



B I O P H A R M A

Investor Presentation

Redeye Growth Day 2022, Stockholm
June 2, 2022

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Head of Investor Relations



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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.

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Hansa Biopharma today

Successful track record...
Strong momentum...
Promising future...

A validated technology

VALIDATION ACROSS THREE AREAS

- ✓ Approval in kidney transplantations
- ✓ Proof of concept in autoimmune diseases
- ✓ Partnerships to explore gene therapy

Idefirix® is our first approved drug in Europe*

KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

Broad pipeline in transplantation and autoimmunity

PROGRAMS IN CLINICAL DEVELOPMENT

US kidney transplants
Anti-GBM
Guillain-Barré syndrome (GBS)
Antibody mediated kidney transplant rejection (AMR)

Established a high-performance organization

NEW COMPETENCIES ADDED

140 employees March 2021
(~3x in 3 years)

Highly qualified team with 20 years on average in life science
Purpose driven culture

With recent capital injection Hansa is financed into 2023

FINANCIALS

SEK 754m in Cash (USD ~80m)
end of March 2022

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~300n

Listed on Nasdaq Stockholm
18,000 shareholders
Foreign ownership make up ~40% through leading international life science specialist funds



Patient*

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

*Idefirix approved in EEA under conditional approval for kidney transplantation

**Actual patient has given consent to provide images

Many milestones achieved during the last 18 months

TLV

TANDVÄRDS- OCH
LÄKEMEDELSFORMÄNSVERKET

Healthcare Technology Assessment published by Swedish "TLV", with a favorable conclusion for using Idefix® in highly sensitized patients incompatible with a deceased donor

idefix
(imlifidase)

Hansa Biopharma records first commercial sale of Idefix®



First national market access agreement achieved for Idefix® in Sweden and Finland (hospital basis)



Full national reimbursement agreement achieved for Idefix® in the Netherlands



First patient enrolled in the U.S. pivotal randomized controlled study "ConfideS" in highly sensitized kidney transplant patients

MEDISON
Delivering Innovative Healthcare

New multiregional commercialization partnership with Medison Pharma for imlifidase in kidney transplant in Central Eastern Europe and Israel



Pricing and reimbursement achieved for Idefix® in Germany



Marketing authorization in Israel for Idefix® (imlifidase)



Market access granted in France through a reimbursed Early Access Program



Temporary marketing authorization granted in Switzerland

2021

January

February

March

April

May

June

July

August

September

October

November

December

2022

January

February

March

April



Hansa Biopharma enters pre-clinical research collaboration with argenx BV to explore potential combination therapies with imlifidase and efgartigimod

argenx

Positive 3-year follow-up data published in American Journal of Transplantation demonstrating graft survival of 84% after imlifidase treatment and transplantation



Hansa Biopharma AB certified as a Great Place to Work® for second consecutive year



Market access agreement achieved in Greece on a hospital basis



Agreement with AskBio to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease



Results of the Phase 2 study of imlifidase in patients with anti-GBM disease published in Journal of the American Society of Nephrology



Solid sales growth reported in Q1
Sales expected to remain volatile during the initial launch years



HANSA
BIOPHARMA

Imlifidase

A novel approach to eliminate pathogenic IgG

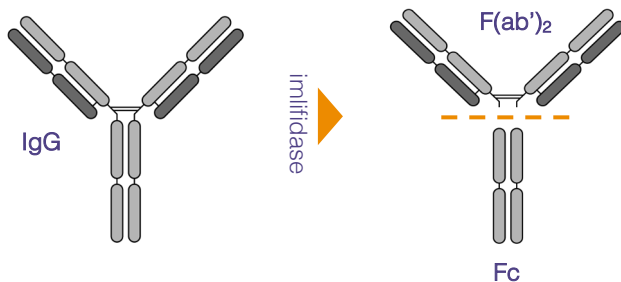
Origins from a bacteria *Streptococcus pyogenes*

- Species of Gram-positive, spherical bacteria in the genus *Streptococcus*
- Usually known from causing a strep throat infection



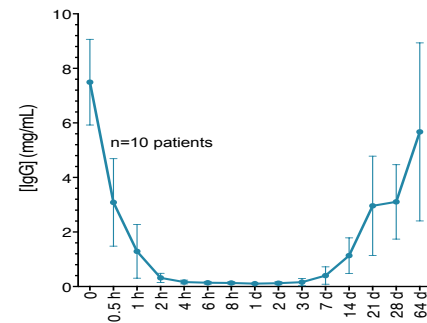
A unique IgG antibody-cleaving enzyme

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one F(ab')₂ fragment and one homo-dimeric Fc-fragment

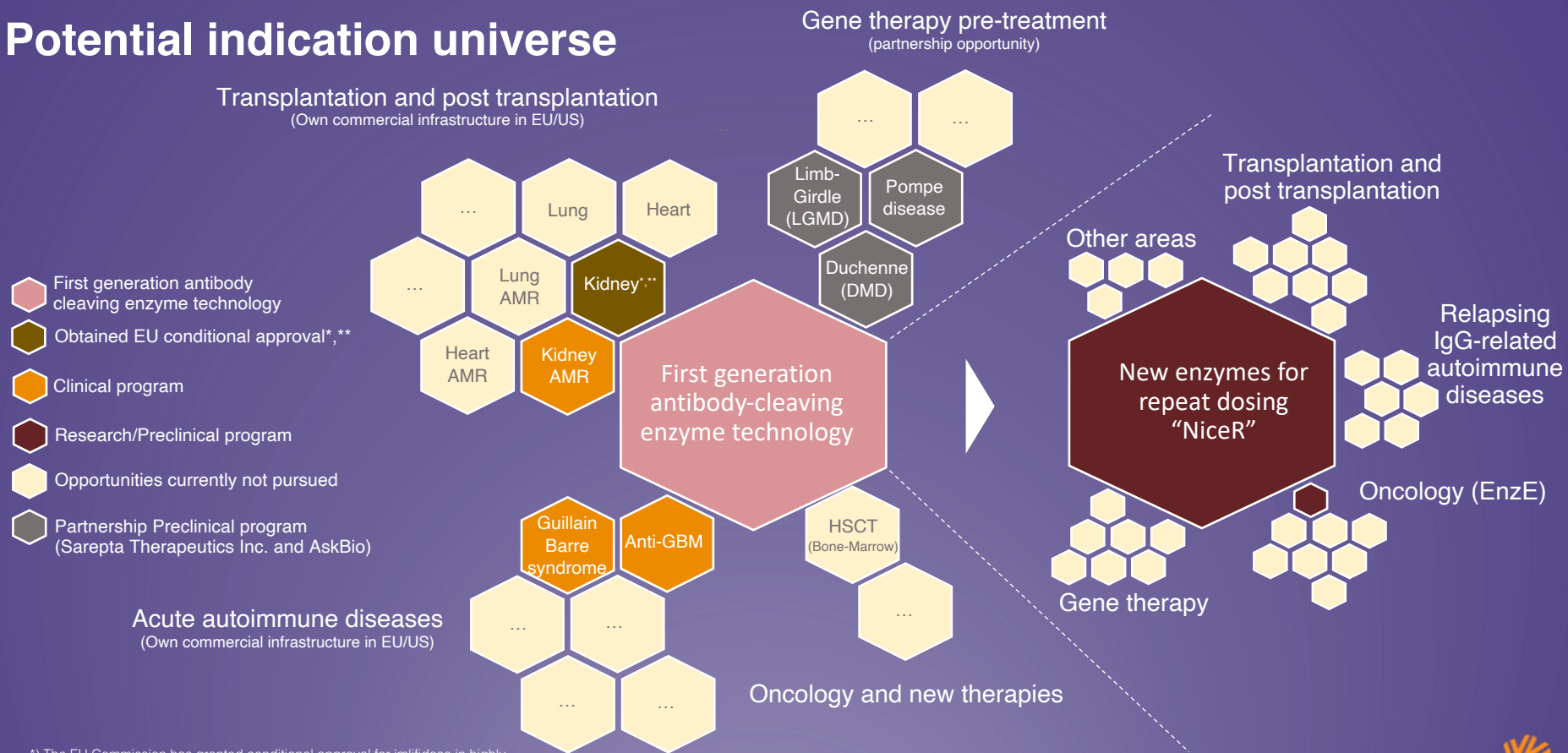


Inactivates IgG in 2-6 hours

- Rapid onset of action that inactivates IgG below detectable level in 2-6 hours
- IgG antibody-free window for approximately one week



