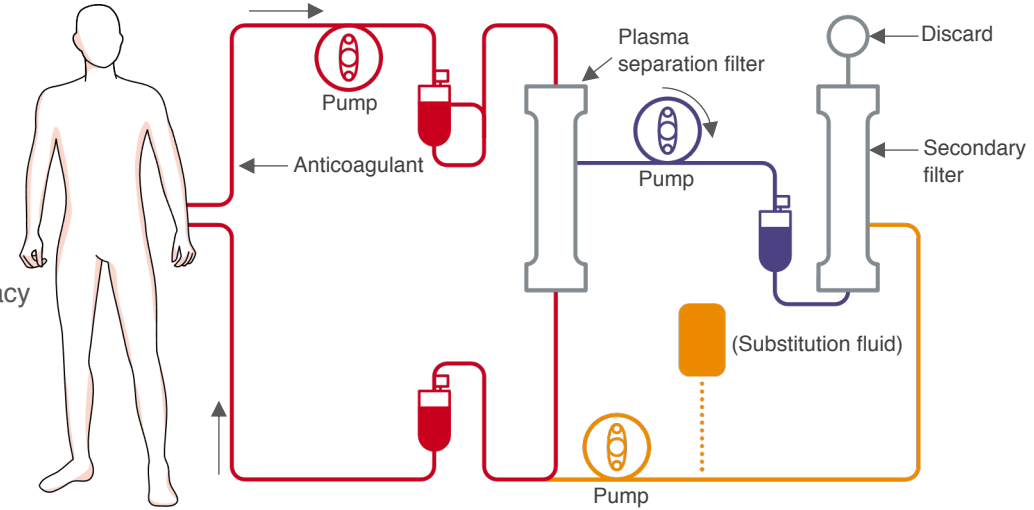




Punjala Oral M2 BTS 2020

Today's desensitization options are inadequate

- Plasmapheresis/DFPP
- Immunoabsorption (Therasorb)
- IvIG- high (2g/kg) or low (0.5g/kg) dose
- Complement inhibitors
- Anti-CD20 (Rituximab):
  - Systematic Review of Rituximab in Desensitization
  - Macklin et al Transplantation 2014: Limited evidence
- Bortezomib: Stegall Transplantation 2011: Limited efficacy
- Splenectomy
- For Deceased Donors:
  - IvIG +anti-CD20



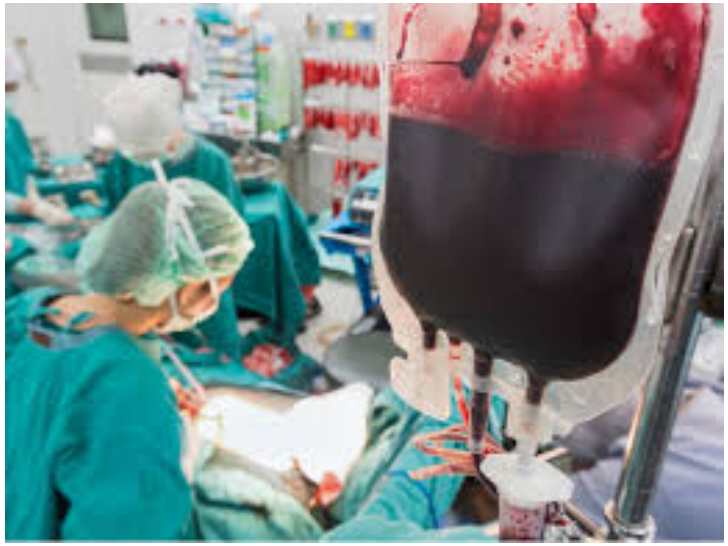
Antibody mediated rejection episodes occurs in 40-50% of sensitized patients*

Treatment:

Plasmapheresis
Anti-thymocyte globulin
Complement inhibitors

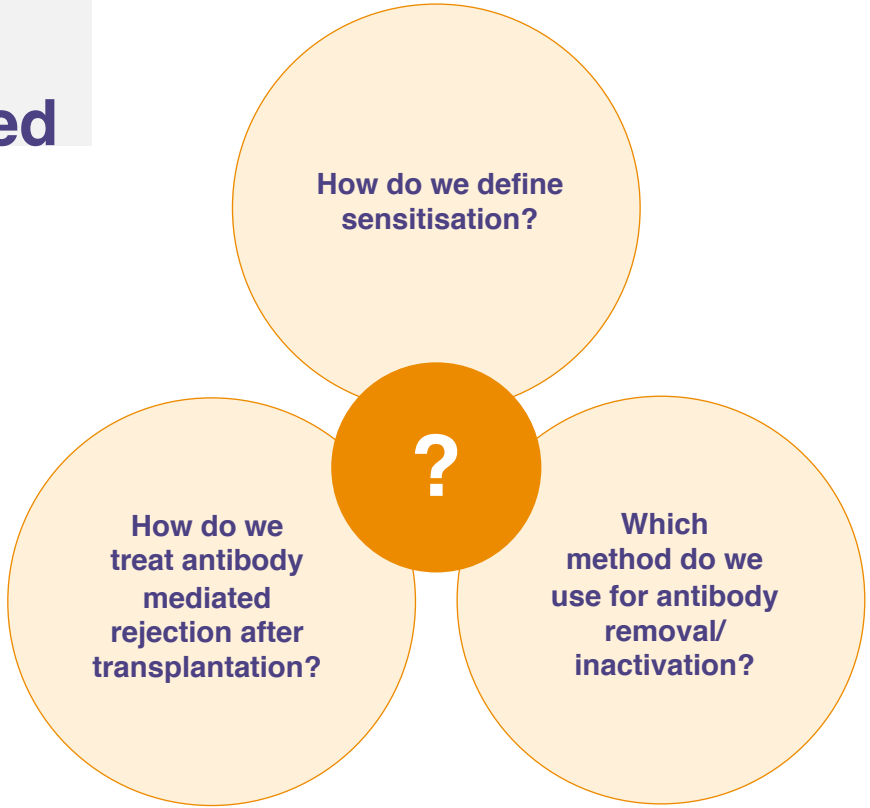
Problems:

Bleeding
Infection- which may be life threatening



* Difference in outcomes after antibody-mediated rejection between abo-incompatible and positive cross-match transplantations. Couzi et al Transplant Int 2015

The unmet need



European Society Transplantation: Transplant Learning Journey 2.0: How to manage patients with HLA Antibodies- kindly supported by Hansa

Delisting: a means of transplanting some DD patients with antibodies

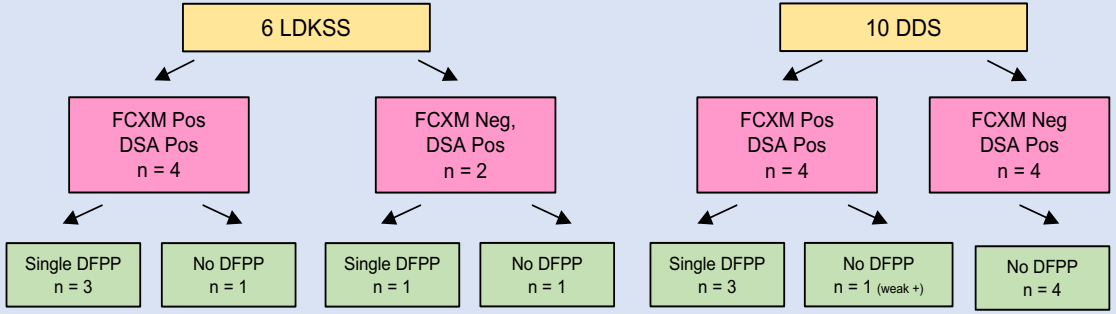
Principle

Remove unacceptable Ags from registered profile on waiting list or NKSS

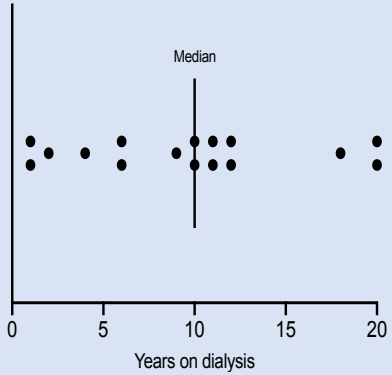
Either

Best guess:
Remove Ags where low level Ab
Plasmapheresis:
Remove Ags for Ab we know we can remove
Aim for a negative FCXM pre-transplant

- On the basis of this delisting approach, we have transplanted 16 patients to date:



- Median follow-up was 1083 days (range 86 to 1912)
- Overall graft survival of 69% to this point
  - 1 LD & 1 DD graft failed after 1047 and 1083 days respectively
- 3 DD grafts were lost within the first few days of transplantation giving a 1-yr graft survival of 81%
  - 2 of these 3 had single DFPP pre-transplant, suffered multi-organ failure and died



Sran K et al. Poster PO199 at ESOT 2019 Abstract 4395913 15th Sept

Safety and efficacy of imlifidase in highly-sensitised kidney transplant patients:

results from the International phase II study

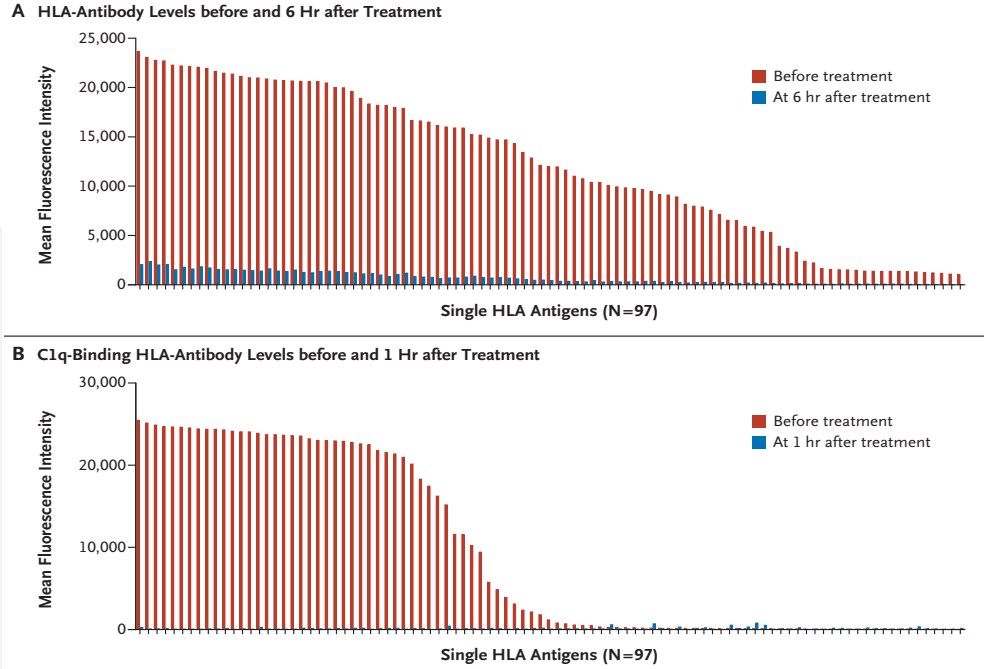
S.C. Jordan, C. Legendre, N.M. Desai, T. Lorant, M. Bengtsson, L. Laxmyr, B.E. Lonze, A. Vo, K.J. Wood, C. Kjellman, L. Winstedt, R.A. Montgomery

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation

S.C. Jordan, T. Lorant, J. Choi, C. Kjellman, L. Winstedt, M. Bengtsson, X. Zhang, T. Eich, M. Toyoda, B.-M. Eriksson, S. Ge, A. Peng, S. Järnum, K.J. Wood, T. Lundgren, L. Wennberg, L. Bäckman, E. Larsson, R. Villicana, J. Kahwaji, S. Louie, A. Kang, M. Haas, C. Nast, A. Vo, and G. Tufveson



Jordan SC et al. New Engl J Med 2017;377:442–53.

Imlifidase specifically cleaves IgG antibodies

IgG is cleaved in a two-step process[1,2]

STEP 1: Single-cleaved IgG molecule (scIgG) with one intact heavy chain is generated

STEP 2: One $F(ab')_2$ fragment and one Fc fragment generated

Cleaves IgG at the lower-hinge region to form F(ab')2 and Fc fragments[1–3]

Cleaves all forms of IgG (free, bound to antigen and membrane-bound)

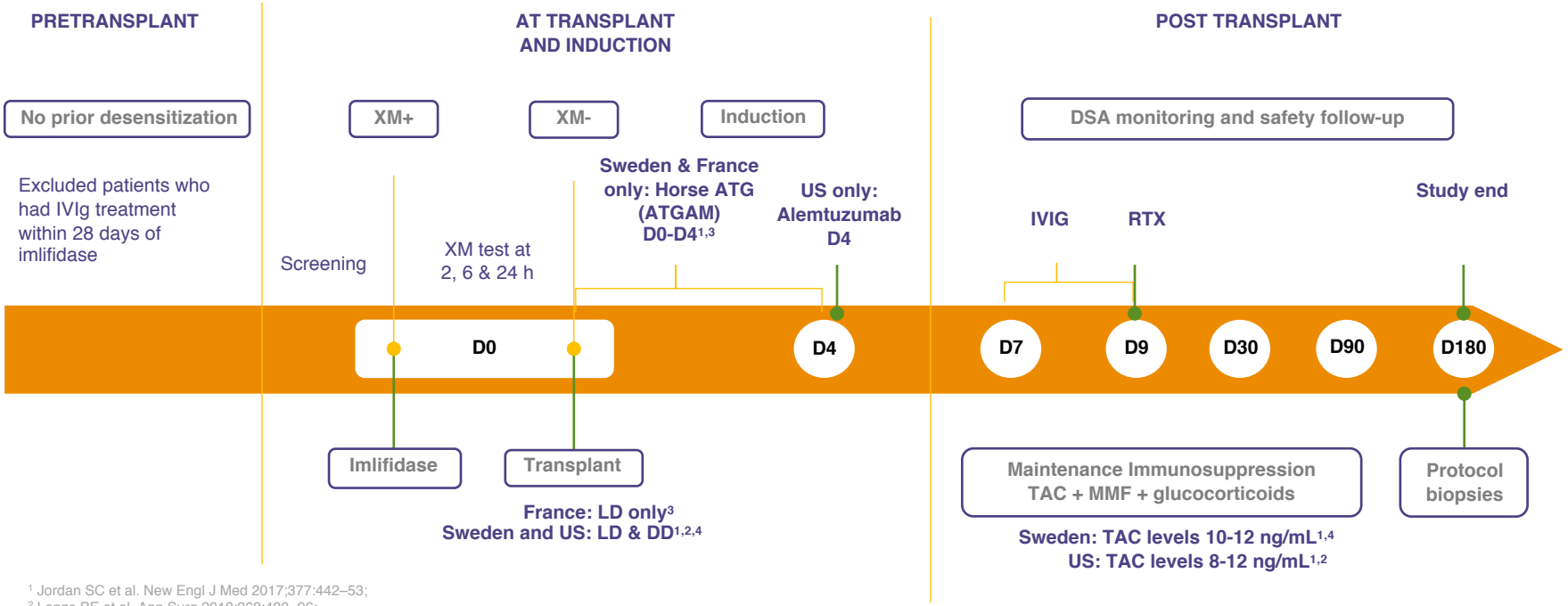
Effectively neutralizes IgG Fc-dependent effector functions, including ADCC, ADCP, and CDC[1–3]

Highly-specific towards IgG3

Other molecules (ie IgA, IgD, IgE and IgM) are not cleaved

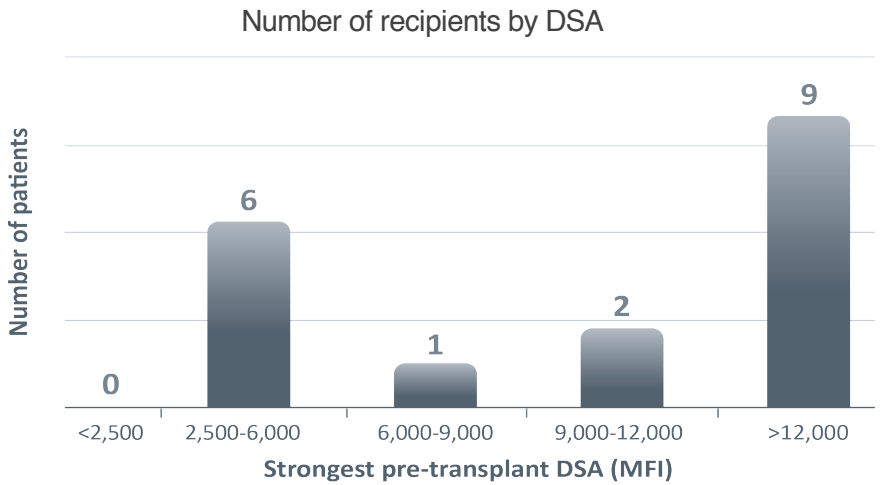
[1] Winstedt L et al. PLoS One 2015;10:e0132011;
[2] Ryan MF et al. Mol Immunol 2008;45:1837–46;
[3] Vindebro R et al. FEBS Lett 2013;587:1818–22.

