HANSA BIOPHARMA

Investor Presentation

ABG Life Science Conference, Stockholm
May 18, 2022

Søren Tulstrup
President & CEO

Forward-looking statements

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

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

*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

2021 January

February
TLV – Tandvårds- och Läkemedelsförmånsverket
Healthcare Technology Assessment published by Swedish "TLV", with a favorable conclusion for using Idefirix® in highly sensitized patients incompatible with a deceased donor

March
Idefirix (imlifidase)
Hansa Biopharma records first commercial sale of Idefirix®

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

April

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

June

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

August
Full national reimbursement agreement achieved for Idefirix® in the Netherlands

Hansa Biopharma AB certified as a Great Place to Work® for second consecutive year
Great Place To Work. Certified JUNE 2021–MAY 2022 SWE

September

October

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

Market access agreement achieved in Greece on a hospital basis

December
MEDISON – Delivering Innovative Healthcare
New multiregional commercialization partnership with Medison Pharma for imlidase in kidney transplant in Central Eastern Europe and Israel

2022 January
Agreement with AskBio to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease
AskBio

February
Pricing and reimbursement achieved for Idefirix® in Germany

Market access granted in France through a reimbursed Early Access Program

March
Idefirix (imlifidase)
Marketing authorization in Israel for Idefirix® (imlifidase)

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

April
Idefirix (imlifidase)
Temporary marketing authorization granted in Switzerland

Solid sales growth reported in Q1

Sales expected to remain volatile during the initial launch years

May

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Imlifidase

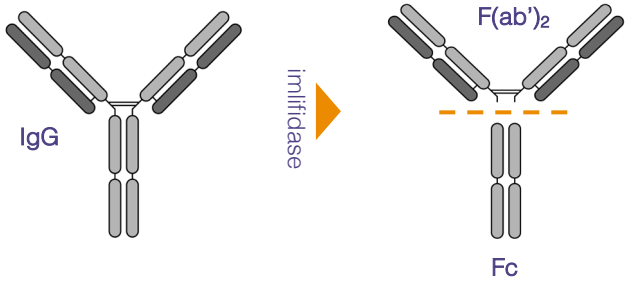
A novel approach to eliminate pathogenic IgG