Potential indication universe

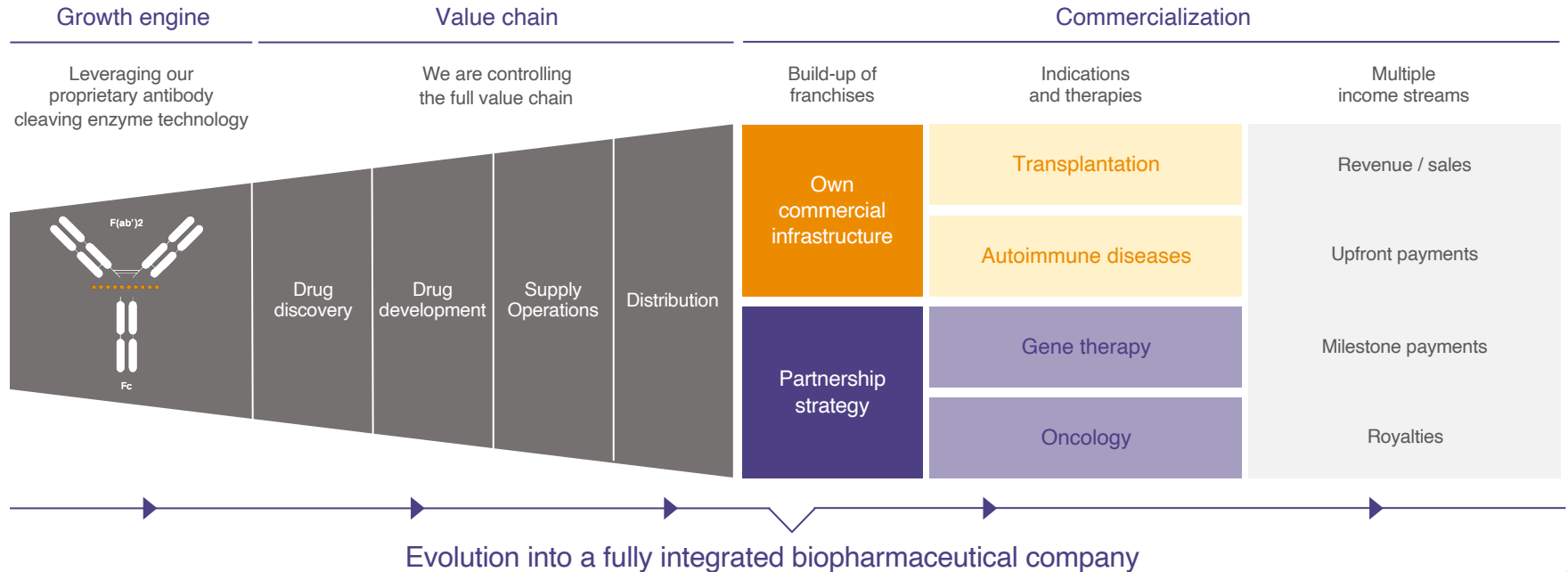


*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.

**) In the US a new study has commenced targeting a BLA filing by H1 2024

Our Business model

Leveraging our technology platform to develop new therapies targeting rare diseases with unmet medical need across a range of indications



Idefirix® (imlifidase) has received conditional approval in the European Union

Low complexity transplants ← → Higher complexity transplants

~70% of patients^{1,2}

Non or less sensitized
(cPRA < 20%)

15-20% of patients^{1,2}

Moderately sensitized
(20% < cPRA < 80%)

10-15% of patients^{1,2}

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

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

Actual patient has given consent to provide images

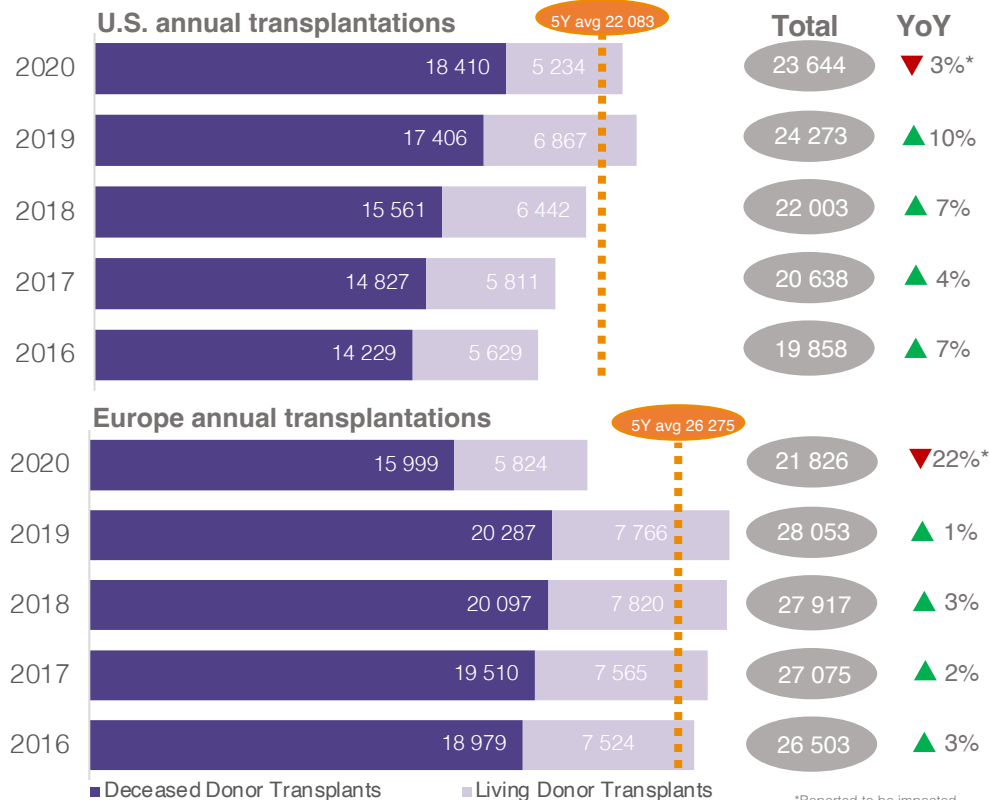
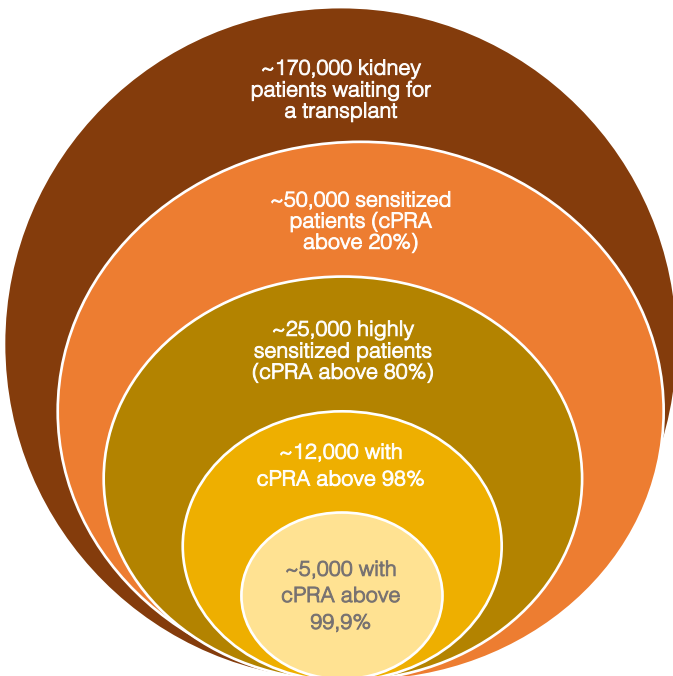
¹ EDQM. (2020). International figures on donation and Transplantation 2019
² SRTR Database and individual assessments of allocation systems