Study design addresses key components of the transplant management (Study 06)



[1] Jordan SC et al. New Engl J Med 2017;377:442–53;
[2] Lonze BE et al. Ann Surg 2018;268:488–96;
[3] Hansa Biopharma. Data on file.
[4] Lorant T et al. Am J Transplant 2018;18:2752–62. DD, deceased donor; LD, living donor; MMF, mycofenolate mofetil; RTX, rituximab; TAC, tacrolimus; TP, transplant

Pretransplant antibody data reflects highly sensitized patient population



Median recipient cPRA: 99.6%

Within 24 hours of imlifidase administration

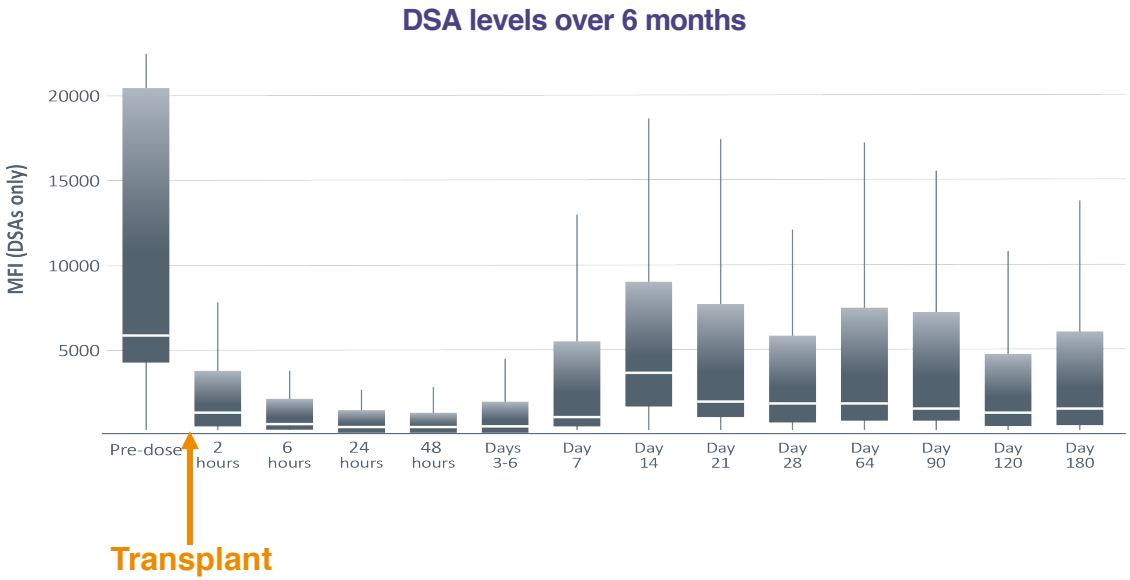
17 of 18 crossmatches converted from POSITIVE to NEGATIVE

1 patient had borderline positive flow crossmatch at transplant

3 patients received a second dose prior to transplant

Jordan SC et al. Presented at ATC 2019, Boston
cPRA, calculated panel reactive antibody;
MFI, median fluorescence intensity

DSAs are effectively inactivated post-imlifidase

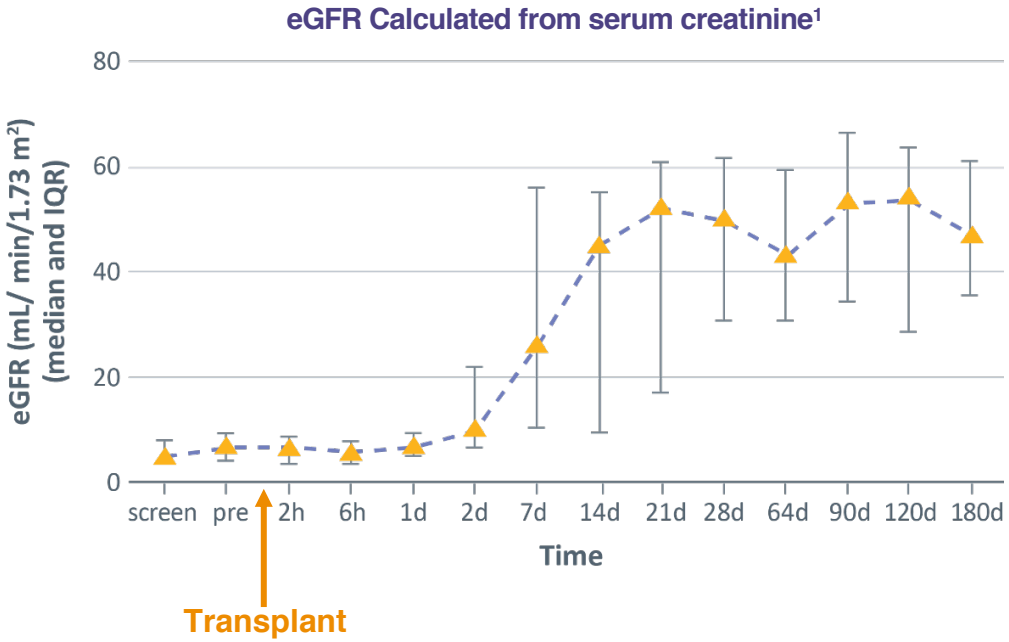


GS 89% (2 PNF)

39% AMR

Jordan SC et al. Presented at ATC 2019, Boston

Renal function over time after imlifidase treatment



Mean eGFR at 6 months:
50 ml/min/1.73m2
(IQR 36-61)

[1] Hansa Biopharma. Data on file.

Conclusions

Highly sensitized recipients are an increasing problem, especially on the deceased donor waiting list

Idefirix® is a promising desensitization treatment for patients who would otherwise remain on dialysis without access to a potentially life-saving transplant

Our European launch strategy

Henk Doude van Troostwijk
SVP & CCO

Significant potential across Europe and US in highly sensitized kidney transplant patients

EU: Idefirix ready to be launched

- Conditional approval adopted by the EU Commission for highly sensitized kidney transplant patients
- Establishment of commercial and medical team
- Brand strategies and targeted launch tactics
- Building awareness and Key Opinion Leader advocacy through MSL's in key European markets
- Building the infrastructure and distribution

  Ongoing engagement with payers and healthcare providers around patient access and reimbursement

  Post-approval study to be initiated in 2H 2021

US: BLA filing expected by 2023

- Given the US Kidney Allocation System (KAS) FDA has requested a RCT to be completed prior to potential BLA submission
- Discussions with the FDA are currently ongoing

  Setting up centres and patient enrolment will be initiated upon finalization of study protocol

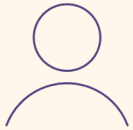
  First patient expected to be dosed 1H 2021

  Potential BLA submission planned for 2023

Idefirix approved in EU under conditional approval

Highly focused and coordinated launch strategy

One Patient at a time

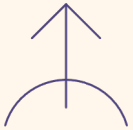


Idefirix patients identified

- Evaluation instruments differ by country
- Complement to priority allocation programmes
- Initial Package progress and pharmacovigilance and Medical Information in place

Intro to “wave one” centres

- Centralized marketing and strategy reduces duplication of efforts
- Ensures consistency of messaging
- Speeds up implementation



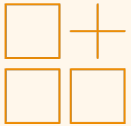
Development and Learning

- Hands on experience
- IST
- Registry and follow up

One Hansa ready to launch

Leverage strengths of both Medical and Commercial teams

- Unmet need quantified
- Supported by global value messages and economic, budget impact modelling



Clusters instead of fully built country organizations

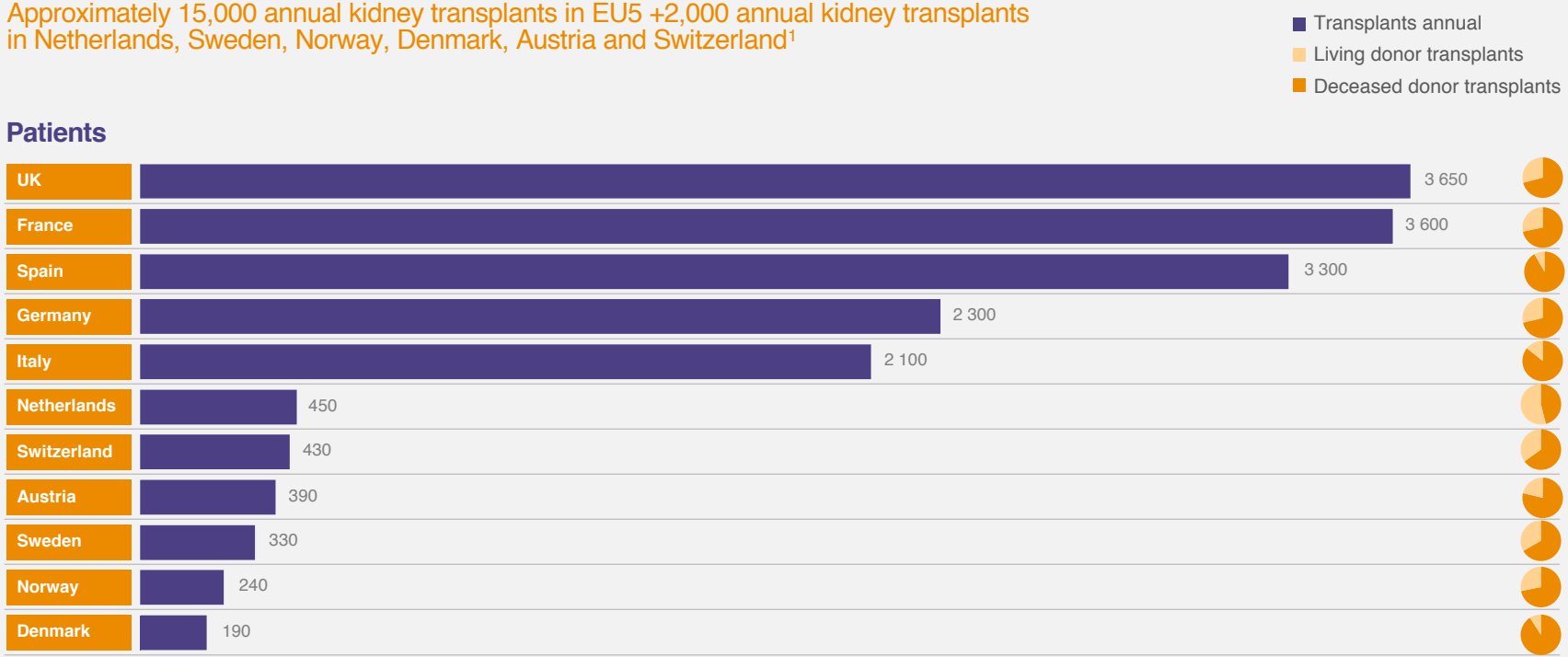
- Territory Managers and Market Access with orphan drugs expertise
- Facilitate cross fertilization and agility among countries
- Financially prudent

Pivotal functions in place to launch

- Territory Managers
- MSL’s
- Market Access
- Patient Advocacy
- Supply chain and distribution

European kidney transplantation landscape

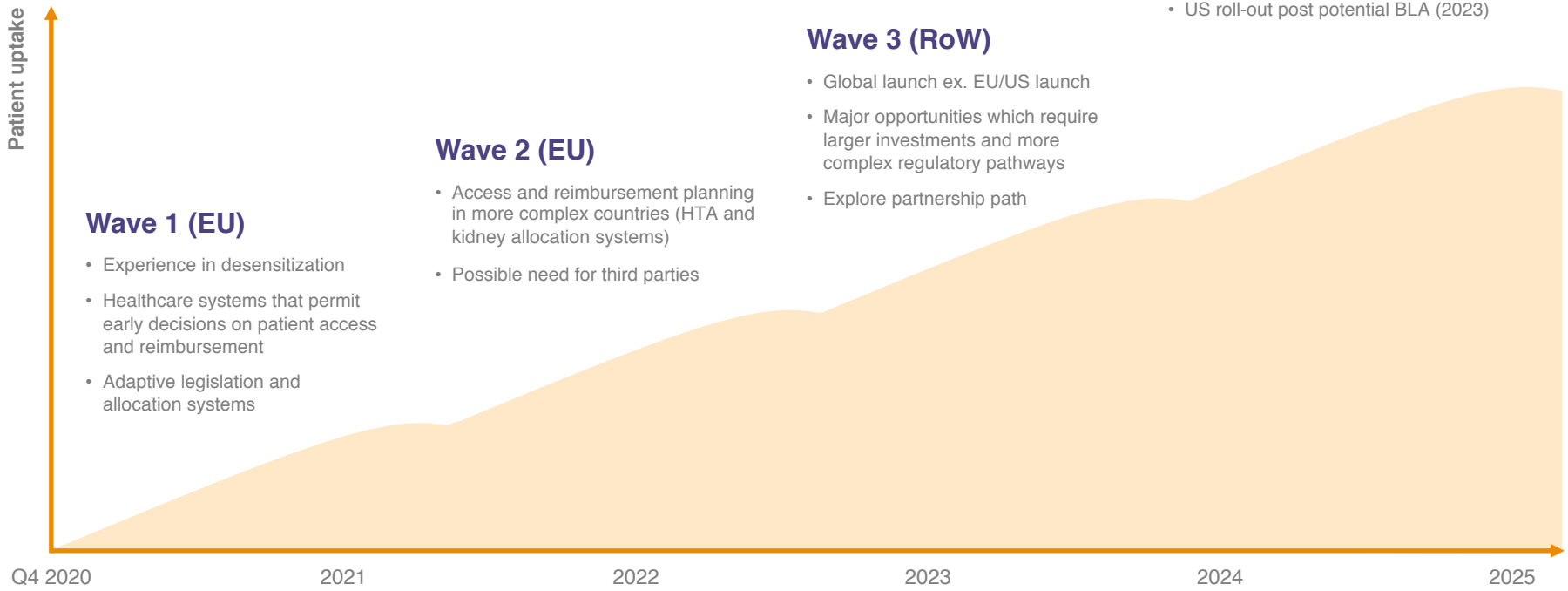
Approximately 15,000 annual kidney transplants in EU5 +2,000 annual kidney transplants in Netherlands, Sweden, Norway, Denmark, Austria and Switzerland[1]