Origins from a bacteria *Streptococcus pyogenes*

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

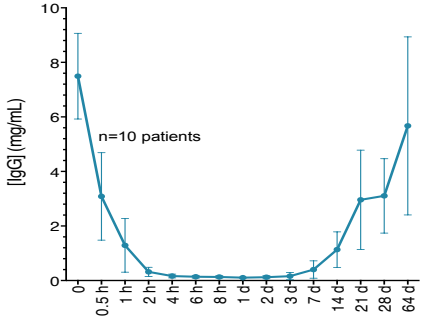
A unique IgG antibody-cleaving enzyme

- 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



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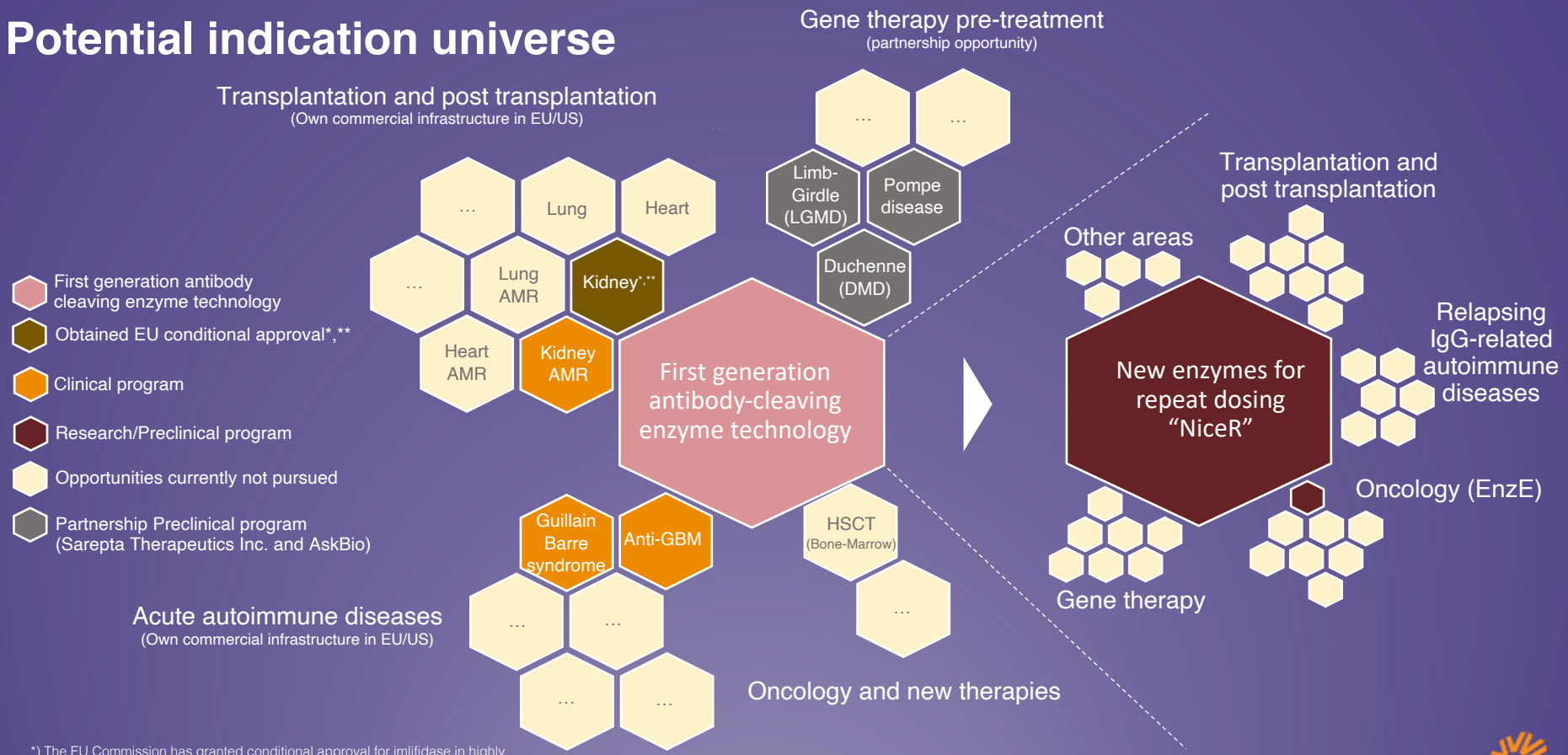
Potential indication universe



*) 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

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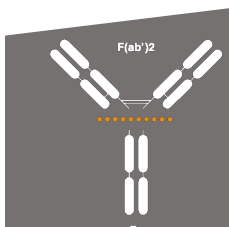
Our Business model

Leveraging our technology platform to develop 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

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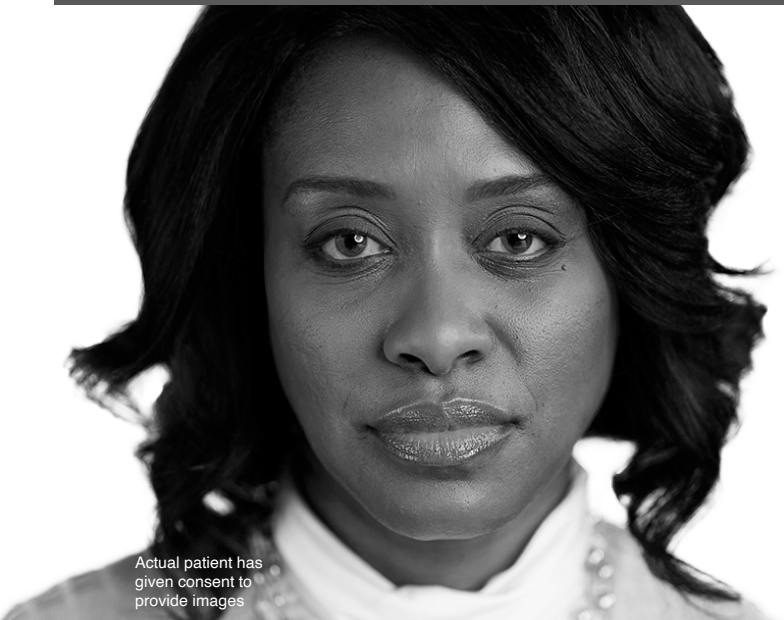
Idefirix® (imlifidase) has received conditional approval in the European Union

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 has 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

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[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.