The kidney transplantation landscape in Europe and the U.S.

Up to 15% of patients waiting for a new kidney are highly sensitized

~50,000 transplants done annually in the U.S. and Europe

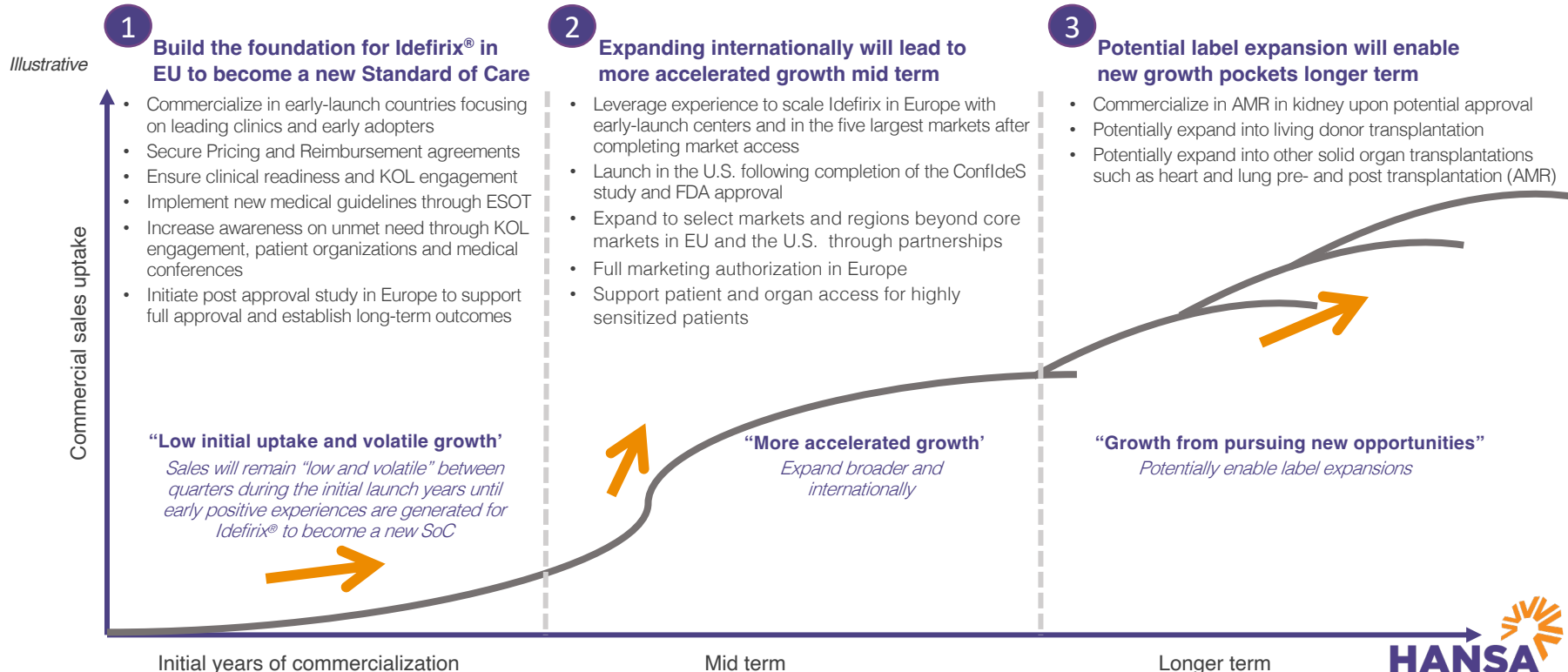
Breakdown of the kidney transplant waitlist in U.S. and EU



*Reported to be impacted by the COVID-19 pandemic

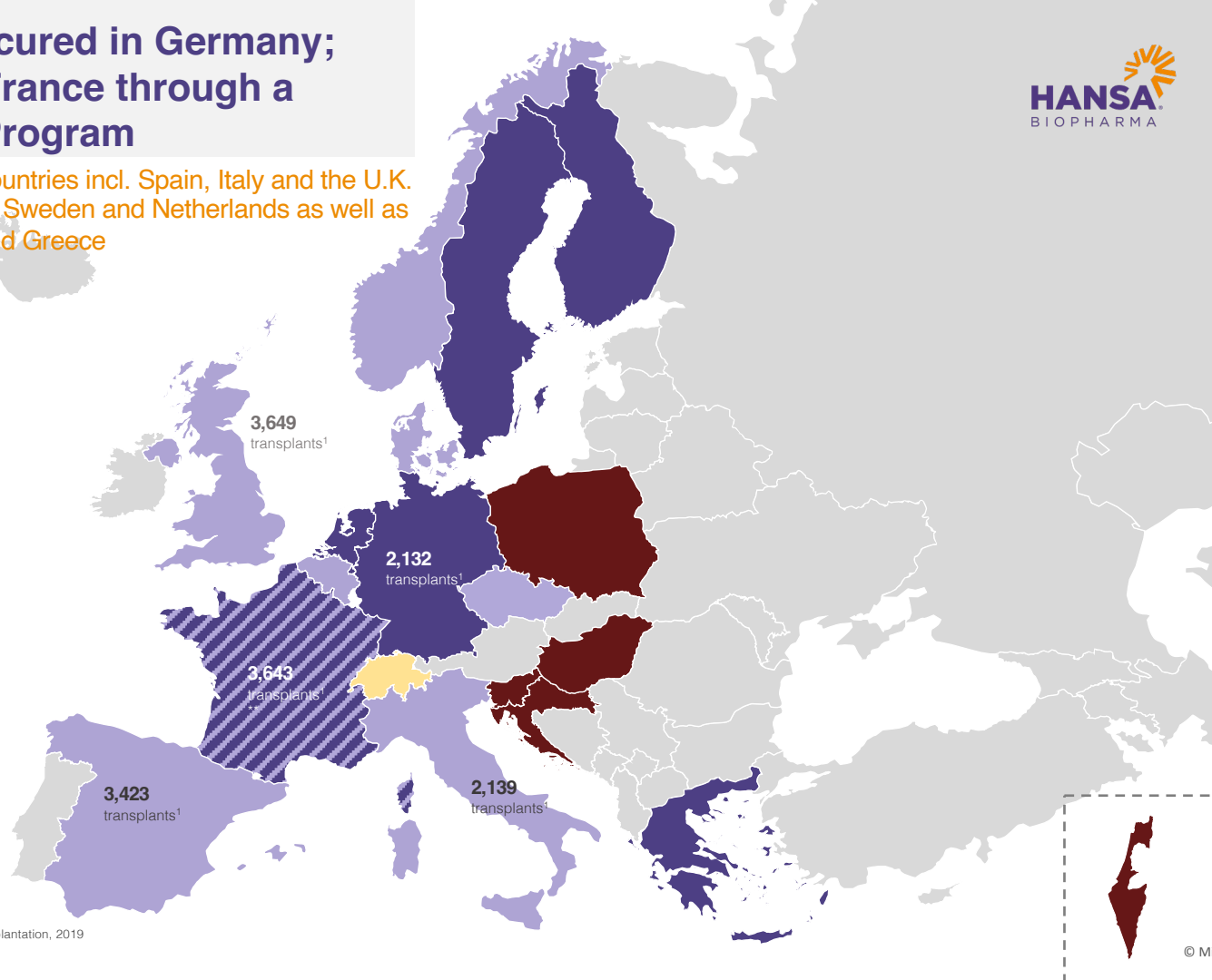
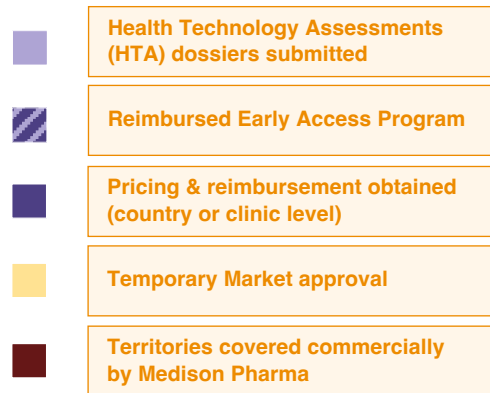
Our center focused and sequenced launch process will help build the foundation for Idefirix® to become a new Standard of Care in transplantation

