



## Investor Presentation

Needham Annual Healthcare Conference  
April 13, 2022

Søren Tulstrup  
President & CEO



*...at Hansa Biopharma we envision a world where all patients with rare immunologic diseases can lead long and healthy lives...*



# 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 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\*

### 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

133 employees December 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 889m in Cash (USD ~98m)  
December 2021

## Created shareholder value and diversified our ownership base

### MARKET CAPITALISATION (USD): ~0.3bn

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 15 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)



Pricing and reimbursement for Idefix® obtained in France on an early access basis

2021

January

February

March

April

May

June

July

August

September

October

November

December

2022

January

February

March

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



HANSA  
BIOPHARMA

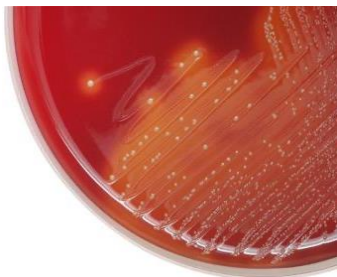


# Imlifidase

A novel approach to eliminate pathogenic IgG

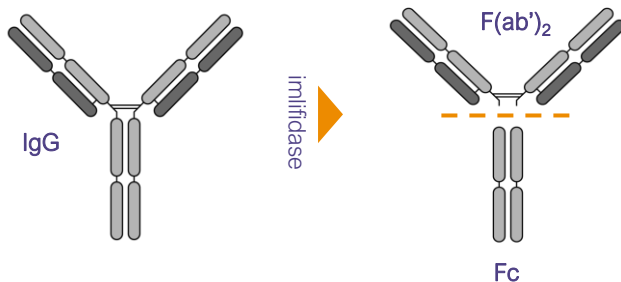
## Origins from a bacteria *Streptococcus pyogenes*

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



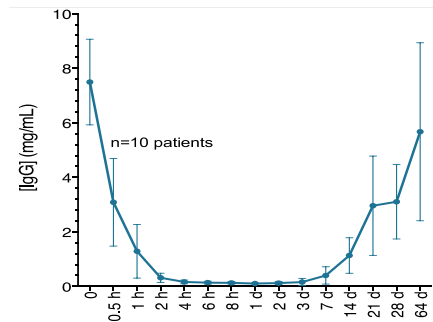
## A unique IgG antibody-cleaving enzyme