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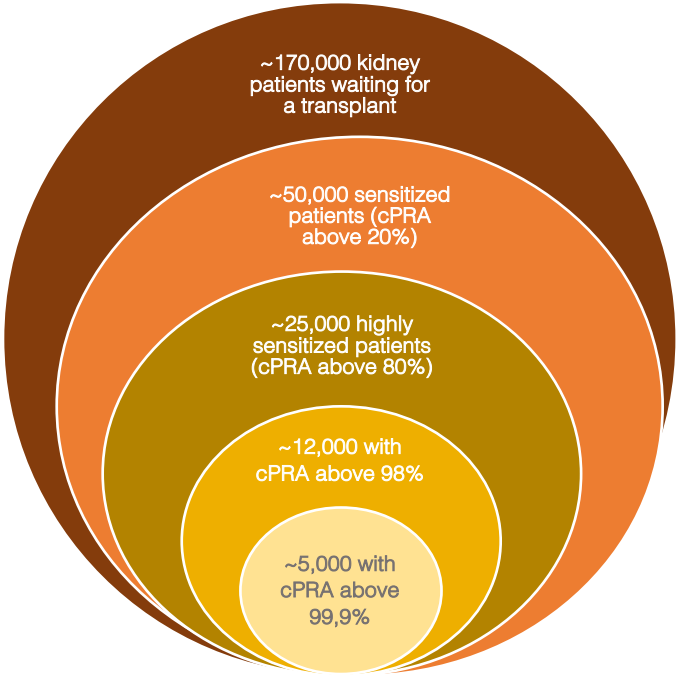
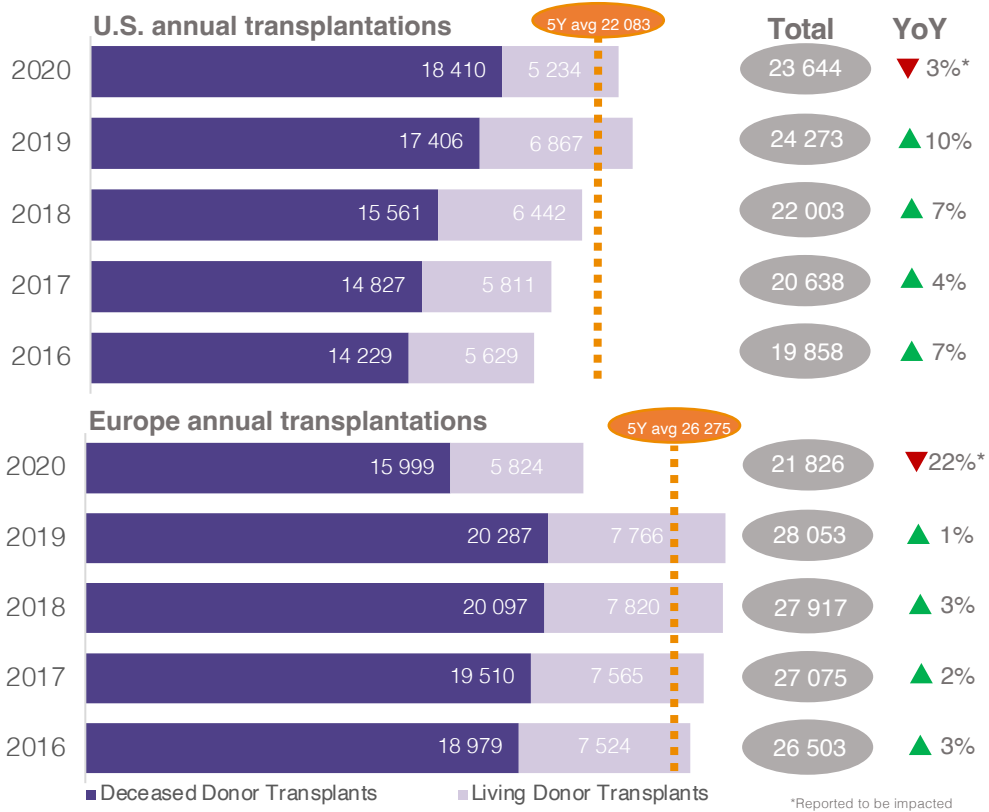
Up to 15% of patients waiting for a new kidney are highly sensitized