Idefirix® is the first and only approved treatment in Europe for desensitization treatment of highly sensitized kidney transplant patients. The long-term market uptake is highly dependent on successful early experiences in key early adopter centers



Full commercial access secured in Germany; Market access granted in France through a reimbursed Early Access Program

Market access procedures ongoing in 11 countries incl. Spain, Italy and the U.K.
During 2021 market access was secured in Sweden and Netherlands as well as
on an individual hospital basis in Finland and Greece



¹Annual kidney transplantations 2019 (pre-Corona)

*Transplantation data is from Global Observatory on Donation and Transplantation, 2019

**Pricing & reimbursement obtained in France on an early access basis

U.S. ConfideS study: First patient enrolled Dec'21; BLA submission expected H1 2024

U.S. trial design

64 highly sensitized kidney patients with the highest unmet medical need

- Patients with a cPRA score of $\geq 99.9\%$ will be enrolled

1:1 Randomization

- When a donor organ becomes available and a positive crossmatch with the intended recipient indicates that the organ is not compatible, the patient will be randomized to either imlifidase or to a control arm, where patients either remain waitlisted for a match or receive experimental desensitization treatment*

Primary endpoint

- Mean estimated glomerular filtration rate (eGFR) "kidney function" at 12 months.
- For randomized patients who do not undergo transplantation, lose their graft or die before 12 months, eGFR will be set to zero, consistent with kidney failure

Secondary endpoint

- Patient survival at 12 months

Up to 15 leading transplantation centers in the U.S. will be engaged in the study

- Robert A. Montgomery, M.D. Professor of Surgery and Director, NYU Langone Transplant Institute, NYC is appointed to be the principal investigator

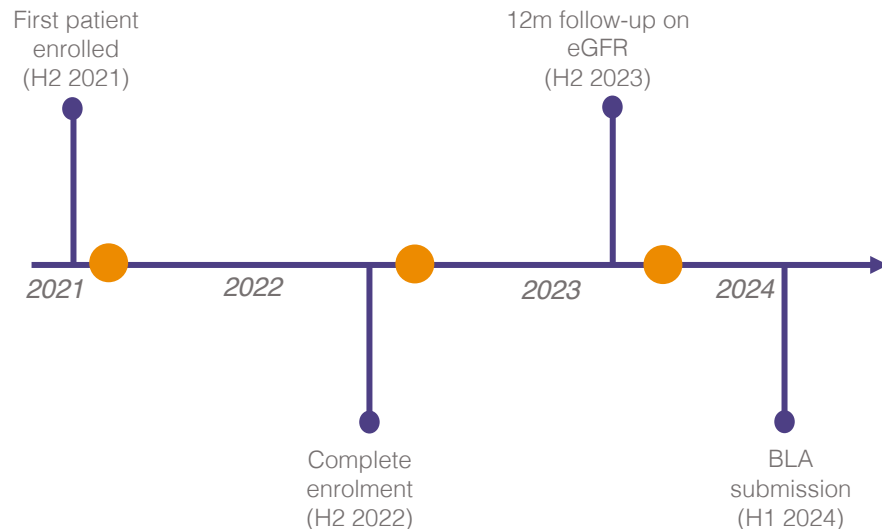
Status enrollment as of April 21, 2022 (Q1 Report)



- 16/64 patients enrolled for randomization
- Nine centers are active and open for recruitment
- Completion of enrollment expected H2 2022

- Patients enrolled
- Patients remaining

Timeline



U.S. kidney transplantation landscape

Our ConfideS study is currently enrolling patients across nine leading transplantation centers across seven states covering ~10% of annual kidney transplants in the U.S. ; Aim to have up to 15 centers recruiting patients