[1] Waitlist data from 2019; transplant data from 2018.
Sources: Different sources incl. Global Observatory on Donation & Transplantation, 2018; EDQM, 2020

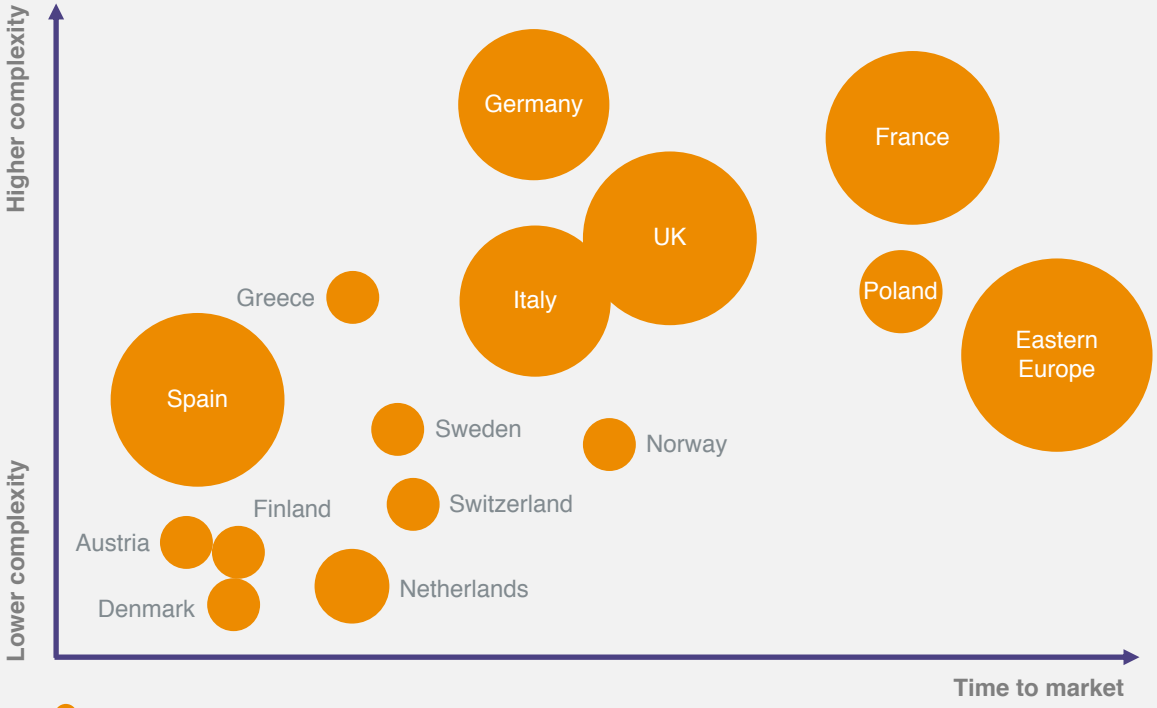
Plans for global expansion

Launching in waves with centre-by-centre approach in Europe



Patient access and reimbursement

Processes can be long and complicated in some markets; initial focus on countries that permit earlier patient access and reimbursement decisions such as Nordics



Market access strategy

Decision based on where to commercialize:

- Commercial opportunity with highly sensitized patients unlikely to be transplanted and Opinion Leaders at targeted centres willing to treat
- Expected time to market with payer decisions on patient access and reimbursement
- Complexity includes Health Technology Assessments (HTA) and kidney allocation systems

The first phase of the market access strategy is now operationalized by

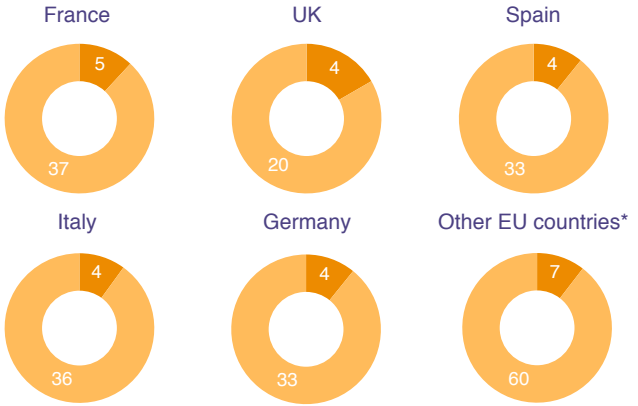
1. HTA submissions in Wave 1 countries, including robust requirements in the UK
2. Cost effectiveness and budget impact modeling
3. Global value messaging and tools for stakeholder discussions

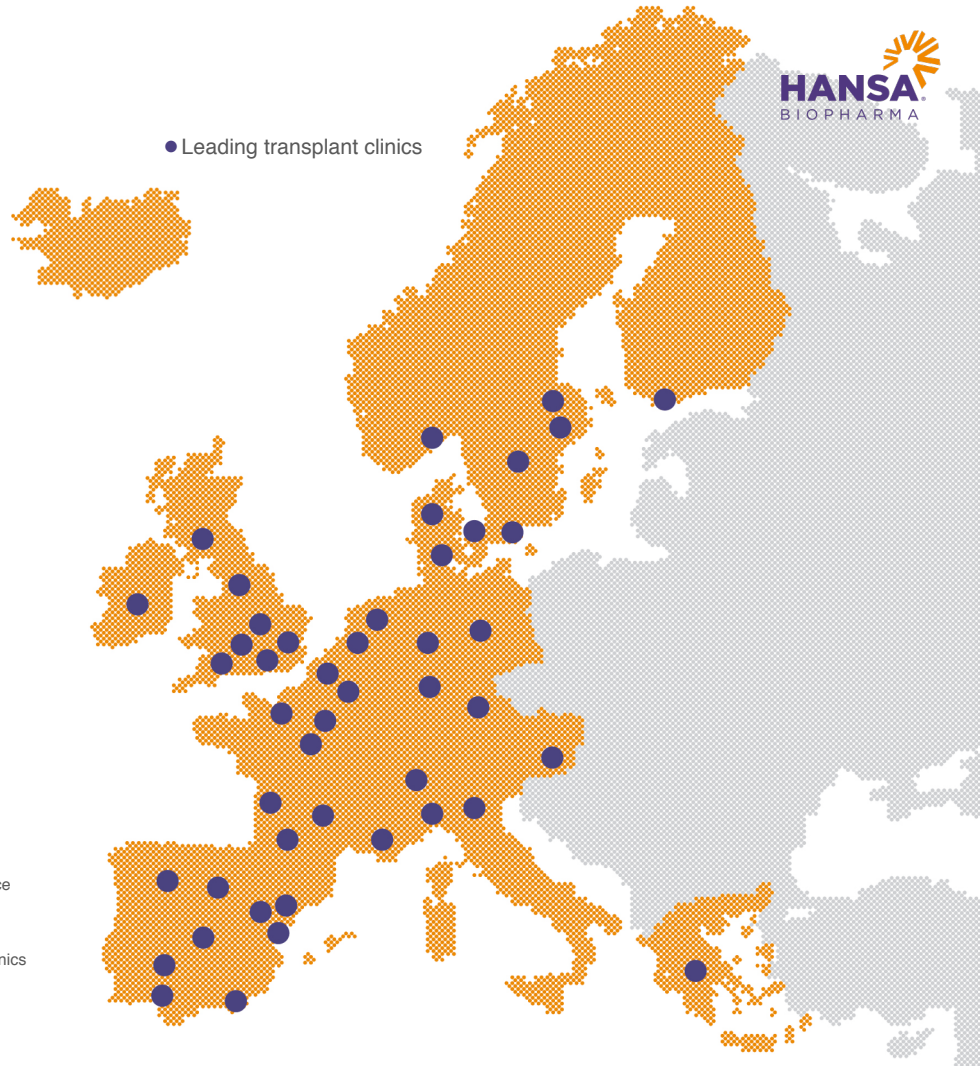
Early launch in centres of excellence

First launch wave defined

1. Launch Idefirix® with kidney transplant specialists who have experience in desensitization
2. Create positive momentum with Idefirix as the new Gold Standard in desensitization protocols
3. Prepare post approval study to confirm filing data

Leading transplantation centres perform the majority of all transplantations in EU





Idefirix approved in EU under conditional approval

*Other EU countries incl. Sweden, Denmark, Norway, Austria, Switzerland, Netherlands, Belgium, Poland, Czech Rep. and Portugal

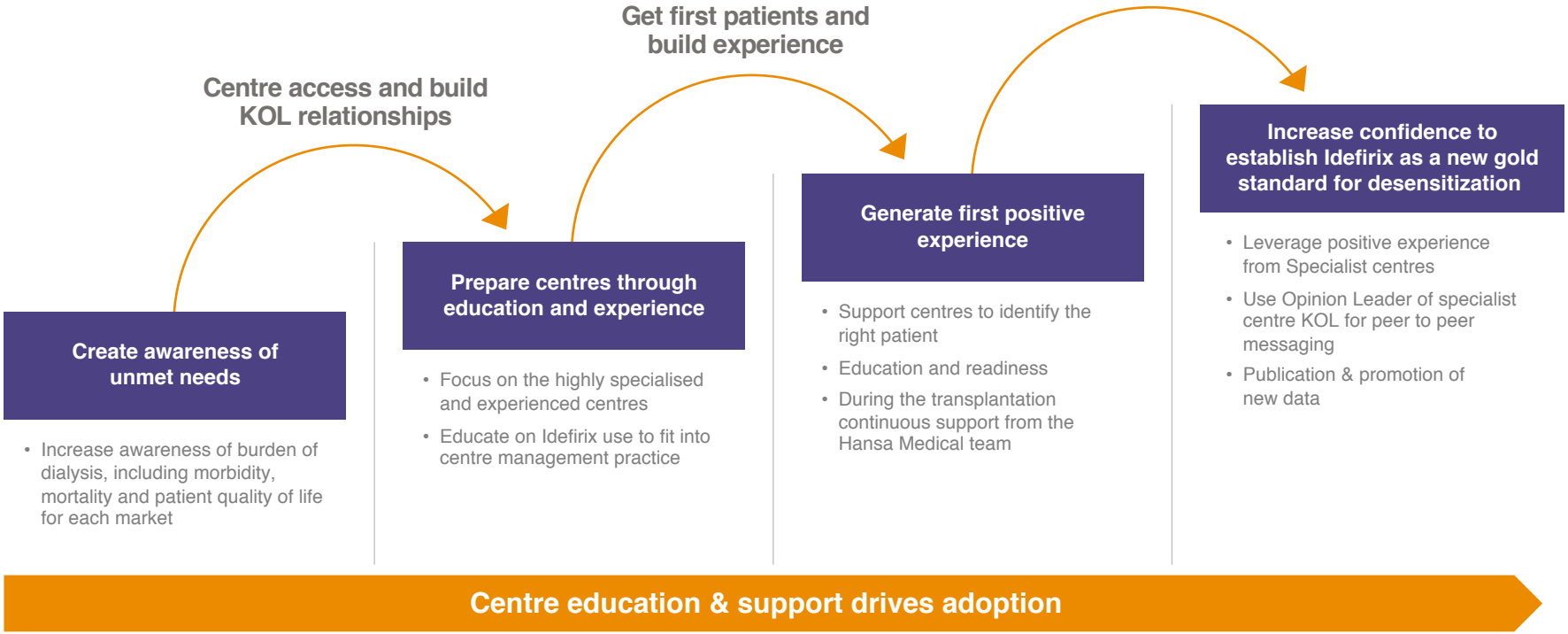
Launch Readiness: How we are increasing awareness around Idefirix®

Through MSL's, KOL engagement, publications and branding while building the infrastructure for our first launch

Commercial and Medical affairs team in place	**Establishment of Market Access and Marketing** **Establishment of Medical Affairs (7 MSL's in EU)** **Patient Advocacy** **Core commercial team established**
Advisory Board and KOL Engagement	**Advisory Board**  Prof. Kathryn Wood  Prof. Christophe Legendre  Prof. Robert Montgomery  Prof. Stanley Jordan
Medical presentations and publications support	AST American Society of Transplantation · ESOT · American Journal of Transplantation · The New England Journal of Medicine
Brand strategies and targeted launch tactics	idefirix® imlifidase **Targeting centres of excellence or early adopters to ensure positive outcome**
Flexible supply chain infrastructure	Commercial product manufacturing ▶ Packaging and labelling ▶ Distribution ▶ Clinics and hospitals ▶ Patients

Tailored support to expand use

Stepwise approach to desensitization and Idefirix® adoption



Idefirix approved in EU under conditional approval

YESTERDAY

Highly sensitized patients were waiting and waiting[1,2]

TODAY

With Idefirix (imlifidase) you can get patients transplant-ready[1–3]

TOMORROW

Your patients' new life awaits[1,2,4]

You can now inactivate DSAs with a **single infusion of Idefirix**, converting a positive crossmatch to negative within hours so your highly sensitized patients can be transplanted at last.[1–3]

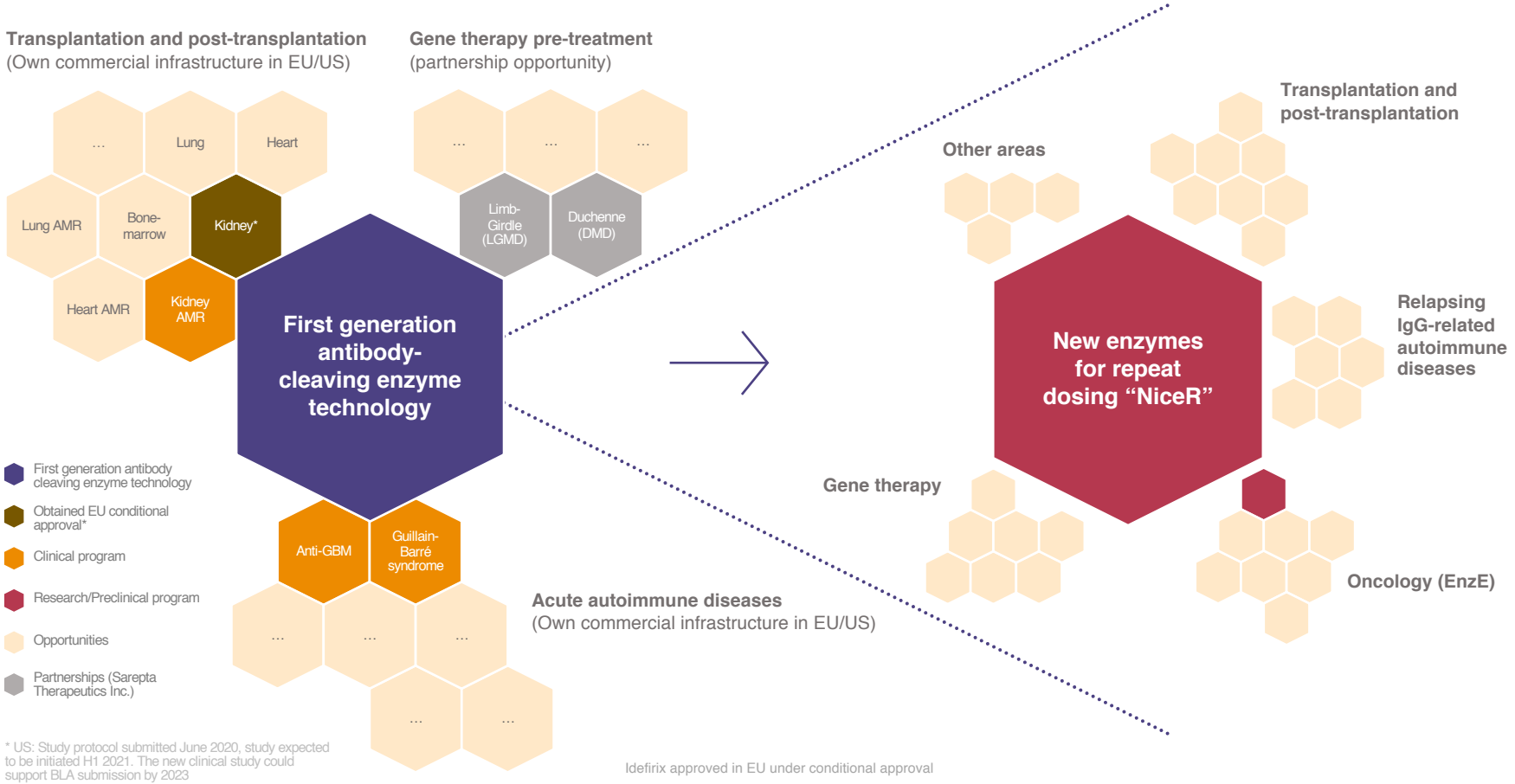
Idefirix (imlifidase)

1. Jordan SC, et al. *N Engl J Med*. 2017;377:442-453. 2. Lonze BE, et al. *Ann Surg*. 2018;268(3):488-496. 3. Akalin E. *AJKD*. 2018;71(4):458-460. 4. Rambod M, et al. *Health Care Manag* (Frederick). 2011;30(1):23-8.