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



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



*Reported to be impacted by the COVID-19 pandemic

Source: The U.S. Department of Health and Human Services and .irodat.org

Source: Global Observatory on Donation and Transplantation, http://www.transplant-observatory.org/

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

Illustrative

Commercial sales uptake

1 Build the foundation for Idefirix® in EU to become a new Standard of Care

- Commercialize in early-launch countries focusing on leading clinics and early adopters
- Secure Pricing and Reimbursement agreements
- Ensure clinical readiness and KOL engagement
- Implement new medical guidelines through ESOT
- Increase awareness on unmet need through KOL engagement, patient organizations and medical conferences
- Initiate post approval study in Europe to support full approval and establish long-term outcomes

"Low initial uptake and volatile growth'

Sales will remain "low and volatile" between quarters during the initial launch years until early positive experiences are generated for Idefirix® to become a new SoC

2 Expanding internationally will lead to more exponential growth mid term

- Leverage experience to scale Idefirix in Europe with early-launch centers and in the five largest markets after completing market access
- Launch in the U.S. following completion of the ConfIdeS study and FDA approval
- Expand to select markets and regions beyond core markets in EU and the U.S. through partnerships
- Full marketing authorization in Europe
- Support patient and organ access for highly sensitized patients

"More exponential growth'

Expand broader and internationally

3 Potential label expansion will enable new growth pockets longer term

- Commercialize in AMR in kidney upon potential approval
- Potentially expand into living donor transplantation
- Potentially expand into other solid organ transplantations such as heart and lung pre- and post transplantation (AMR)

"Growth from pursuing new opportunities"

Potentially enable label expansions

Initial years of commercialization | Mid term | Longer term

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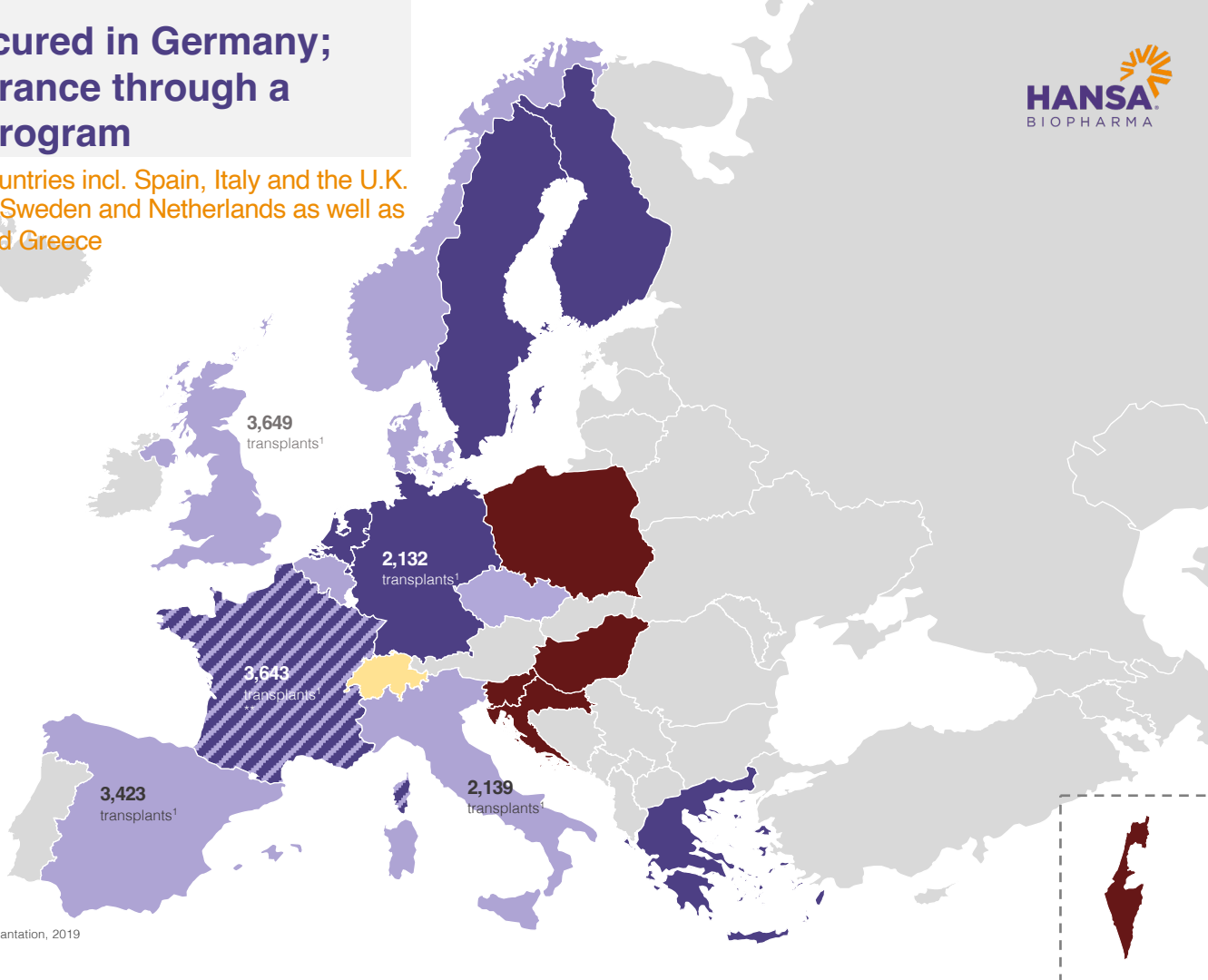
Full commercial access secured in Germany; Market access granted in France through a reimbursed Early Access Program