>23,000¹ annual kidney transplantations

~71%¹ deceased donor

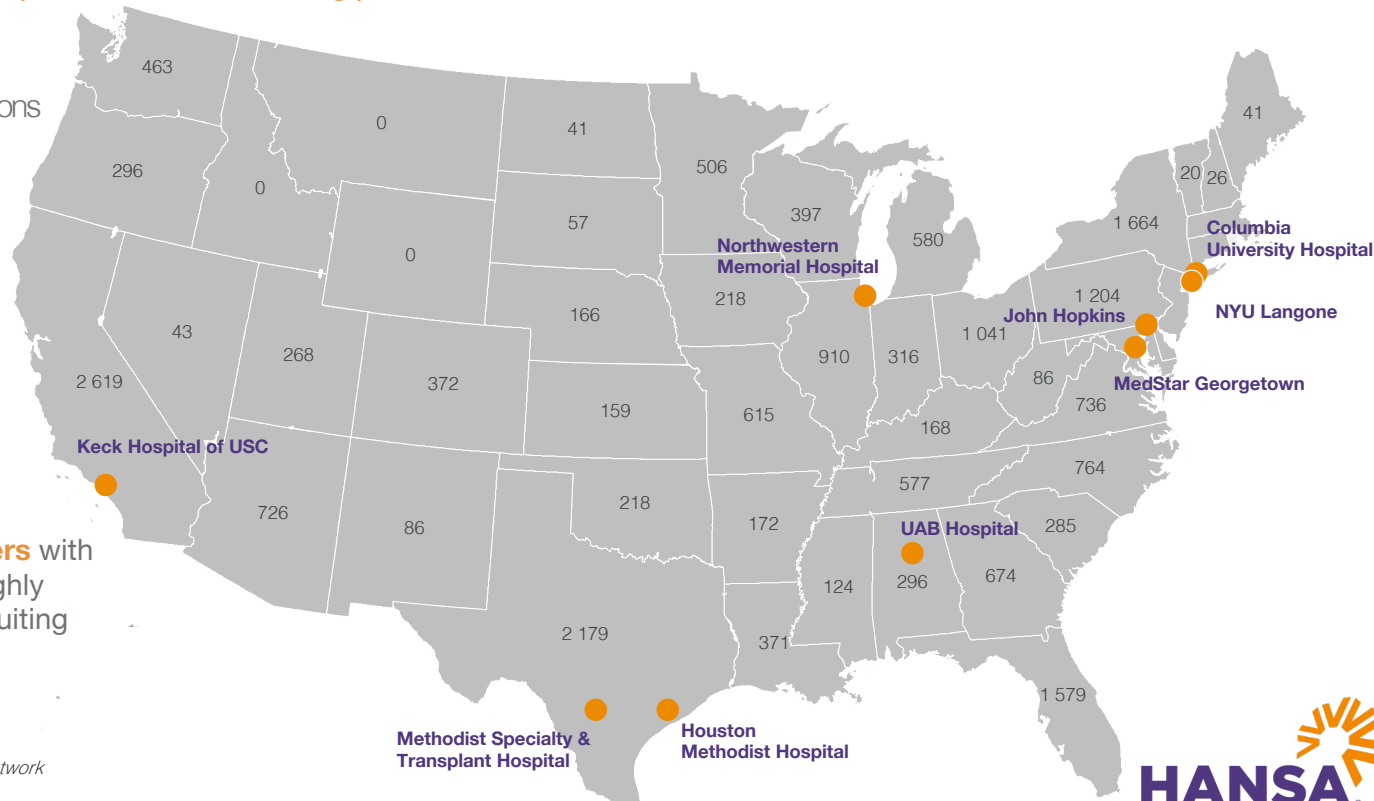
~90,000² waiting for a kidney transplant

10-15%³ of waitlisted patients are highly sensitized

Nine leading transplantation centers with experience in desensitization and highly sensitized patients are currently recruiting

2,252¹ combined annual kidney transplants

312¹ highly sensitized (>80% cPRA)



¹2019 data from Organ Procurement & Transplantation Network

²United Network for Organ Sharing

³EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems

Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Program	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients ^{1,2}						*)	EU: Additional agreements around reimbursement from H2'21
	US: Kidney transplantation in highly sensitized patients ^{1,2}							Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease ³							Pivotal Phase 3 study expected to commence in 2022 (50 patients)
	Antibody mediated kidney transplant rejection (AMR)							First data read-out H2 2022
	Guillain-Barré syndrome (GBS)							Completion of enrollment (30 patients) H2 2022
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical phase
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Preclinical phase
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy							Research phase

¹ Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)

² Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

³ Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

Completed

Planned

Ongoing

Conditional approval
based on Phase 2 data

Our unique antibody cleaving enzyme technology may have relevance across a range of indications

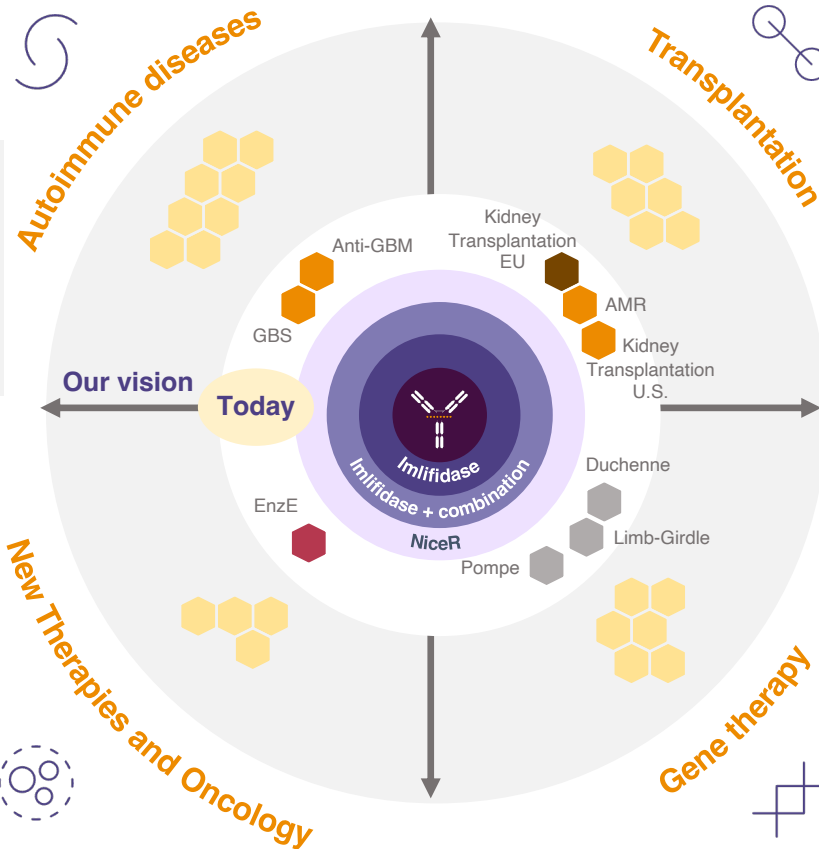
Targeting rare IgG mediated diseases

Anti-GBM paves the way for development in other autoimmune diseases

- Rapidly progressive glomerulonephritis
- Neurological disorders
- Skin and blood disorders

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogeneic stem cell (bone marrow) transplantation (HSCT)
- Enzyme-based antibody Enhancement (EnzE)



Expanding our commercial franchises

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

Shaping a new standard for desensitization will help enable new indications in transplantations

- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types

Exploring opportunities in gene therapy

- Encouraging preclinical data published in Nature
- Partnership with Sarepta
- Wide indication landscape beyond

Completed enrollment in Phase 2 program in Antibody Mediated Rejection (AMR) post kidney transplantation

Long term graft survival is challenged by AMR episodes post transplantation

Indication

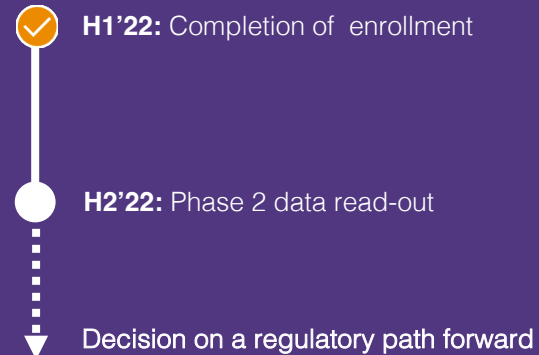
- Acute antibody mediated rejection episodes post transplantation occurs in 5-7% of kidney transplants¹ annually and is a significant challenge to long term graft survival
- Today's standard of care include plasma exchange, steroids and IVIg.
- There is no approved treatment for AMR