Opportunities beyond kidney transplantation

Professor Achim Kaufhold M.D., PhD
SVP & CMO

Potential indication universe

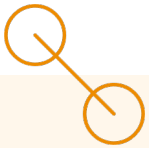


* US: Study protocol submitted June 2020, study expected to be initiated H1 2021. The new clinical study could support BLA submission by 2023

Idefirix approved in EU under conditional approval

We have a clear strategy

Leveraging our proprietary antibody-cleaving enzyme platform beyond desensitization in kidney transplantation



Transplantation

Other solid organs (e.g. heart, lung)

Antibody-mediated Rejection

Bone marrow transplantation

Haploidentical donors

Autoimmune diseases

Predominantly IgG-mediated diseases

Guillain-Barré syndrome

Anti-GBM disease

Gene therapy

Eliminate pre-existing neutralizing antibodies

Graft survival continues to be a significant challenge

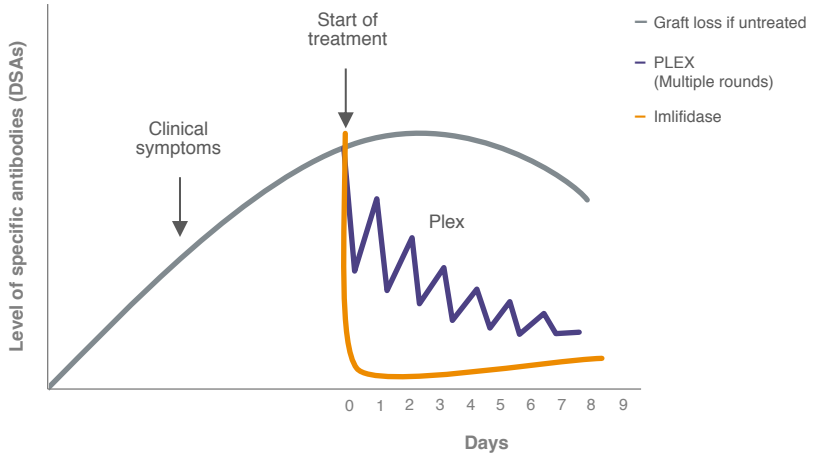
for patients affected by Antibody-Mediated Rejection (AMR) episodes post-transplantation

There is no approved treatment for AMR

- Significant challenge, mainly to long-term graft survival
- AMR episodes are driven by IgG attack (strength of DSA)
- Mainstay therapy: PLEX, IVIg, steroids, rituximab
- Treatment recommendations are largely based on expert opinion
- Graft failure leads to dialysis and return to the waitlist
- Issue across kidney and other solid organ transplantations

Potential of using imlifidase vs. PLEX in AMR

Illustrative



Phase 2 study in AMR episodes initiated

Phase 2 study in active AMR episodes initiated to test imlifidase ability to reduce the amount of DSA post-transplantation

Design of the AMR trial

- Randomized, open-label, controlled study in 30 patients
- Patients must meet Banff 2017 criteria for active or chronic active AMR
- Infusion of imlifidase (0.25 mg/kg) in 20 patients and of 5-10 sessions of PLEX in 10 patients
- Following imlifidase or PLEX, all patients receive steroids, high-dose IVIg and a single dose of rituximab
- Kidney biopsies at baseline, Day 29, Day 180, frequent follow-ups for 180 days for DSA and kidney function

Main objectives

- To assess the efficacy of imlifidase compared to PLEX in removal of DSA in patients with AMR after transplantation
- To evaluate the safety, PK/PD, and efficacy in the elimination of DSA, occurrence of AMR, and kidney function

Status

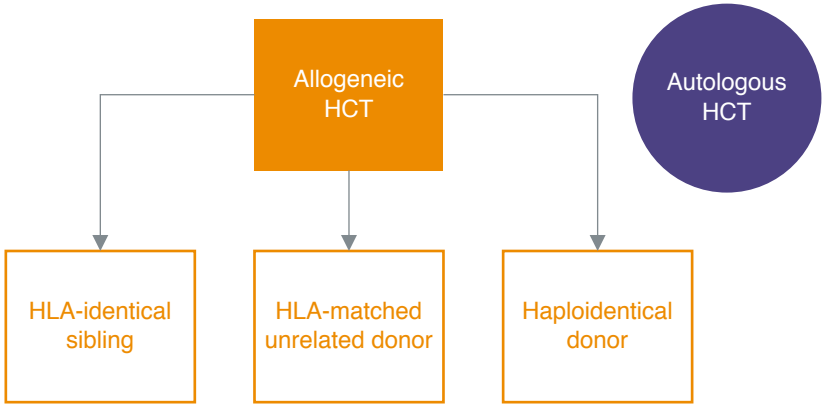
- 4 of 30 patients enrolled
- 6/10 sites are recruiting patients across the U.S., EU and Australia
- Enrollment expected to be completed in H2 2021 (expected to be reinitiated in Q4 2020 after a temporary halt due to COVID-19 pandemic)
- Data readout H2 2022

Presence of Donor-Specific Antibodies is a barrier to successful allogeneic bone marrow engraftment

Transplantations are often acutely needed, which precludes the time to find an adequately matched donor

- Transplantation is a curative treatment of several malignant and non-malignant diseases
- Prophylaxis of GVHD by post-transplantation cyclophosphamide
- Timely availability of a suitable HLA-matched donor is a big challenge in hematopoietic cell transplantation
- DSA are a barrier to bone marrow engraftment
- Allogeneic stem cell transplantation often leads to poor graft function in sensitized patients
- Current desensitization methods are inadequate in many patients

Hematopoietic cell transplantations (HCT)



Exploring potential use of imlifidase in bone marrow transplantation

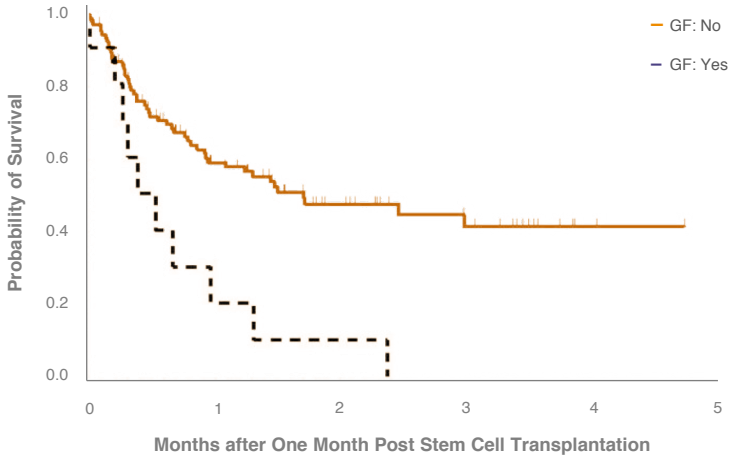
Haploidentical Hematopoietic Cell Transplantation (HHCT)

Haploidentical donors are increasingly considered

- Haploidentical donors are readily available and highly motivated for the vast majority of patients
- Rapid growth of HHCT utilization
- Prevalence of DSA in HHCT between 10-21% (up to 50% in patients with a history of multiple pregnancies)[1]
- Clear association between presence of DSA and primary graft failure, delayed engraftment and poor survival
- Various desensitization regimens employed to date
- Consensus recommendations published[1] from the EBMT[2] on testing, monitoring and treatment of patients with DSA

[1] Ciurea et al., Bone Marrow Transplantation, 2018
[2] European Society for Blood and Marrow Transplantation

Survival for patients with primary graft failure (GF)



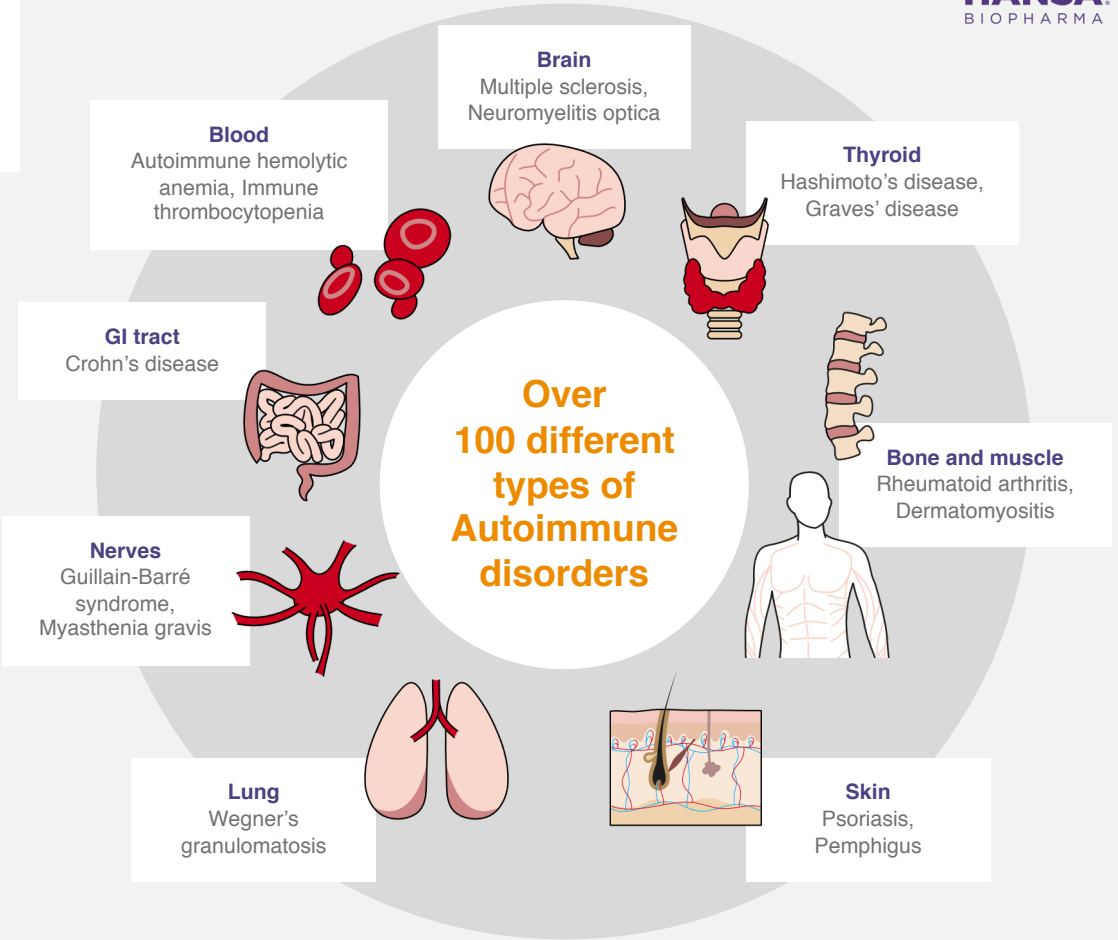
Source: Ciurea et al., Biol. Blood Marrow Transplant, 2015

Autoimmune attacks

Where the body's immune system damages its own tissue by mistake remains a big challenge and requires immediate treatment

What is an autoimmune disease?

- Humoral or cell-mediated immune responses to self-antigens (breaking of tolerance)
- Requires genetic predisposition, and often triggered by viral, bacterial and/or other environmental factors
- 3-5% of populations in Europe and North America affected; mainly women (75%)[1]

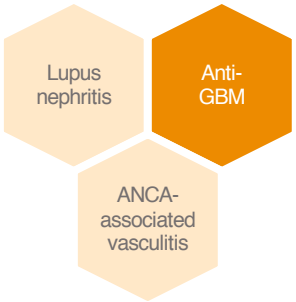


[1]Autoimmune Disease in Women: Endocrine Transition and Risk Across the Lifespandoi: Maunil K. Desai 1 and Roberta Diaz Brinton2,3* 10.3389/fendo.2019.0

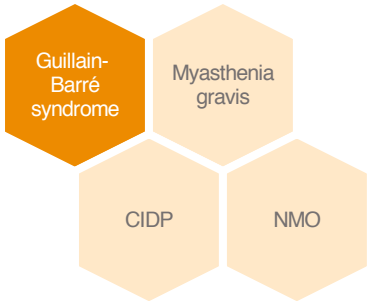
Our unique antibody-cleaving platform

may have relevance in numerous autoimmune diseases
where IgG autoantibodies play an important role

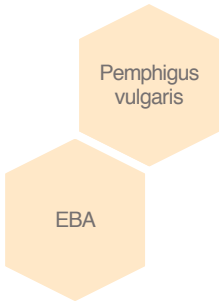
Rapidly progressive glomerulonephritis



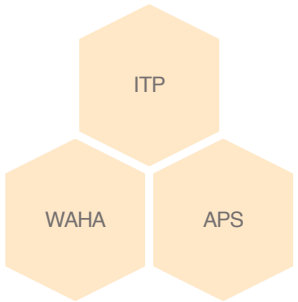
Neurological disorders



Skin disorders



Blood disorders



CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy
NMO: Neuromyelitis optica
EBA: Epidermolysis bullosa acquisita

ITP: Immune thrombocytopenia
WAHA: Warm antibody hemolytic anemia
APS: Antiphospholipid syndrome