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

- Health Technology Assessments (HTA) dossiers submitted
- Reimbursed Early Access Program
- Pricing & reimbursement obtained (country or clinic level)
- Temporary Market approval
- Territories covered commercially by Medison Pharma



[1]Annual 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 ≥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

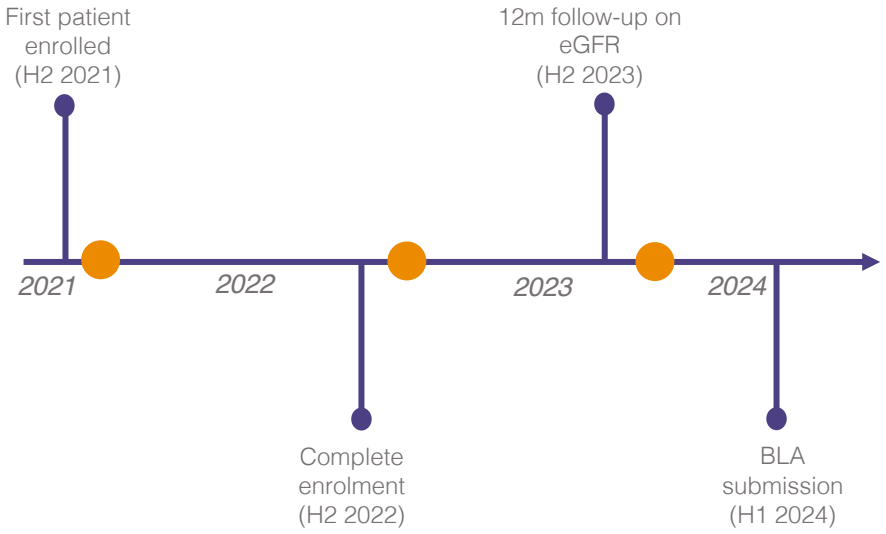
- Robert A. Montgomery, M.D. Professor of Surgery and Director, NYU Langone Transplant Institute, NYC is appointed to be the principal investigator

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



*Experimental desensitization treatment can include any combination of plasma exchange (PLEX), intravenous IVIg, anti-CD20 antibody, and eculizumab. Link to the full protocol at ClincalTrials.gov

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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)							Completion of enrollment (30 patients) H1 2022
	Guillain-Barré syndrome (GBS)							Timeline guidance under review
	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 el 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
Ongoing
Planned
Conditional approval based on Phase 2 data