¹ Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

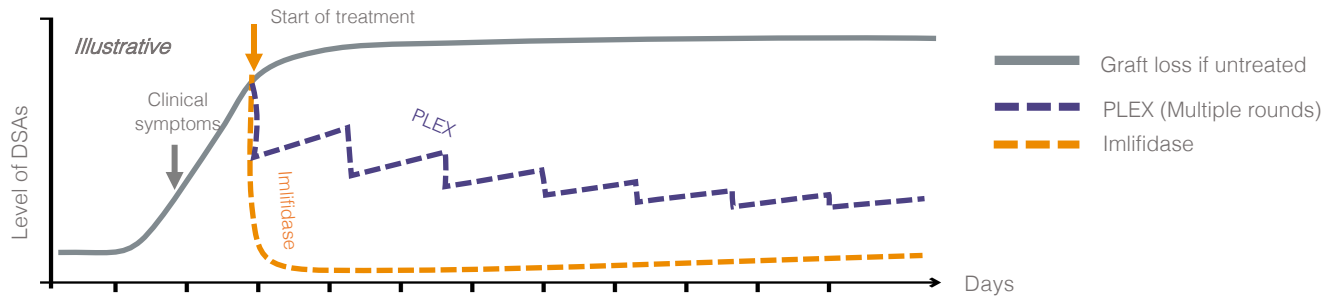
Phase 2 Study

- 30 out of a target of 30 patients with active or chronic active AMR episodes post kidney transplantation have been enrolled and randomized 2:1 to imlifidase vs. SoC
- The AMR phase 2 program is a randomized, open-label, multi-center and controlled study
- 20 individuals will be randomized to receive imlifidase treatment comprised of one intravenous dose of 0.25mg/kg, while 10 individuals in the active control arm will receive 5-10 sessions of plasma exchange (PLEX)
- Efficacy and safety is monitored over a six-month period post treatment.

Path forward



Potential of using imlifidase vs. PLEX in AMR

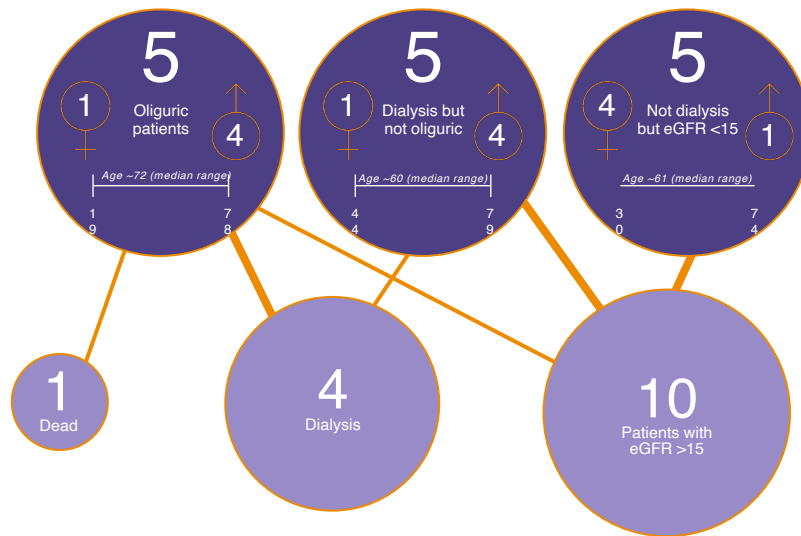


U.S. FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a Phase 3 across U.S. and EU with the first patient is expected to be enrolled in 2022

10 out of 15 patients were dialysis independent after six months vs. the historical cohort, where only 18% had functioning kidney

New Anti-GBM Phase 3 study of imlifidase in 50 patients

- Global protocol in place and approved by FDA. Selection of investigators and site set up is now ongoing
- New Phase 3 trial will be an open-label, controlled, randomized, multi-centre trial comparing imlifidase and SoC with SoC alone
- EMA submission preparation in progress
- Plans to expand the trial to include Japan



Segelmark et al. JASN (2022)

¹ Journal of the American Society of Nephrology <https://pubmed.ncbi.nlm.nih.gov/35260419/>

²McAdoo et al.: Patients double-seropositive for ANCA and anti-GBM antibodies have varied renal survival, frequency of relapse, and outcomes compared to single-seropositive patients. *Kidney Int* 92: 693–702, 2017

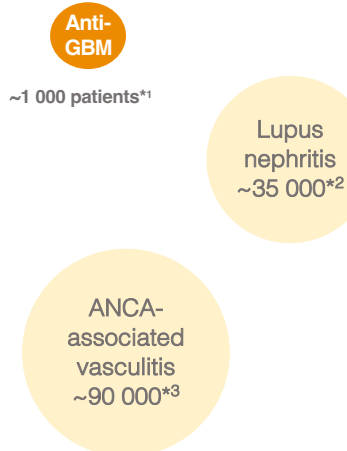
Hansa's antibody cleaving enzyme technology

may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

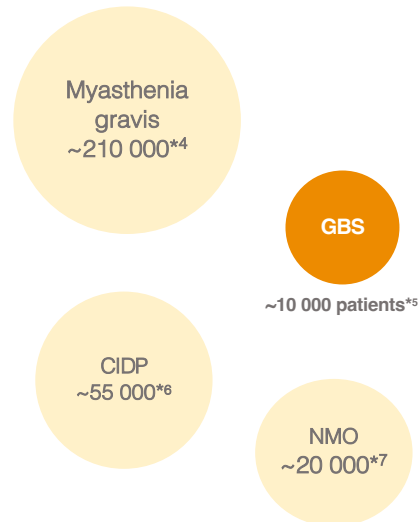
- Clinical programs
- Potential autoimmune indications (currently not pursued)

*Total disease populations in EU & US, based on prevalence and population data

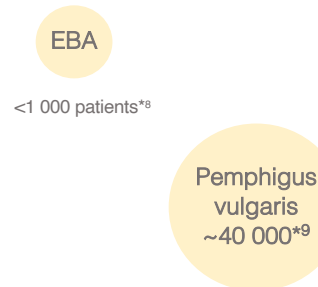
Rapidly progressive glomerulonephritis



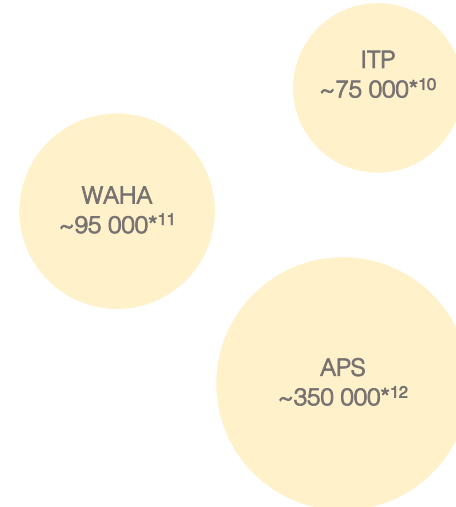
Neurological disorders



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

¹DeVrieze, B.W. and Hurley, J.A. *Goodpasture Syndrome*. StatPearls Publishing, Jan 2021.

²<https://www.ncbi.nlm.nih.gov/books/NBK459291/> [accessed 2021-03-29]

³Patel, M. et al. *The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK*. Arthritis & Rheumatism, 2006.

⁴Berti A, Cornec D, Crowson CS, Specks U, Matteson EL. *The Epidemiology of ANCA Associated Vasculitis in the U.S.: A 20 Year Population Based Study*. Arthritis Rheumatol. 2017;69.