Idefirix approved in EU under conditional approval

Guillain-Barré syndrome is an acute autoimmune attack

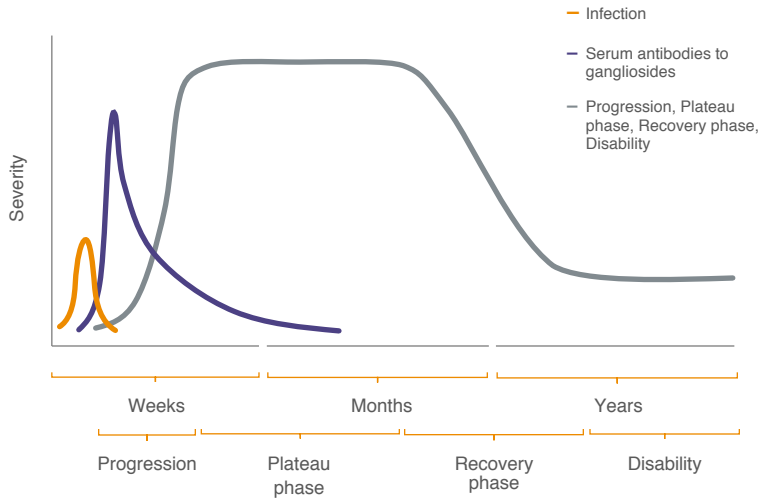
on the peripheral nervous system, potentially affecting anyone at any age

Aggressive disease with possibility of leading to paralysis or death

- Rapidly and progressively weakens extremities (e.g. paralyzing arms, legs)
- Triggered frequently by viral infections (such as Influenza, Zika virus, EBV, CMV)
- Triggered frequently by bacterial (such as *C. jejuni, M. pneumoniae*) infections; rarely by vaccinations
- Protracted course over months and years can result in severe, permanent disability
- 20-30% require mechanical ventilation; mortality 5-7%
- 1-2 per 100’000 annually; highest among the elderly population
- Treatment with IVIg or PLEX, and supportive care

Human autoimmune diseases: a comprehensive update doi: 10.1111/joim.12395

Guillain-Barré syndrome time course



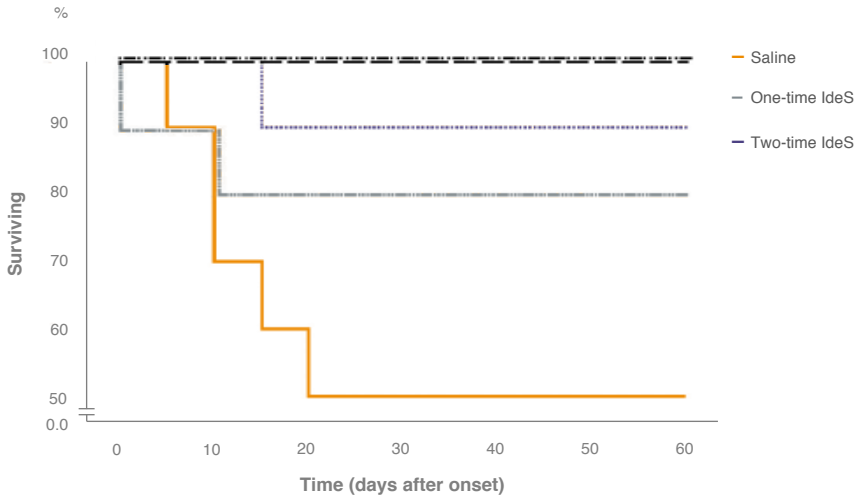
Source: Lancet 2016; 388: 717–27
http://dx.doi.org/10.1016/S0140-6736(16)00339-1

Encouraging animal data in Guillain-Barré syndrome (GBS)

Improved outcomes for rabbits treated with imlifidase

Model of acute motor axonal neuropathy showed that imlifidase compared to saline significantly

- reduced anti-GM1 IgG
- lowered frequency of C3 deposition in anterior spinal roots
- improved clinical signs
- improved survival rates



Source: Wang et al, Experimental Neurology, 2017

Phase 2 study to evaluate safety, tolerability and efficacy of imlifidase

in patients with Guillain-Barré syndrome (GBS)

Design of the GBS trial

- Open-label, single-arm trial in combination with SoC treatment given within 10 days of onset of GBS
- Infusion of 0.25mg/kg imlifidase at Day 1, followed by IVIg (400 mg/kg) at Days 3-7, and follow-up of PK/PD for 14 days, safety and efficacy parameters at 6 months and 12 months
- 30 patients targeted and matched to controls based on geographical location, age, presence of diarrhea, severity of condition
- Outcome compared to matched controls (up to 4 controls per patients) from the IGOS[1] database

[1] IGOS: International GBS Outcome Study

Main objective

- To evaluate safety, tolerability, PK/PD, and efficacy of imlifidase in GBS patients in combination with SoC intravenous immunoglobulin

Idefirix approved in EU under conditional approval

Status

- 4/30 patients enrolled.
- 6/10 sites are recruiting patients
- Recruitment will be done across France, UK and The Netherlands
- Enrollment is expected to be completed in H2 2021 (reinitiated in Q4 2020 after temporary halt due to Covid-19)
- Data readout H2 2022

In 2018, the FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS

Key messages

Hansa's proprietary IgG-cleaving technology is a platform technology with several potential applications

Broad potential as desensitization regimen in transplantation

Potential to provide incremental efficacy in several autoimmune diseases

Lead indications under investigation in autoimmune disease space: anti-GBM disease and GBS

First candidate of second-generation IgG-cleaving enzyme ("NiceR") program for treating relapsing diseases identified

First steps into gene therapy underway

Anti-GBM disease Phase 2 data-readout

Prof. Mårten Segelmark M.D.
Lead investigator and professor at Lund University and Linköping's University

Elisabeth Sonesson
Director & Head of Clinical Operations
Hansa Biopharma

Speaker disclosures

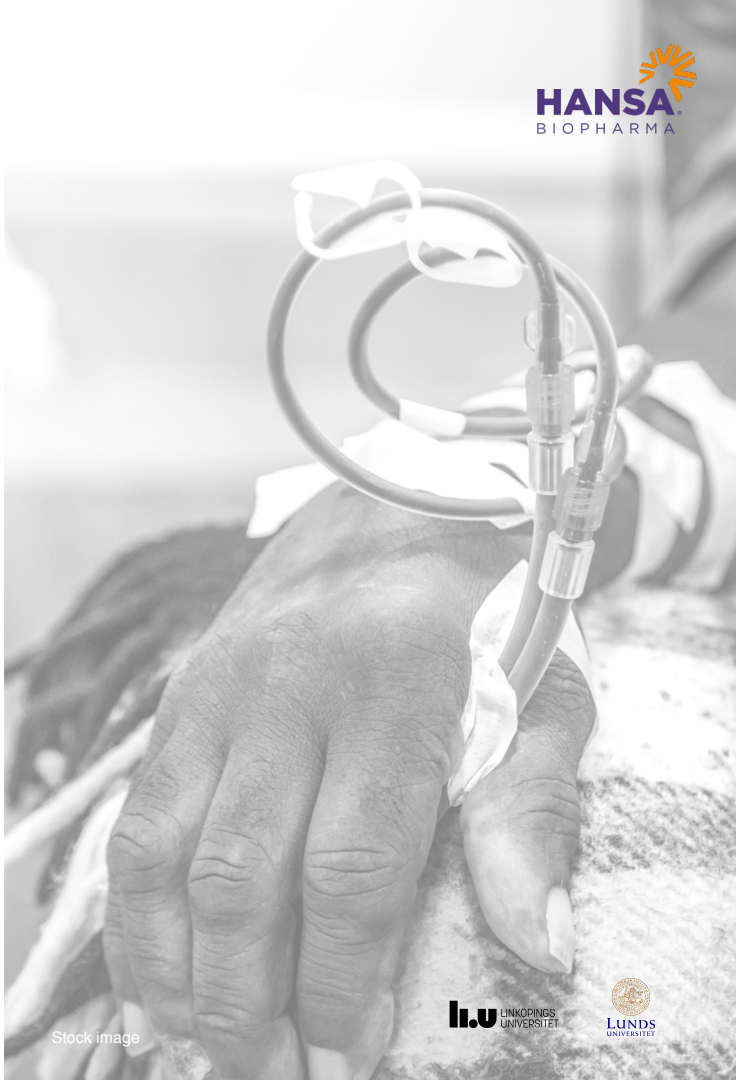
I have received honoraria and funding for study activities from Hansa Biopharma related to the anti-GBM phase 2 study

I am receiving travel expenses from Hansa Biopharma to attend and speak at the Hansa Biopharma Capital Markets Day

Anti-GBM is a serious ultra-rare and acute autoimmune disease

Facts about Anti-GBM disease

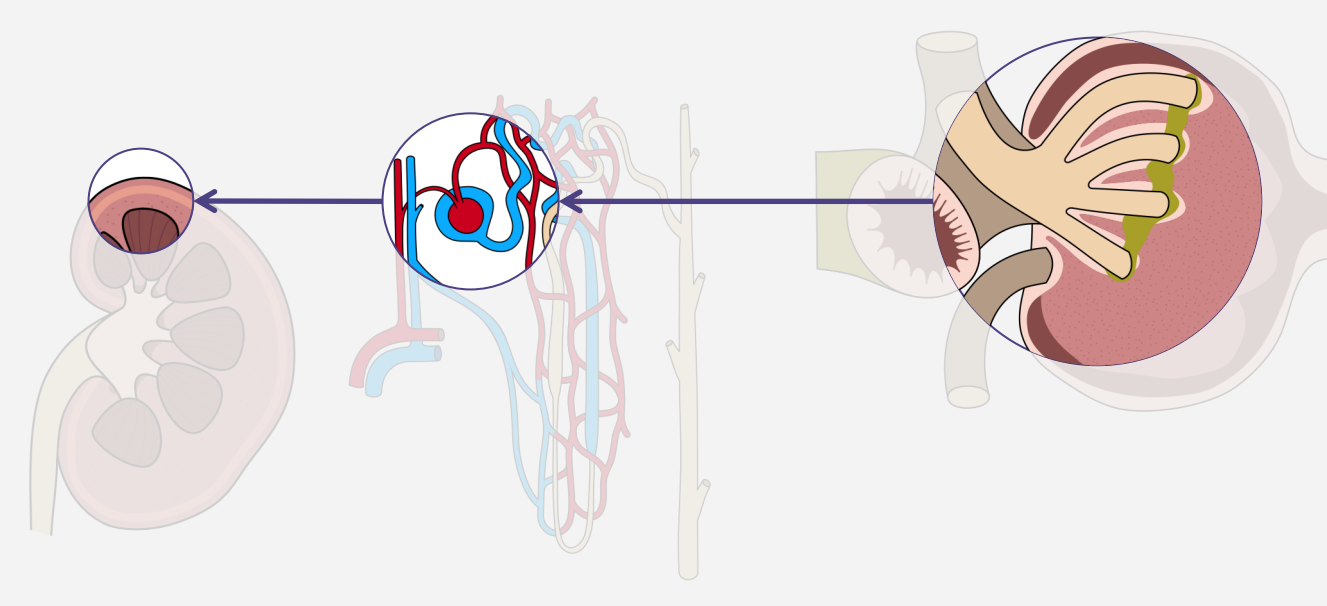
Acute autoimmune disease	**Disease driven by IgG antibodies**
Affects 1.6 in million; mainly adult	**2/3 of patients will lose kidney function and end up in dialysis**
50% of patients will have lung involvement	**High mortality rate (17%)**



Sources: Herody et al 1993, Merkel et al 1994, Daly et al 1996, Levy et al 2001, Li et al 2003, Segelmark et al 2003, Cui et al 2005, Taylor et al 2011, Dammacco et al 2013, Zhang et al 2014, Alchi et al 2015, Huart et al, 2016, MacAdoo et al 2017; Kluth et al (1999); Hellmark et al (2014)

Anti-GBM is a Glomerulonephritis (GN)

- Glomerulonephritis (GN) is a group of inflammatory kidney diseases
- In GN the inflammation starts in the glomeruli
- GN is a leading cause of kidney disease necessitating renal replacement therapy (dialysis or transplantation)
- **Autoantibodies of IgG class can be found in most forms of GN (and in many other disease)**
- Anti-GBM disease is a model disease were autoantibodies have proven part in the disease process

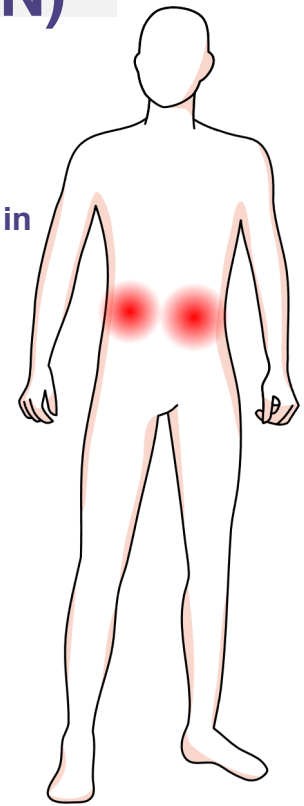


https://www.kidney.org/atoz/content/glomerul

Anti-GBM is a Glomerulonephritis (GN)

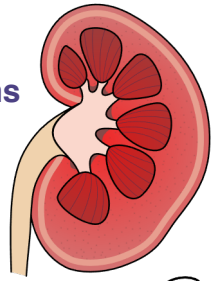
GN is a leading cause for kidney disease

Inflammation in the glomeruli



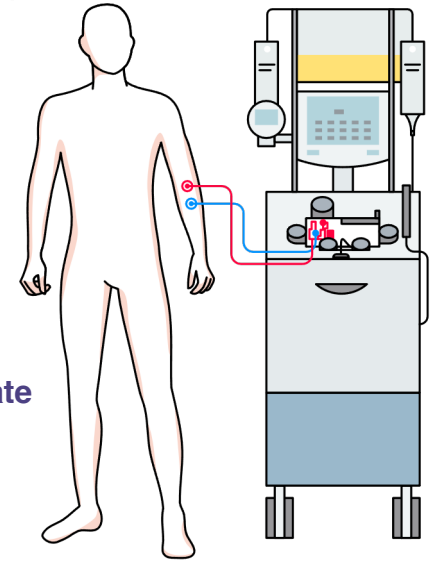
Early symptoms are unspecific

But can lead to rapid destruction of the kidney and/or the lung



Today's treatments are inadequate

Early diagnostics and treatments are crucial



Early diagnosis is crucial for halting disease progression

2/3 of patients will normally lose kidney function and end up in dialysis after six months

661

Patients in 13 studies

Patients studied since 2000 across 12 countries

~17%

(76/442)

Deaths at 6 months follow-up

~35%

(200/576)

Patients alive with their native kidney after six months

~73%

(139/190)

Native kidneys at 6-12 months with a creatine level <500-600

~9%

(34/373)

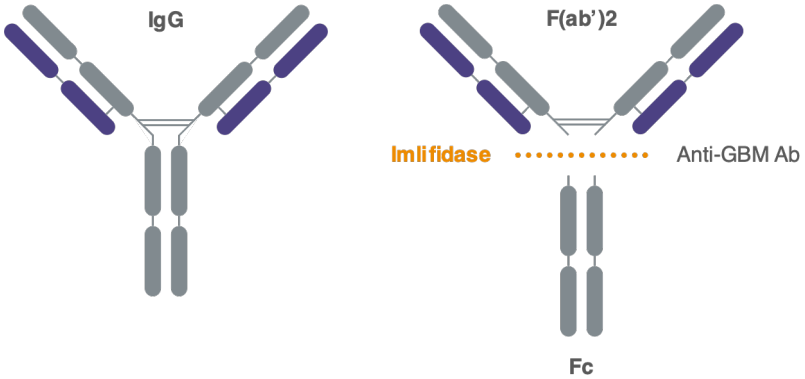
Native kidneys at 6-12 months if dialysis or creatine level >500-600

Sources: Herody et al 1993, Merkel et al 1994, Daly et al 1996, Levy et al 2001, Li et al 2003, Segelmark et al 2003, Cui et al 2005, Taylor et al 2011, Dammacco et al 2013, Zhang et al 2014, Alchi et al 2015, Huart et al, 2016, MacAdoo et al 2017