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

Targeting rare IgG mediated diseases

Expanding our commercial franchises

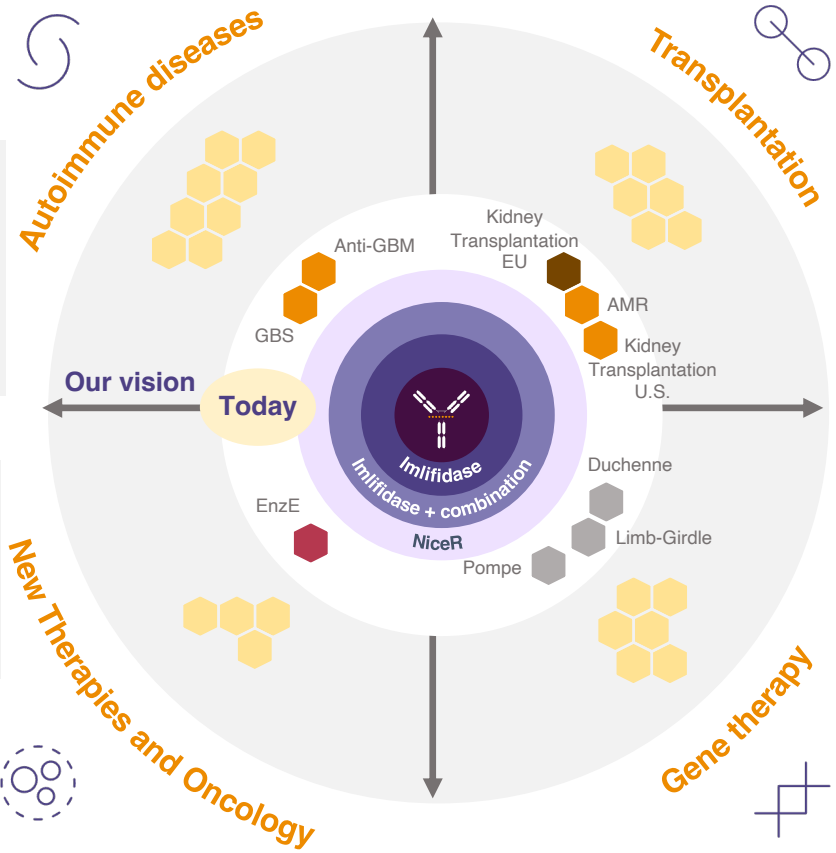
- Regulatory approval (conditional)
- Clinical development
- Partnership (preclinical development)
- Preclinical development

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

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



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

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Results from Phase 2 study of imlifidase in anti-GBM disease published in Journal of American Society of Nephrology (JASN)[1]

U.S. FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a Phase 3 study of imlifidase in 50 patients across U.S. and EU with the first patient is expected to be enrolled in 2022

The JASN publication recognises the potential in deactivation of autoantibodies in autoimmune diseases

CLINICAL RESEARCH www.jasn.org

Endopeptidase Cleavage of Anti-Glomerular Basement Membrane Antibodies in vivo in Severe Kidney Disease: An Open-Label Phase 2a Study

Fredrik Uhlin,[1,2] Wladimir Szpirt,[3] Andreas Kronbichler,[4] Annette Bruchfeld,[1,5] Inga Soveri,[6] Lionel Rostaing,[7] Eric Daugas,[8] Arnaud Lionet,[9] Nassim Kamar,[10] Cédric Rafat,[11] Marek Myslivecek,[12] Vladimir Tesar,[12] Anders Fernström,[1] Christian Kjellman,[13] Charlotte Elfving,[13] Stephen McAdoo,[14] Johan Mölne,[15] Ingeborg Bajema,[16] Elisabeth Sonesson,[13] and Mårten Segelmark[1,17]

Due to the number of contributing authors, the affiliations are listed at the end of this article.

ABSTRACT

Background The prognosis for kidney survival is poor in patients presenting with circulating anti–glomerular basement membrane (GBM) antibodies and severe kidney injury. It is unknown if treatment with an endopeptidase that cleaves circulating and kidney bound IgG can alter the prognosis.