⁵Myasthenia Gravis. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/myasthenia-gravis/> [accessed 2021-03-29]

⁶Guillain-Barré syndrome. Orpha.net. https://www.orpha.net/consor/cgi-bin/OC_Exp.php?lng=GB&Expert=2103 [accessed 2021-03-29]

⁷Chronic Inflammatory Demyelinating Polyneuropathy: Considerations for Diagnosis, Management, and Population Health. The American Journal of Managed Care. <https://www.ajmc.com/view/chronic-inflammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health> [accessed 2021-03-29]

⁸Marrie, R.A. *The Incidence and Prevalence of Neuromyelitis Optica*. International Journal of MS Care, 2013 Fall: 113-118

⁹Mehren, C.R. and Gniadecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011;10-05

¹⁰Vertenteil, S. et al. *Prevalence Estimates for Pemphigus in the United States*. JAMA Dermatol, May 2019: 627-629.

¹¹Immune Thrombocytopenia. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/immune-thrombocytopenia/> [accessed 2021-03-29]

¹²Warm Autoimmune Hemolytic Anemia. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/> [accessed 2021-03-29]

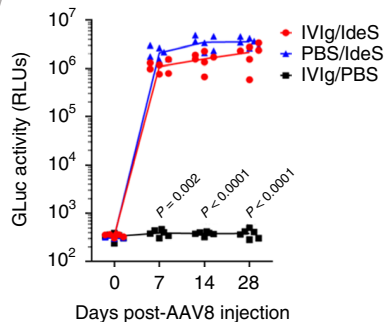
¹³Litvinova, E. et al. *Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria*. Frontiers in Immunology, 2018-12-14.

Imlifidase (IdeS) was highlighted in Nature Medicine¹

with encouraging outcome demonstrating imlifidase as a potential solution to overcome pre-existing antibodies to AAV-based gene therapy

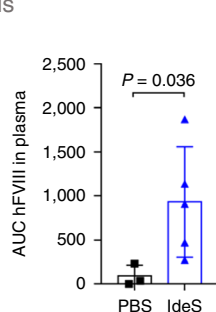
Imlifidase tested in a mouse model

- Imlifidase decreased anti-AAV antibodies and enabled efficient gene transfer



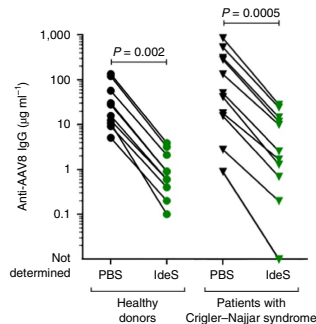
Imlifidase tested in NHP ahead of AAV vector infusion

- 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

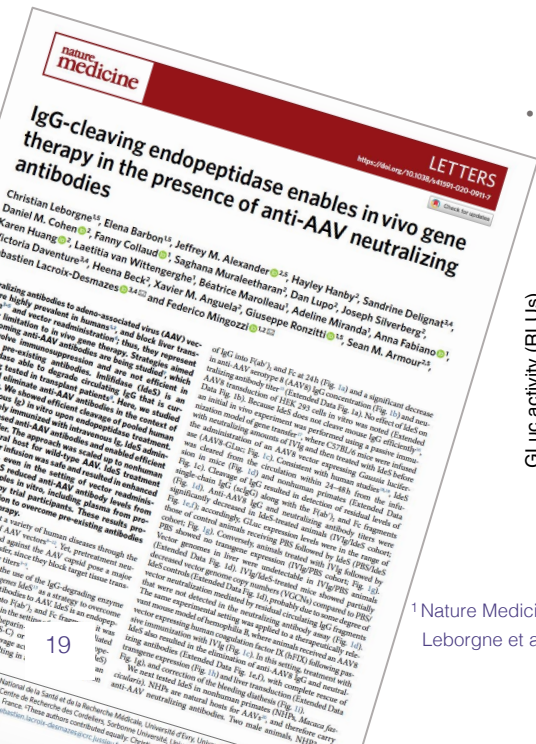


Imlifidase tested in human plasma samples (GT patients)

- 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>
Leborgne et al. Nat Med (2020)



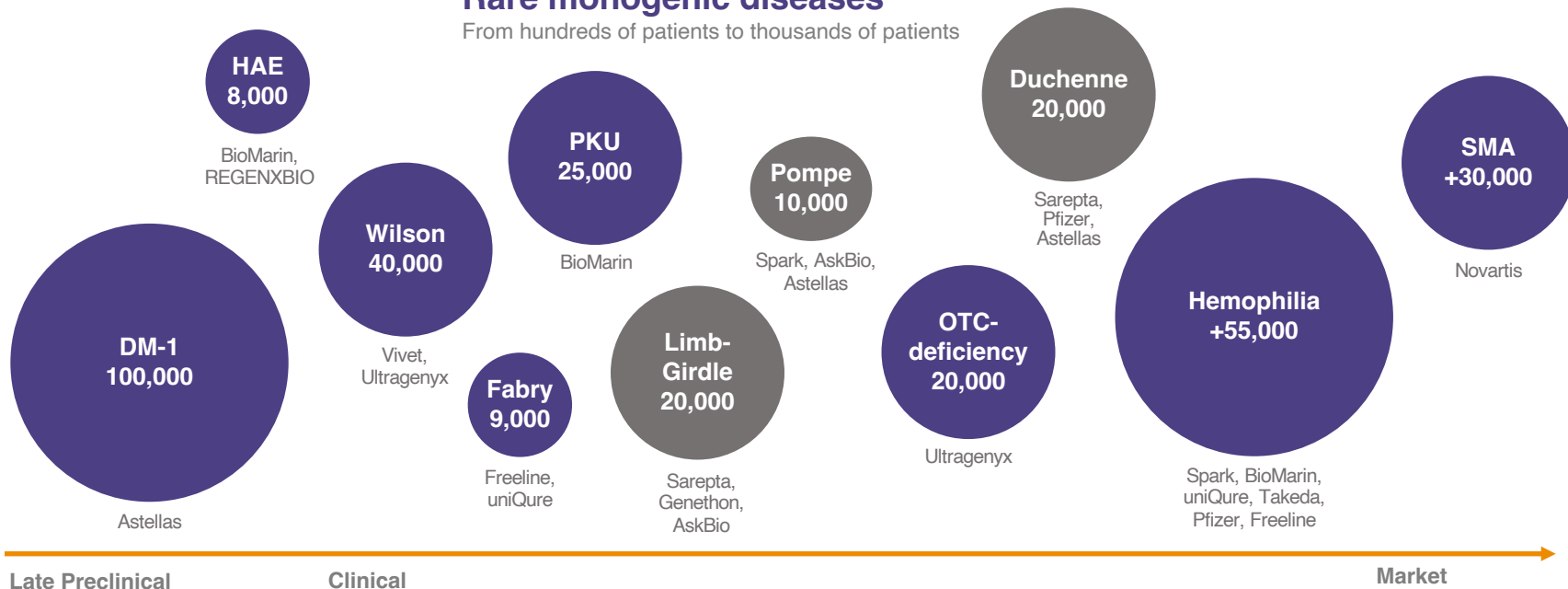
Systemic gene therapy is an emerging opportunity

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

- Preclinical programs with Sarepta and AskBio
- Potential gene therapy indications (currently not pursued)