The idea is that imlifidase in anti-GBM patients may effectively cleave IgG bound to the GBM within a few hours and prevent further renal damage

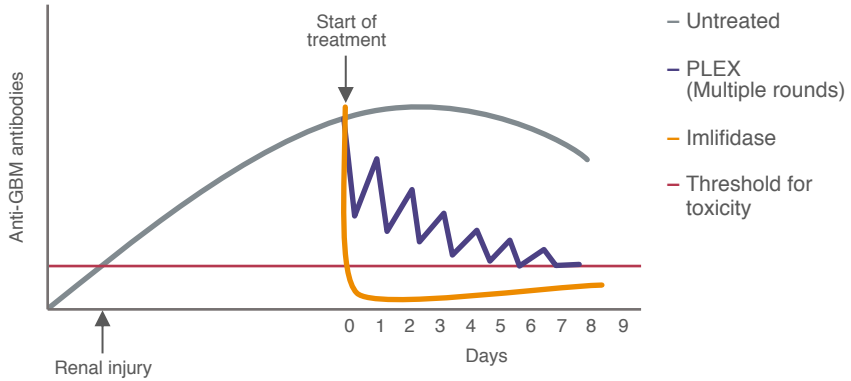
Today only a fraction of the total IgG antibodies are removed with plasma exchange and IgG in the interstitial tissue and bound to the GBM remains

Imlifidase, a unique IgG antibody-cleaving enzyme



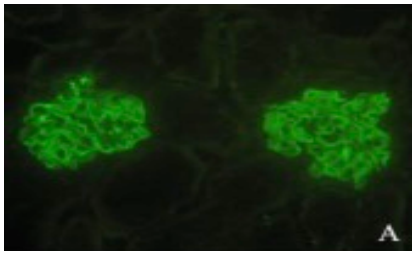
Potential of using imlifidase vs. PLEX in anti-GBM

Illustrative



Imlifidase has demonstrated effective cleavage of kidney-bound antibodies in mice and compassionate treatment

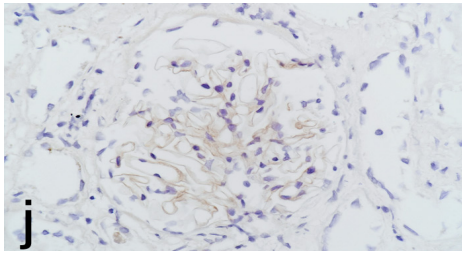
Mouse anti-rabbit IgG (Fc spec)



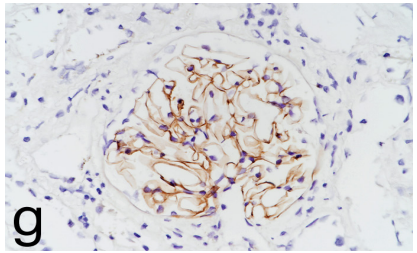
Post placebo treatment

Post imlifidase treatment

Compassionate use 11 days after treatment



Anti-Fab2-fragment



Anti-Fc-fragment

Source: Rui et al NDT, 2010

The GOOD-IdeS trial – an investigator initiated study

to evaluate safety and tolerability and renal function after six months

Design of the anti-GBM trial

One dose of imlifidase (0.25mg/kg) on top of standard of care with 180 days follow-up

- **Open-label**
- **Single arm**
- **Multi-centre study**

15 Patients enrolled with bad prognosis (<15% of normal function)

17 sites involved across 5 European countries. Total catchment area >35 million people

Main objective

Assess efficacy based on renal function at six months after treatment

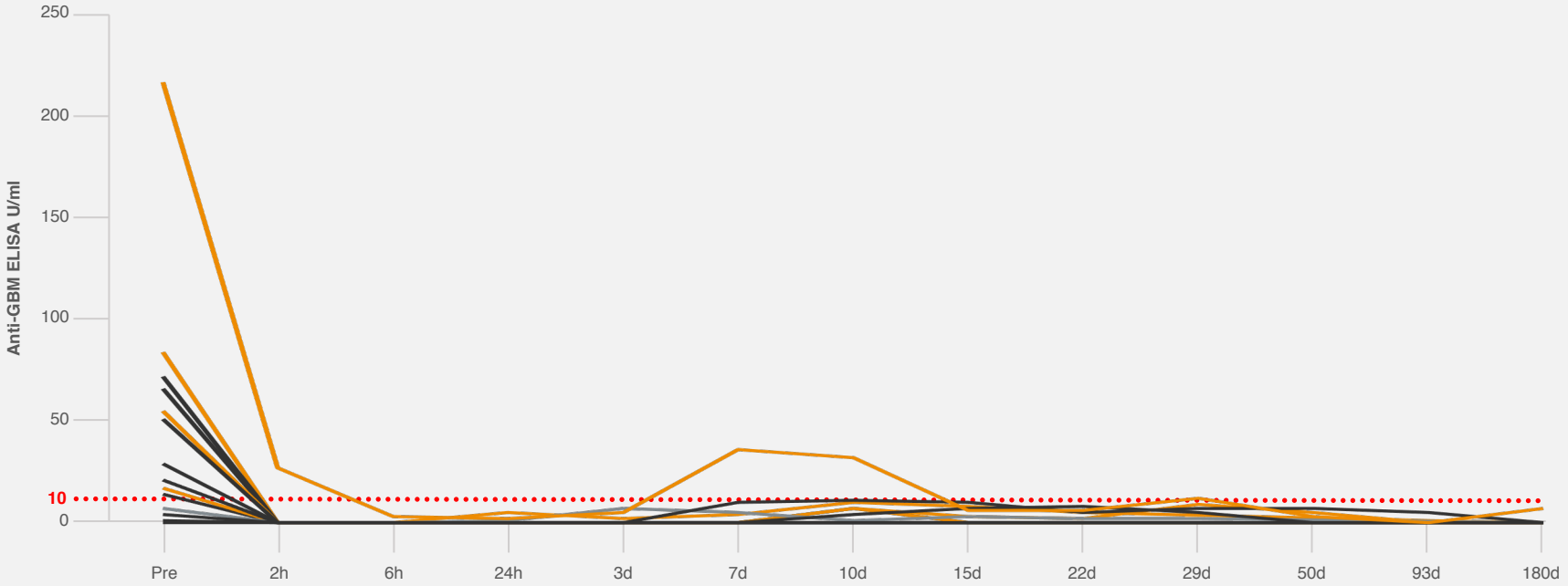
To evaluate the safety and tolerability of imlifidase on top of standard of care

Inclusion criteria

Inclusion: Anti-GBM antibody levels indicating PLEX + eGFR < 15 ml/min/1.73 m^2

Exclusion: Anuria for more than 2 days or dialysis dependency for more than 5 days

Anti-GBM levels during the follow-up

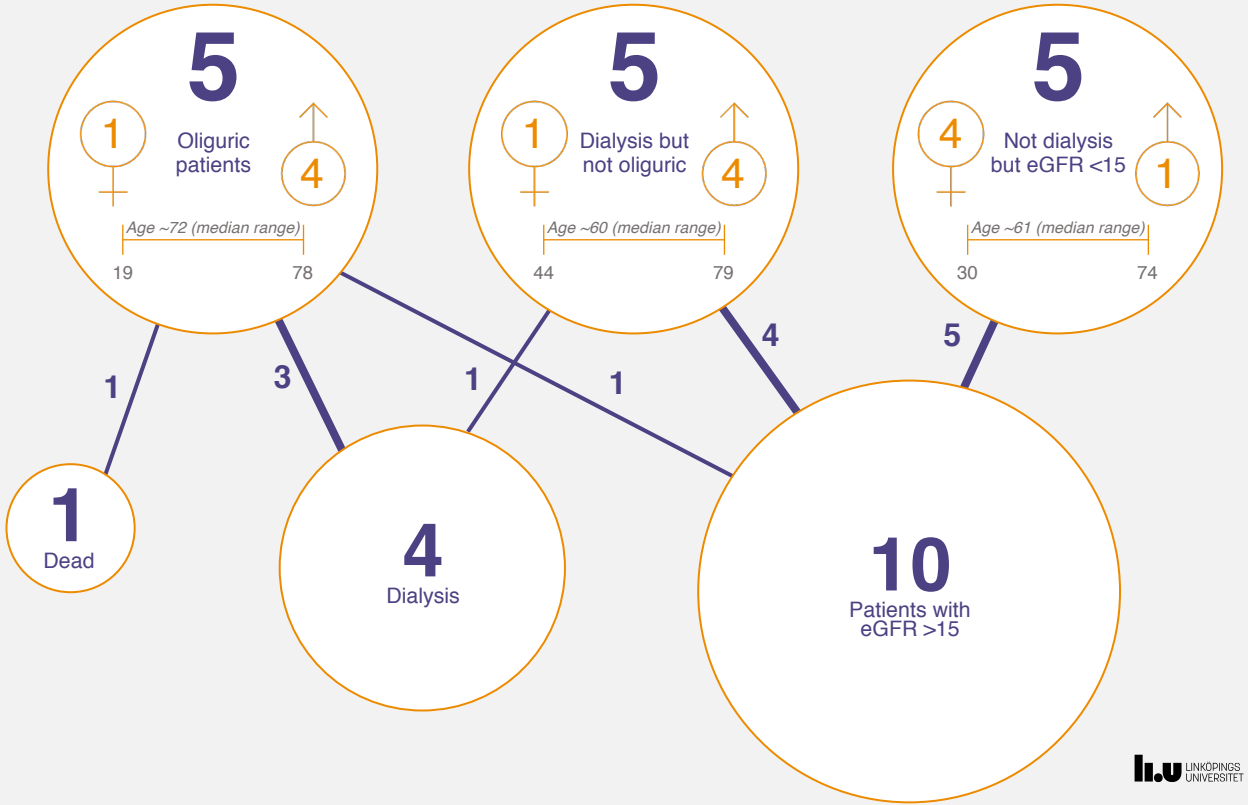


Source The Immunoglobulin G Degrading Enzyme Imlifidase for the Treatment of Anti-GBM Disease – the GOOD-IDES 01 Trial
MÅRTEN SEGELMARK1,2, FREDRIK UHLIN2, ELISABETH SONESSON3 ON BEHALF OF THE GOOD-IDES -1.0 STUDY TEAM

Results show that imlifidase leads to clearance of anti-GBM antibodies

with 2/3 of patients achieving dialysis independence six months after treatment.

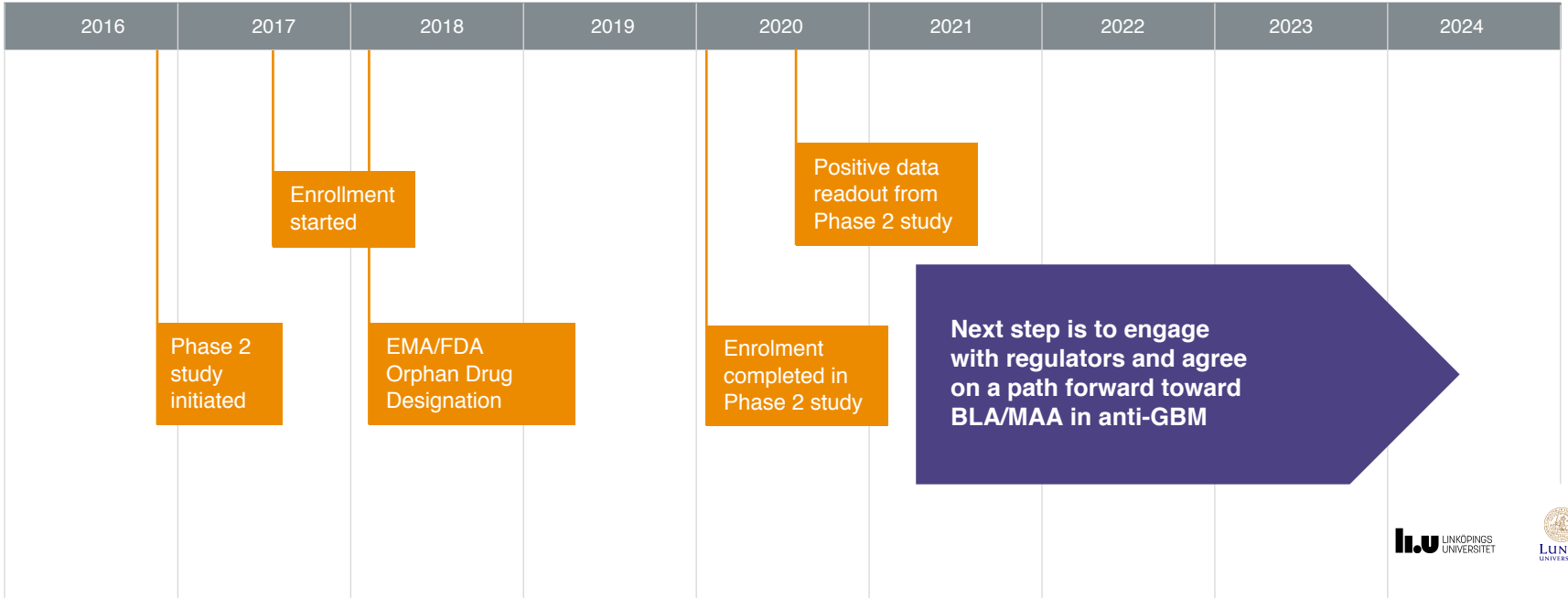
Normally 2/3 of patients will lose kidney function and end up in dialysis after six months



Next steps in anti-GBM disease

Positive outcome from the phase 2 trial in anti-GBM serves a Proof-of-Concept for imlifidase outside transplantation and in acute autoimmune diseases

Timeline in anti-GBM



Imlifidase in gene therapy

Emanuel Björne
VP Business Development

Lena Winstedt
Head of Science

Idefirix (imlifidase) approved in EU under conditional approval

Exploring opportunities in gene therapy

Exploring the opportunities in systemic administration of gene therapy for our unique antibody cleaving enzyme platform to potentially enable gene therapy treatment in Nab+ patients

A revolutionary approach

Significant unmet need

Encouraging pre-clinical data

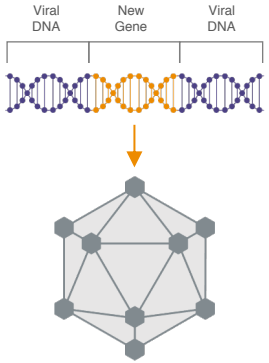
Partnership strategy

Stock images

How does gene therapy work?