Methods An investigator-driven phase 2a one-arm study (EudraCT 2016–004082–39) was performed in 17 hospitals in five European countries. A single dose of 0.25 mg/kg of imlifidase was given to 15 adults with circulating anti-GBM antibodies and an eGFR <15 ml/min per 1.73m². All patients received standard treatment with cyclophosphamide and corticosteroids, but plasma exchange only if autoantibodies rebounded. The primary outcomes were safety and dialysis independency at 6 months.

Results At inclusion, ten patients were dialysis dependent and the other five had eGFR levels between 7 and 14 ml/min per 1.73m². The median age was 61 years (range 19–77), six were women, and six were also positive for anti-neutrophil cytoplasmic antibodies. Then 6 hours after imlifidase infusion, all patients had anti-GBM antibodies levels below the reference range of a prespecified assay. At 6 months 67% (ten out 15) were dialysis independent. This is significantly higher compared with 18% (nine out of 50) in a historic control cohort (P<0.001, Fisher's exact test). Eight serious adverse events (including one de... rted, none assessed as probably or possibly related to the study drug. ...lusions In this pu... ...ed s... ...y, the use of imlifidase was associated with a ...ajor safety issues, but the findin...

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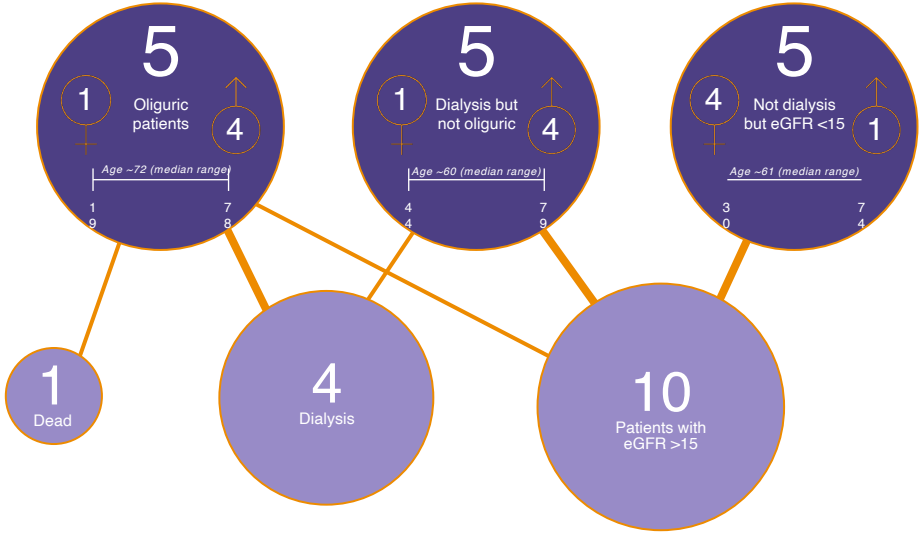
10 out of 15 patients were dialysis independent after six months; The anti-GBM data is significantly better than the historical cohort, where only 18% had functioning kidney



[1] Journal of the American Society of Nephrology https://pubmed.ncbi.nlm.nih.gov/35260419/Segelmark et al. JASN (2022)

[2] McAdoo 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

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Enrollment in Phase 2 program in Antibody Mediated Rejection (AMR) post kidney transplantation close to completion

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 transplants[1] 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

- 29 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 been 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.