Rare monogenic diseases

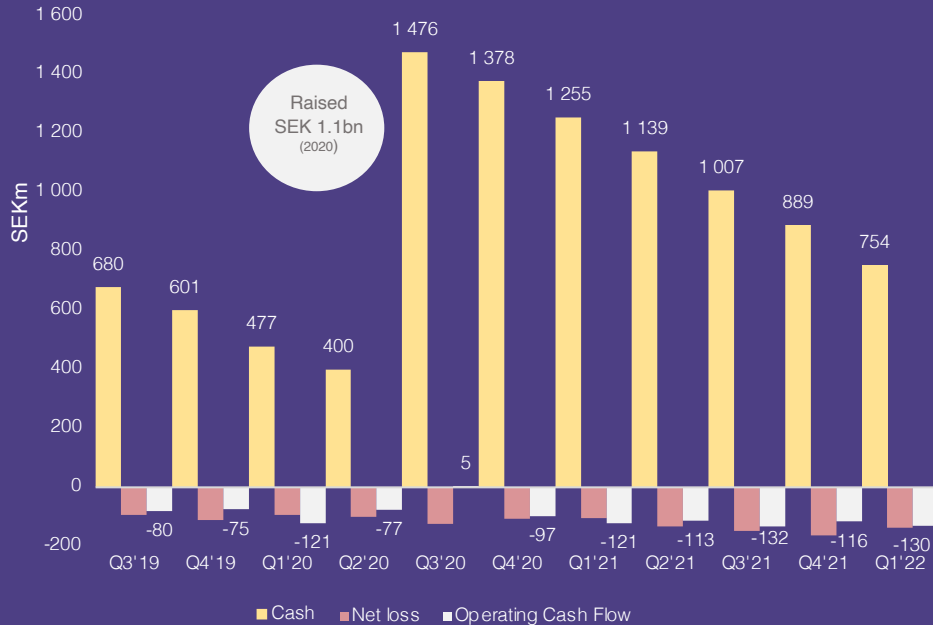
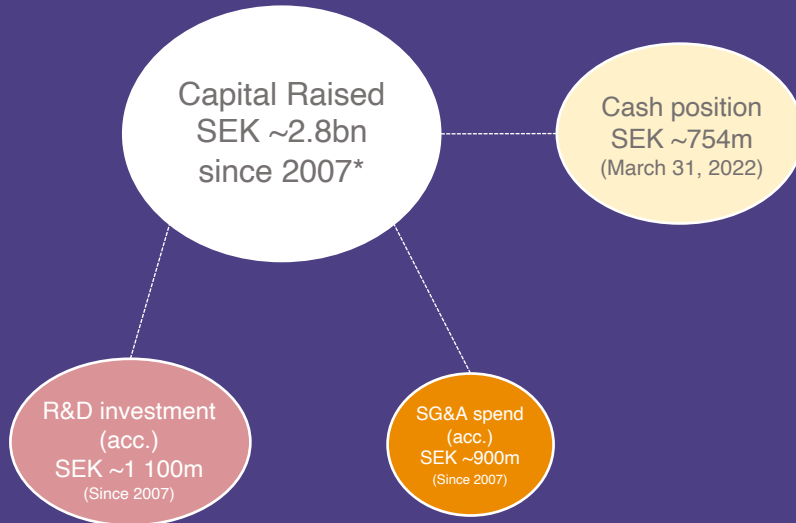
From hundreds of patients to thousands of patients



● Size of indication (US & EU)

Hansa Biopharma is well financed into 2023

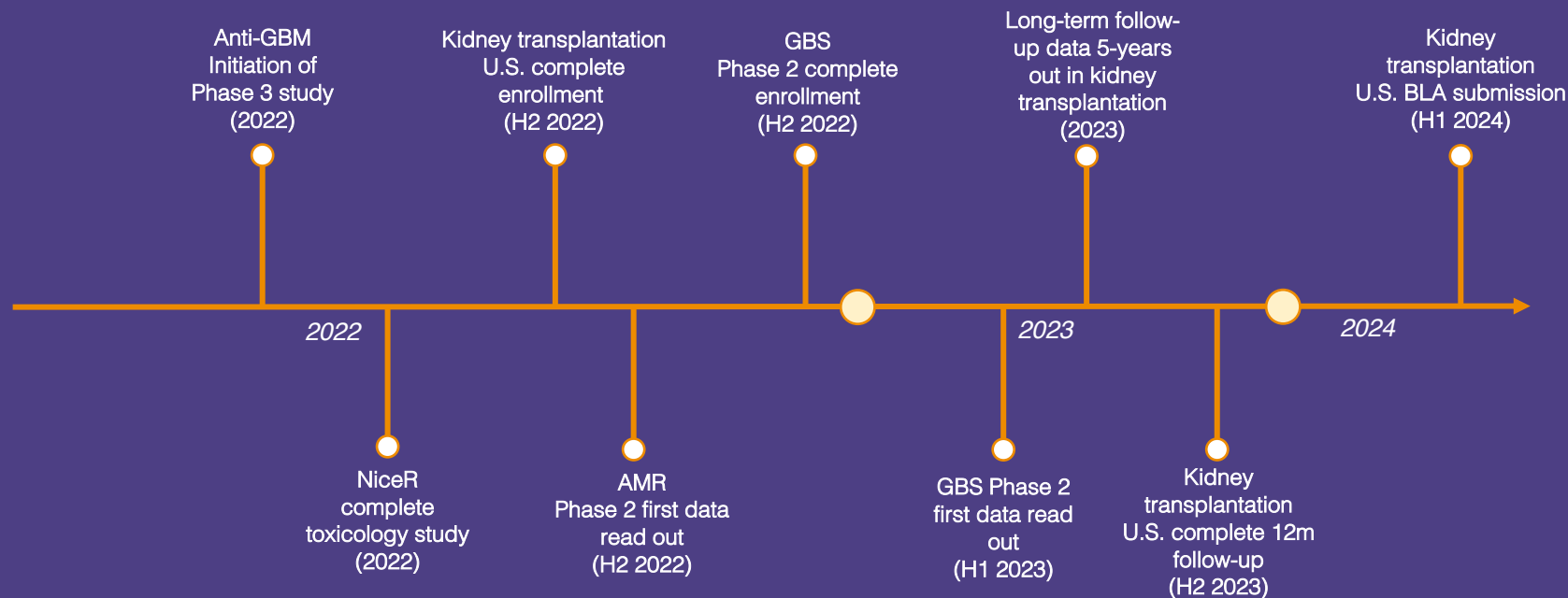
Hansa raised SEK 1.1bn (USD 121m) in a direct share issue in 2020



*Including SEK ~100m upfront payments from Sarepta

Upcoming milestones

Milestones subject to potential COVID-19 impact



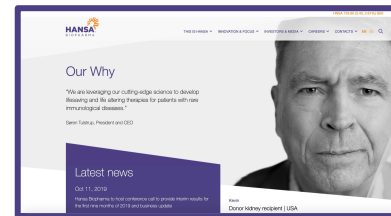
Guidance assumes no persistent impact or further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.



Corporate Contacts

Investor Relations and
Corporate Communications

Visit our web site
www.hansabiopharma.com



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Calendar and events

June 2, 2022

Redeye Growth Day

June 16, 2022

CITI's European Healthcare Conference

June 23, 2022

Paris Spring Midcap Event

June 30 2022

Annual General Meeting 2022

July 12, 2022

William Blair's Biotech Focus Conference 2022, New York

July 21 2022

Half year 2022 report

Aug 9, 2022

BTIG Biotechnology Conference 2022, New York

Aug 10, 2022

Canaccord Annual Growth Conference, Boston

Sept 7, 2022

Pareto annual Healthcare Conference 2022, Stockholm

Sept 7-8, 2022

Citi's 17th Annual BioPharma Conference, Boston

Oct 20, 2022

Interim Report for January-September 2022

Nov 23, 2022

Økonomisk Ugebrev Life Science conference, Copenhagen