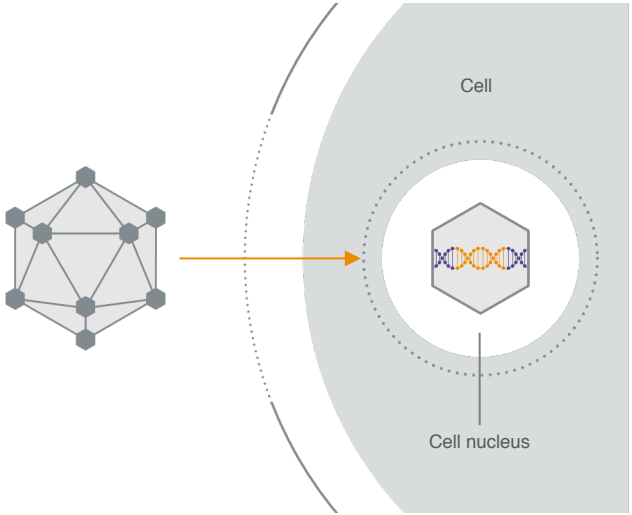
1

A healthy gene is inserted into a capsid from a harmless Adeno Associated Virus (AAV)



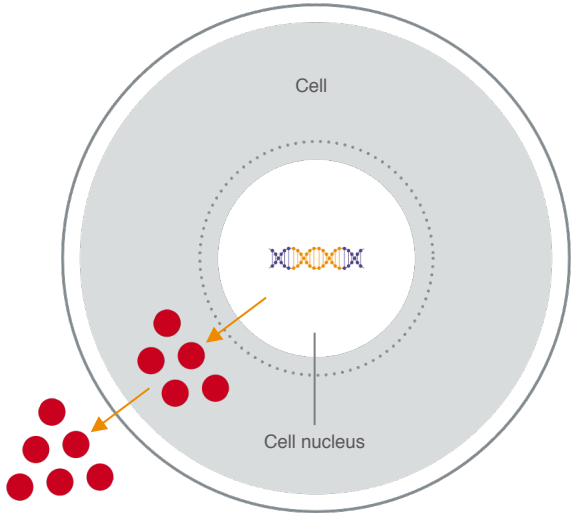
2

The viral particle enters a cell of the target tissue through the cell membrane and delivers the healthy gene into the nucleus



3

The healthy gene results in expression of the protein needed by the patient



Nature Medicine https://doi.org/10.1038/s41591-020-0911-7

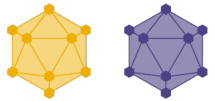
Tropism and target tissue

AAV subtypes targets different tissues

AAV 1, 2 & 5

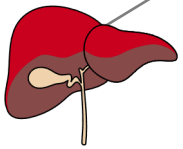
Eye (local target)
~1x10^{11} vg

Brain (local target)
~1x10^{12} vg

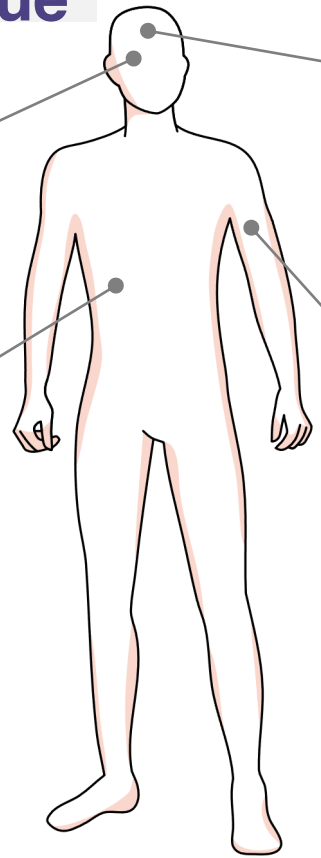


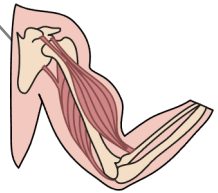
AAV 4 & 8

AAV 3, 7 & 8



Liver (systemic)
~1x10^{14} vg



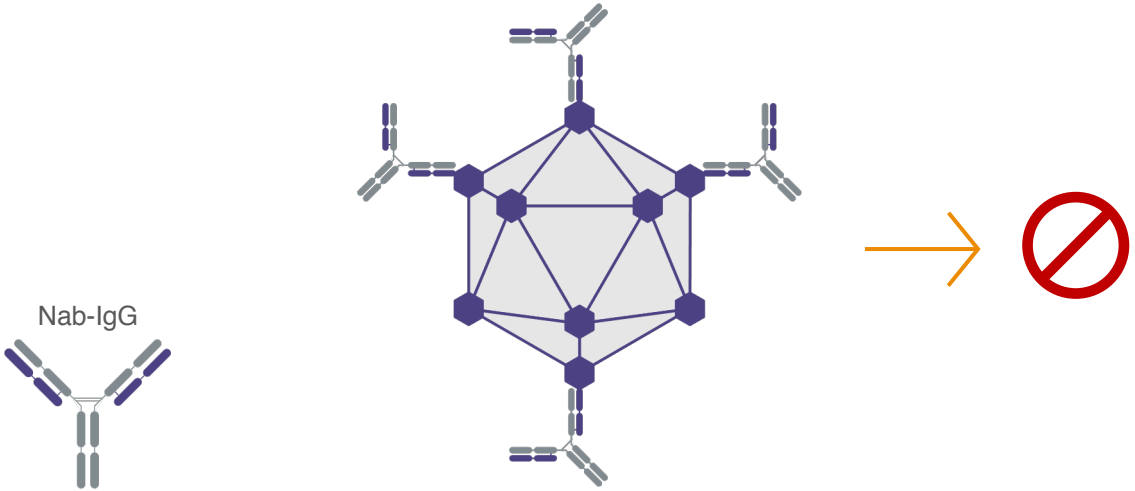


Muscle (systemic)
~1x10^{15} vg

AAV 6, 7, rh74

Target tissues
Dose of gene therapy (vg)

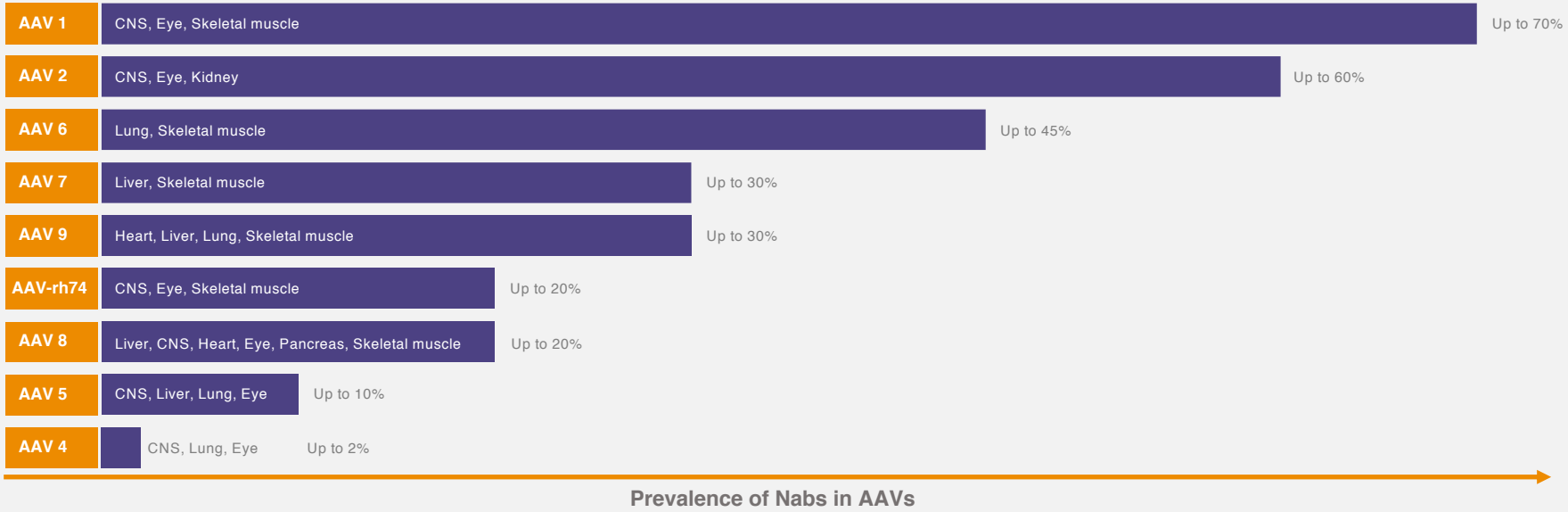
Neutralizing antibodies (Nabs) are immunological barriers in systemically administered gene therapy



Nature Medicine https://doi.org/10.1038/s41591-020-0911-7

The prevalence of Nabs varies significantly

And is a barrier that precludes gene therapies from working in a large group of patients



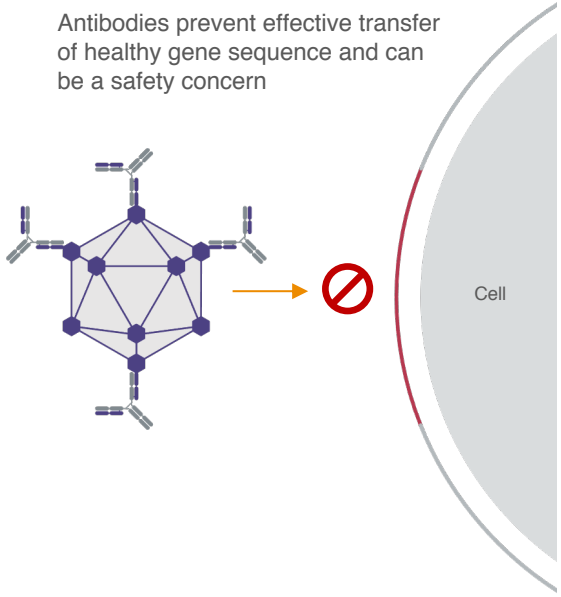
Source: Boutin et al (2010), Griffin et al (2019), Wang et al (2018), Calcedo & Wilson (2013), Falese et al (2017), Haiyan et al (2017), Ellsworth et al (2018), Greig et al (2017)

Our antibody cleaving enzymes have the potential to eliminate neutralizing antibodies

Potentially enabling systemic gene therapy in Nab+ patients

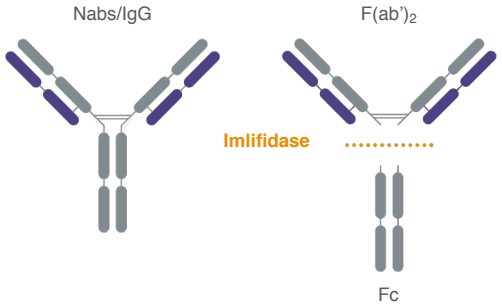
1

Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



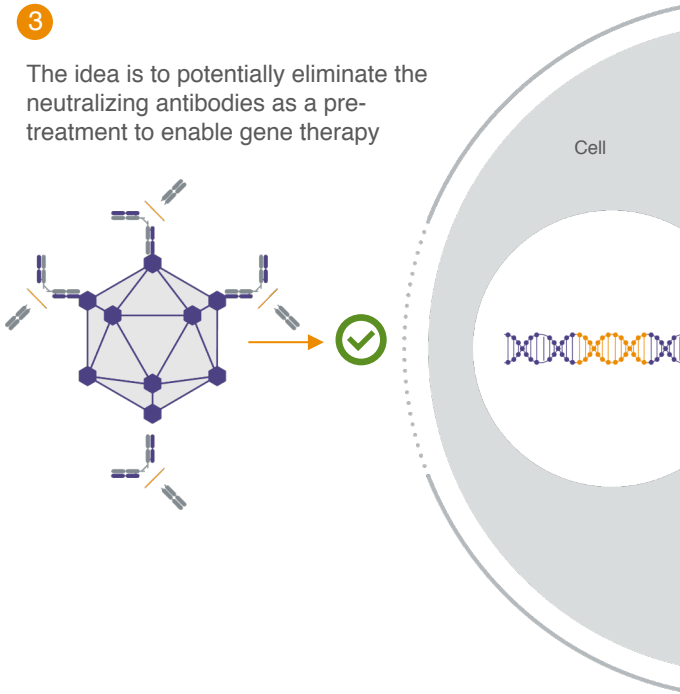
2

Imlifidase is a unique IgG antibody-cleaving enzyme that cleaves IgG at the hinge region with extremely high specificity



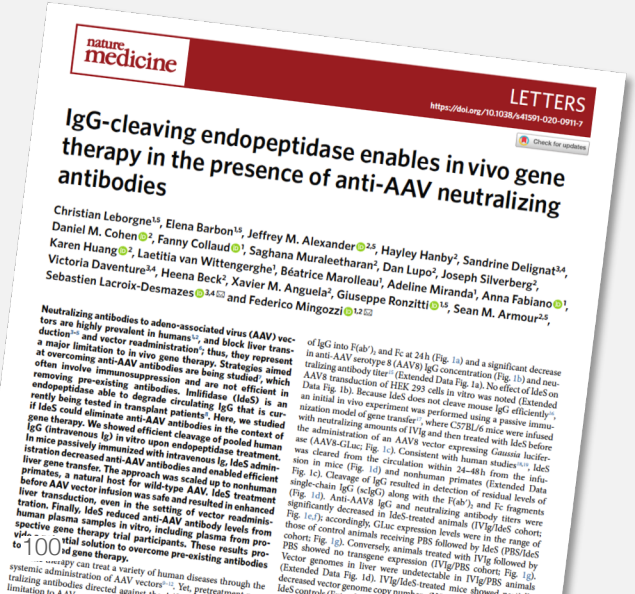
3

The idea is to potentially eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



Imlifidase (IdeS) was highlighted in Nature Medicine[1]

Results from preclinical studies with imlifidase (IdeS) in gene therapy demonstrate imlifidase as a potential pre-treatment to overcome pre-existing antibodies to AAV-based gene therapy


nature medicine

LETTERS

https://doi.org/10.1038/s41591-020-0911-7

Check for updates

IgG-cleaving endopeptidase enables in vivo gene therapy in the presence of anti-AAV neutralizing antibodies

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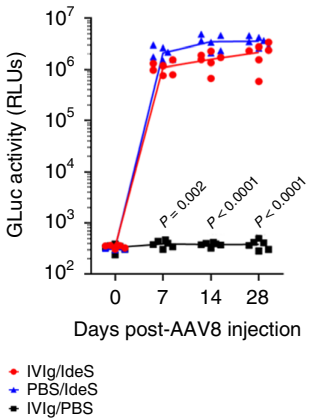
Neutralizing antibodies to adeno-associated virus (AAV) vectors are highly prevalent in humans[1,2], and block liver transduction[3–6] and vector readministration[7]; thus, they represent a major limitation to in vivo gene therapy. Strategies aimed at overcoming anti-AAV antibodies are being studied[8], which often involve immunosuppression and are not efficient in removing pre-existing antibodies. Imlifidase (IdeS) is an endopeptidase able to degrade circulating IgG that is currently being tested in transplant patients[9]. Here, we studied if IdeS could eliminate anti-AAV antibodies in the context of gene therapy. We showed efficient cleavage of pooled human IgG (intravenous Ig) in vitro upon endopeptidase treatment. In mice passively immunized with intravenous Ig, IdeS administration decreased anti-AAV antibodies and enabled efficient liver gene transfer. The approach was scaled up to nonhuman primates, a natural host for wild-type AAV. IdeS treatment before AAV vector infusion was safe and resulted in enhanced liver transduction, even in the setting of vector readministration. Finally, IdeS reduced anti-AAV antibody levels from human plasma samples in vitro, including plasma from prospective gene therapy trial participants. These results provide the rationale for a potential solution to overcome pre-existing antibodies to [illegible] and gene therapy.