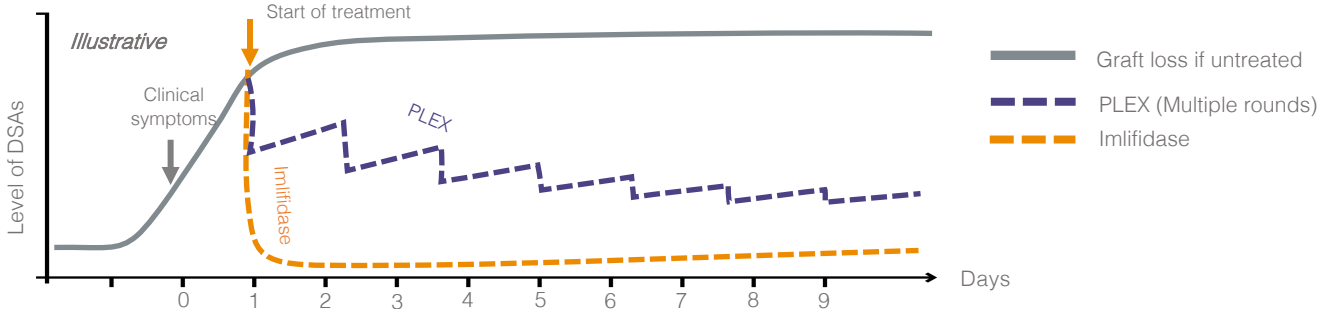
Path forward

H1'22: On track for completion of enrollment

H2'22: Phase 2 data read-out

Decision on a regulatory path forward

Potential of using imlifidase vs. PLEX in AMR



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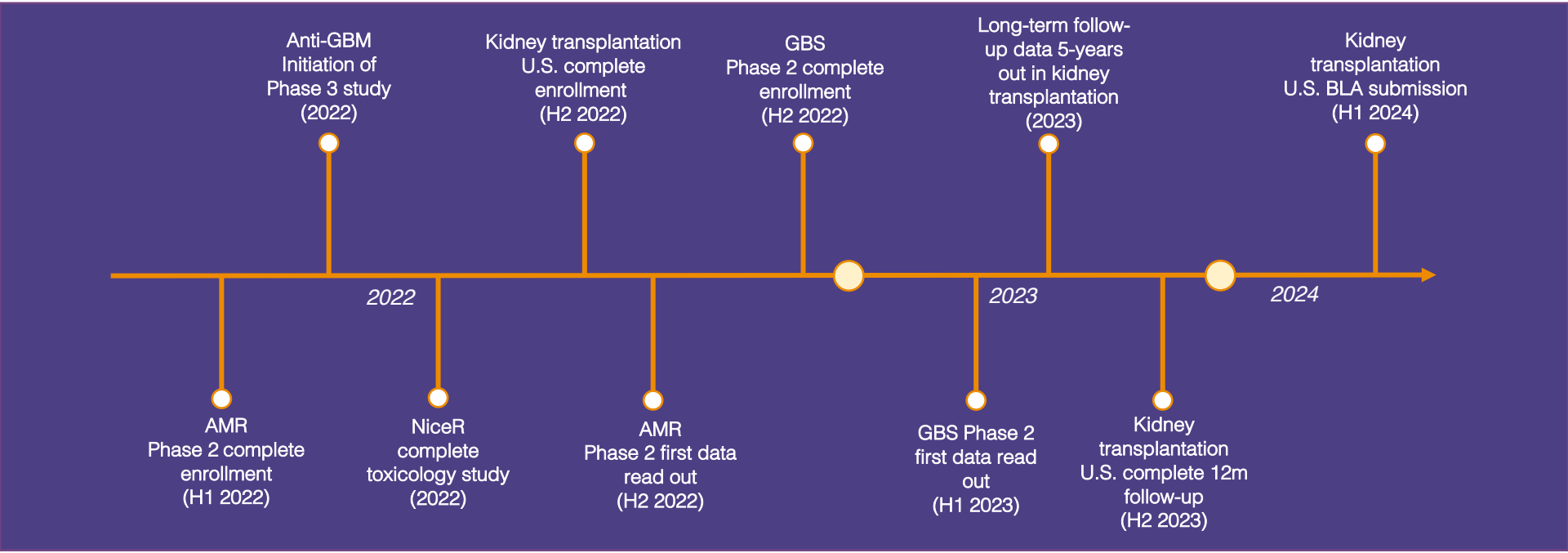
Upcoming milestones

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.

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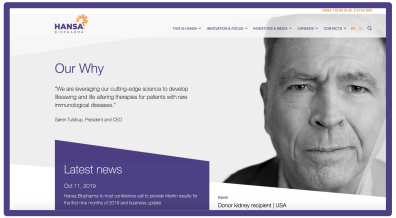
Investor Relations and Corporate Communications

Visit our web site
www.hansabiopharma.com



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Calendar and events

May 18, 2022	ABG ABGSC Life Science Summit 2022, Stockholm
June 2, 2022	Redeye Growth Day
June 16, 2022	CITI's European Healthcare Conference
June 23-24, 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 konference, Copenhagen

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