[illegible] therapy can treat a variety of human diseases through the systemic administration of AAV vectors[9–12]. Yet, pretreatment neutralizing antibodies directed against the [illegible] limitation to A

of IgG into F(ab')2 and Fc at 24 h (Fig. 1a) and a significant decrease in anti-AAV serotype 8 (AAV8) IgG concentration (Fig. 1b) and neutralizing antibody titer[21] (Extended Data Fig. 1a). No effect of IdeS on AAV8 transduction of HEK 293 cells in vitro was noted (Extended Data Fig. 1b). Because IdeS does not cleave mouse IgG efficiently[16], an initial in vivo experiment was performed using a passive immunization model of gene transfer[17], where C57BL/6 mice were infused with neutralizing amounts of IVIg and then treated with IdeS before the administration of an AAV8 vector expressing *Gaussia* luciferase (AAV8-GLuc; Fig. 1c). Consistent with human studies[9,10], IdeS was cleared from the circulation within 24–48 h from the infusion in mice (Fig. 1d) and nonhuman primates (Extended Data Fig. 1c). Cleavage of IgG resulted in detection of residual levels of single-chain IgG (scIgG) along with the F(ab'), and Fc fragments (Fig. 1d). Anti-AAV8 IgG and neutralizing antibody titers were significantly decreased in IdeS-treated animals (IVIg/IdeS cohort; Fig. 1e,f); accordingly, GLuc expression levels were in the range of those of control animals receiving PBS followed by IdeS (PBS/IdeS cohort; Fig. 1g). Conversely, animals treated with IVIg followed by PBS showed no transgene expression (IVIg/PBS cohort; Fig. 1g). Vector genomes in liver were undetectable in IVIg/PBS animals (Extended Data Fig. 1d). IVIg/IdeS-treated mice showed decreased vector genome copy number

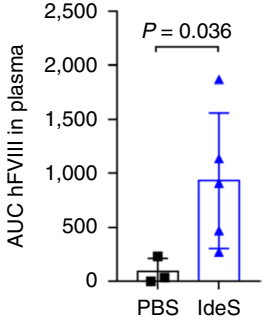
Imlifidase tested in a hemophilia mouse model

Imlifidase decreased anti-AAV antibodies and enabled efficient gene transfer



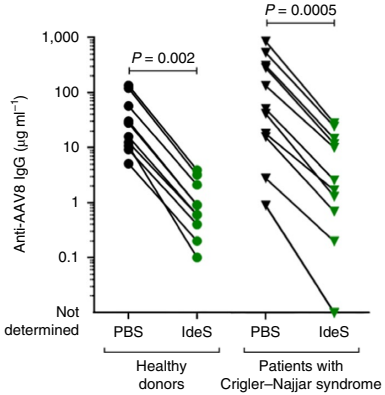
Imlifidase tested in NHP ahead of AAV vector infusion

Pre-treatment with imlifidase in anti-AAV positive nonhuman primates (NHP) ahead of AAV vector infusion was safe and resulted in enhanced liver transduction and hFVIII plasma levels



Imlifidase tested in human plasma samples (GT patients)

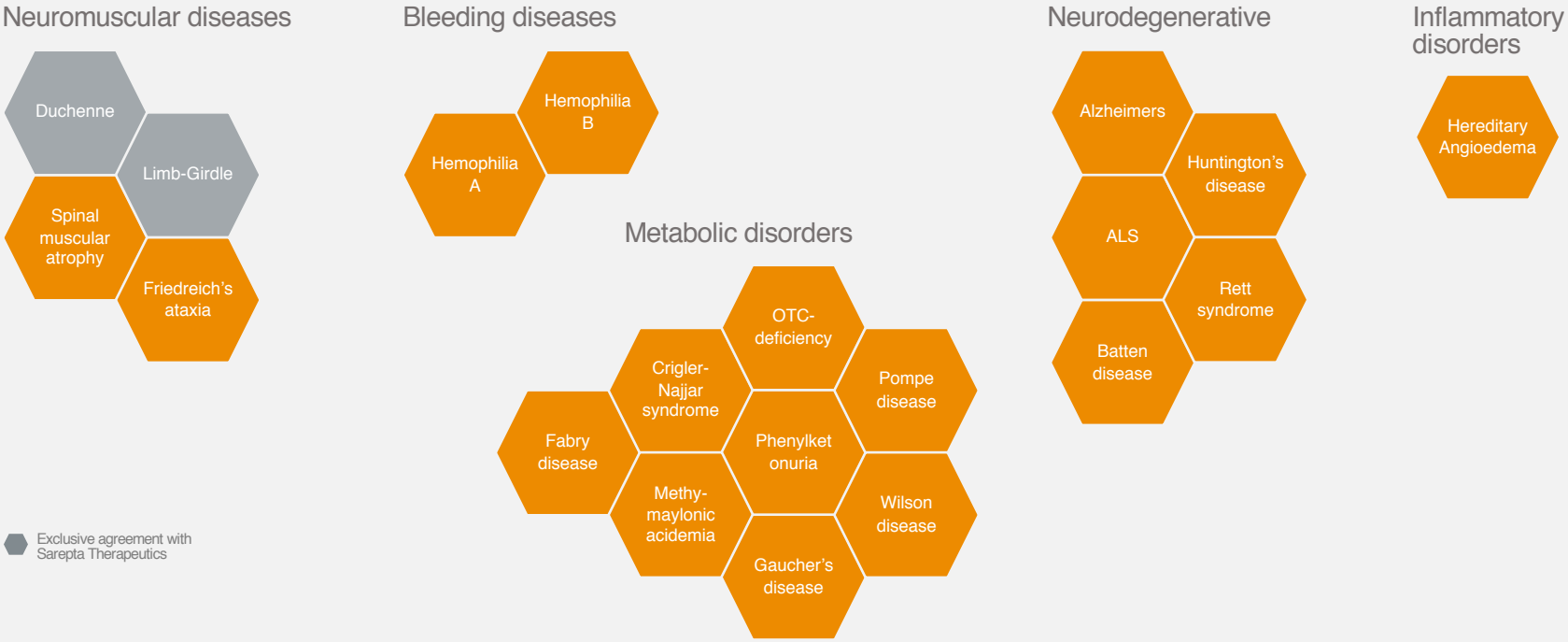
Imlifidase reduced anti-AAV antibody levels from human plasma samples in vitro, incl. plasma from prospective gene therapy trial participants



[1] Nature Medicine https://doi.org/10.1038/s41591-020-0911-7

Current indication area focus for gene therapy companies

monogenic disease areas

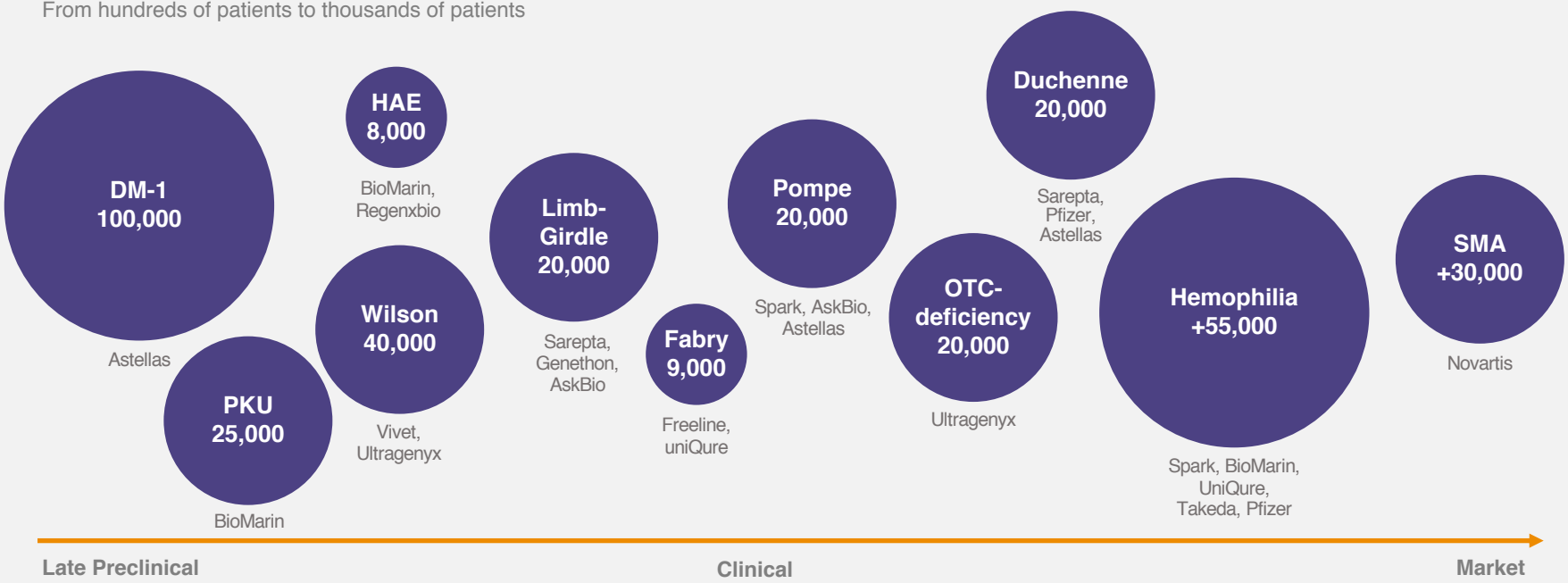


Systemic gene therapy is an emerging opportunity

With a focus on the potential to correct issues causing genes in rare monogenic diseases

Rare monogenic diseases

From hundreds of patients to thousands of patients



Size of indication (US & EU)

Gene therapy is also explored broadly in non-monogenic disease

Potential future extension into disease modifying modalities

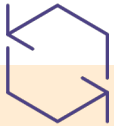
From thousands of patients to millions of patients

Congestive Heart Failure	Parkinson’s disease	Chronic inflammatory disease

Stock images

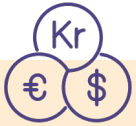
Advancing our enzyme cleaving platform in gene therapy can potentially...

Enable access to gene therapy for thousands



Enable gene therapy re-dosing

Enable a competitive edge for the gene therapy company



Enable significant additional sales for the gene therapy companies

Enable substantial increase in imlifidase sales for Hansa Biopharma

Lower treatment costs for payers

Global and exclusive agreement with Sarepta Therapeutics

Indication exclusivity:

- **Duchenne Muscular Dystrophy (DMD)**
- **Limb-Girdle Muscular Dystrophy (LGMD)**

Hansa's key resources

- Imlifidase know how
- Clinical data and EMA approval
- GMP-grade imlifidase

Sarepta's key resources

- World leader within gene therapy targeted at muscular dystrophies
- Pre-clinical plan: PoC and IND-tox
- Clinical / Regulatory
- Promotion

Upfront payment
USD 10 million upfront

Milestones
Hansa is eligible for a total of up to USD 397.5 million in development, regulatory and sales milestone payments.

Royalties & Sales
Hansa to receive high single-digit to mid-teens royalties on Sarepta's gene therapy sales enabled with imlifidase

Idefirix (imlifidase) is approved in EU under conditional approval

Duchenne and SRP-9001

About Duchenne Muscular Dystrophy (DMD)[1]

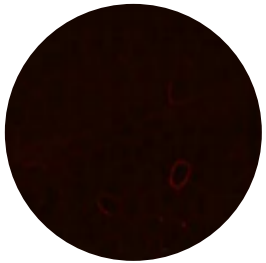
- Rare, fatal neuromuscular genetic disease
- Muscle weakness noticeable by age 3 to 5, and most patients use a wheelchair by the time they are 11
- Cardiac and respiratory muscle deterioration becomes life-threatening
- 1/ 3,500 to 5,000 male births affected 15-20% of Sarepta's patients are Nab+

"On average, DMD takes the life of a child in the United States every day"[2]

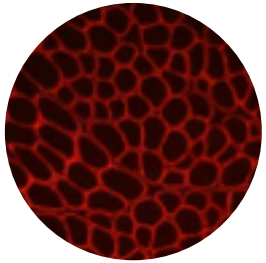
SRP-9001 Micro-dystrophin gene therapy for treatment of DMD

- AAVrh74 vector with transgene micro-dystrophin
- Phase 2 studies ongoing totaling 41+ 4 patients
- Estimated study completion in 2021
- Initial results published in Sept 2020 demonstrates:
  - No SAEs or AE leading to discontinuation
  - Mean micro-dystrophine expression (N=4) vs normal: 74.3% vs 95.8%
  - Subjects exhibited mean of 7.0-point improvement on NSAA from baseline to Year 2

Pre-treatment



Post-treatment



Source:
[1] Sarepta Therapeutics https://investorrelations.sarepta.com/static-files/e9393c38-646f-45ee-9f56-955f3fbfad71
[2] Sarepta Therapeutics https://investorrelations.sarepta.com/static-files/e9393c38-646f-45ee-9f56-955f3fbfad71

Limb-Girdle and SRP-9003

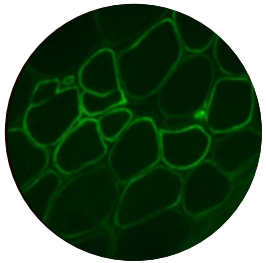
About Limb-girdle muscular dystrophy (LGMD)

- Limb-girdle muscular dystrophy is a group of diseases that cause weakness and wasting of the muscles
- May be caused by a single gene defect affecting specific proteins within muscle cells
- Global prevalence of 1.63 per 100,000 individuals
- 15-20% of Sarepta's patients are Nab+

SRP-9003 β-Sarcoglycan gene therapy for treatment of LGMD

- AAVrh74 vector with transgene β-Sarcoglycan
- Phase 1/2 study ongoing (N=6)
- Initial results published in Sept 2020:
  - Two dosing cohorts at 0.5 and 2.0 (× 1014 vg/kg) respectively (N=3+3)
  - Majority of AEs were mild to moderate which resolved. Two SAEs reported (transient increase in bilirubin and dehydration due to vomiting)
  - Percentage of β-sarcoglycan Positive Fibers: Cohort 1: 51%, Cohort 2: 72%
  - NSAD (North Star Assessment for Dysferlinopathy) total score at 6 months: +3.0 in Cohort 1 and +3.7 in Cohort 2

β-Sarcoglycan



Source: Sarepta Therapeutics
https://investorrelations.sarepta.com/static-files/e9393c38-646f-45ee-9f56-955f3fbfad71

Q&A session

Patients have given consent to provide images

Closing remarks

Hansa Biopharma today

Successful track record...

Strong momentum...

Promising future...

A validated technology

VALIDATION ACROSS THREE AREAS

- Approval in kidney transplantations
- PoC in autoimmune diseases
- Partnership in gene therapy

Idefirix® – our first approved drug

EU KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

Established a high-performance organization

NEW COMPETENCES ADDED

Staff tripled in 5 years

Highly qualified team with 20 years on average in lifescience

Strong R&D driven organization

PURPOSE DRIVEN ORGANISATION

Innovative

Agile

Dedicated

Well capitalized

FINANCED INTO 2023

SEK1.5bn in cash

Raised SEK 1.1bn in Q3 2020

Created value for shareholders

MARKET CAP SEK10bn

10x vs cost of development 13 years

Idefirix approved in EU under conditional approval

Closing remarks

Our strategic priorities

Building tomorrow's Hansa Biopharma

Advance platform in new indications and therapeutic areas

Build new franchises to capture full value of technology platform

- Transplantation
- Autoimmunity
- Gene therapy
- Oncology

Commercialize Idefirix® in first markets and indications

Successfully launch Idefirix® in EU

Generate positive first experiences in key clinics and expand to targeted clinics with a patient focus

Geographical expansion

- Explore opportunities to commercialize Idefirix® beyond core markets

Secure FDA approval and launch Idefirix in the US

- Complete Randomized Control Trial (RCT) and submit BLA under the accelerated approval pathway (2023)

Build organizational capabilities and expand technology platform

Build a first-class commercial organization

Build commercial team and competences in transplantation and autoimmune diseases

Expand R&D capabilities

Pursue innovation, further strengthen scientific expertise and capabilities in rare diseases

Create partnerships

Initially focused around gene therapy and potentially oncology

Idefirix approved in EU under conditional approval


HANSA®
BIOPHARMA