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



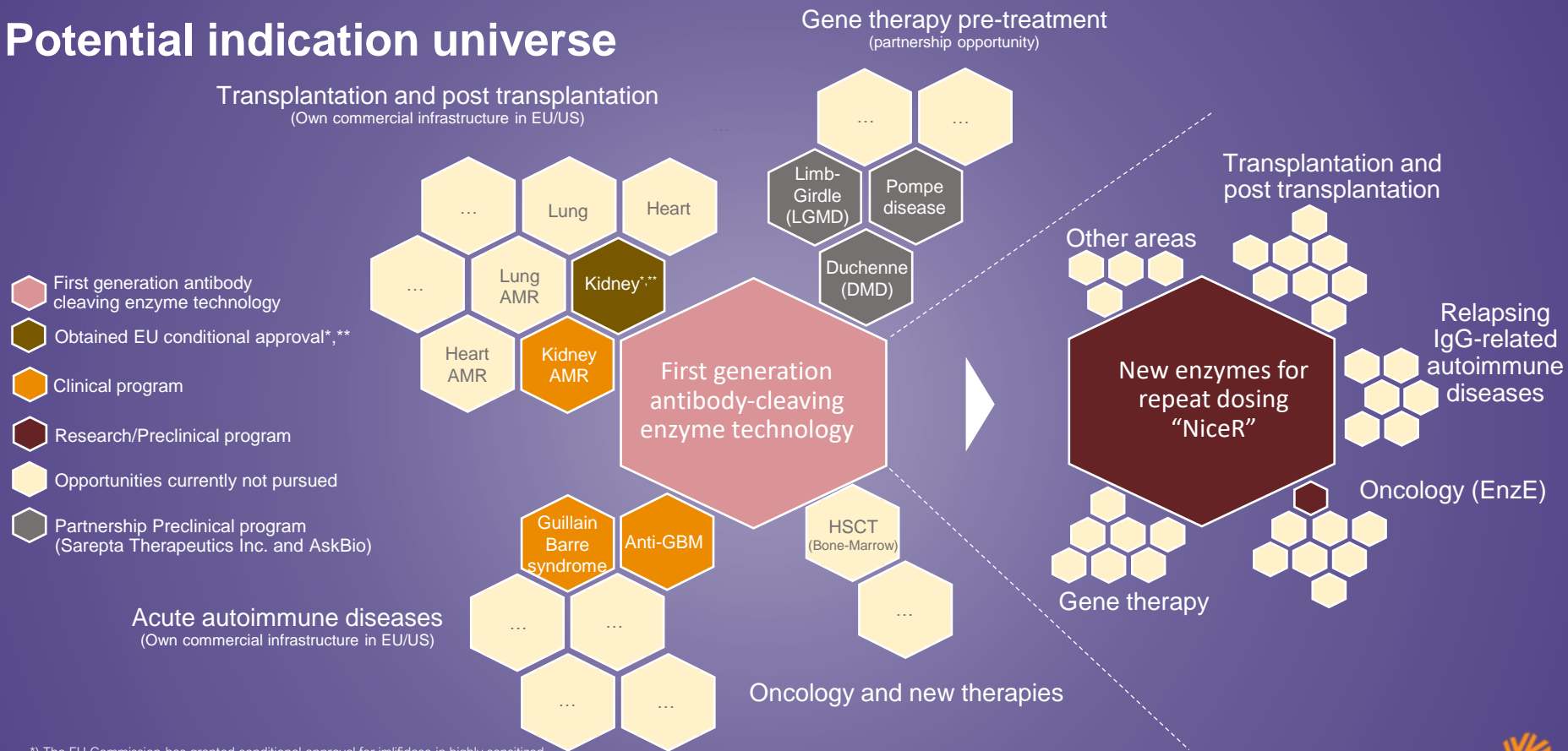
## Inactivates IgG in 2-6 hours

- 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



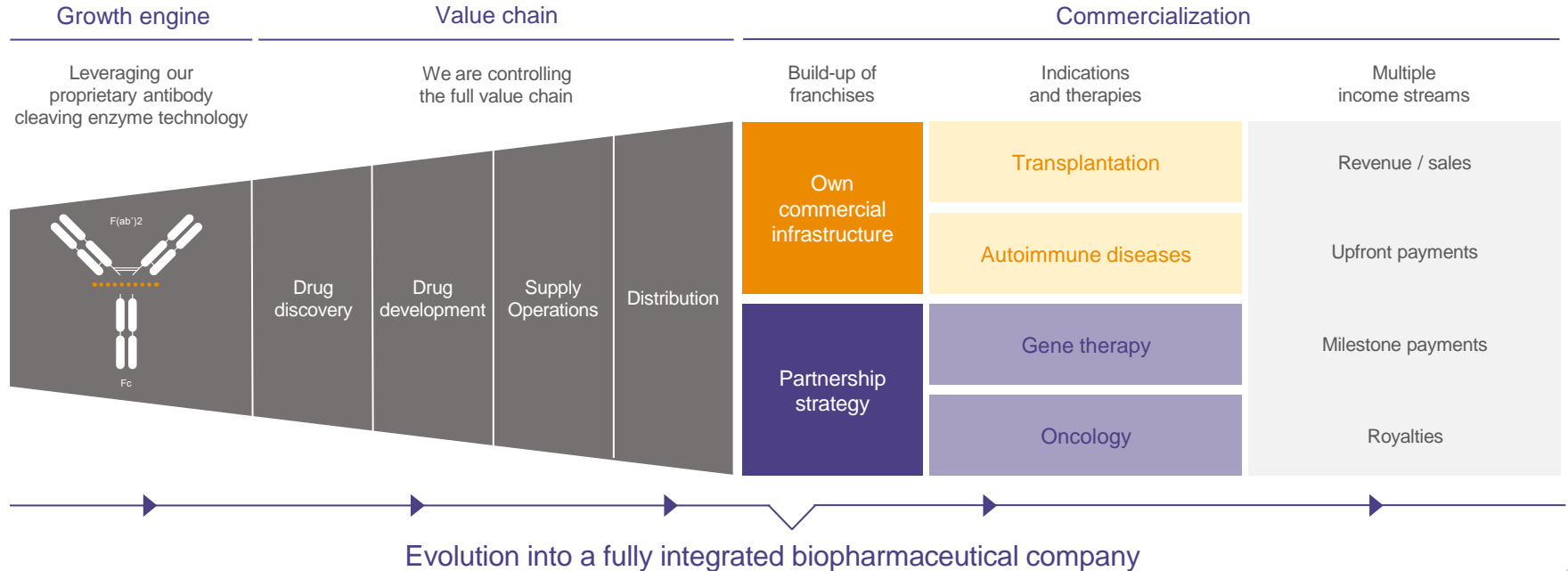
\*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.

\*\*) 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<sup>1,2</sup>

15-20% of patients<sup>1,2</sup>

10-15% of patients<sup>1,2</sup>

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

## 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

<sup>1</sup> EDQM. (2020). International figures on donation and Transplantation 2019

<sup>2</sup> SRTR Database and individual assessments of allocation systems

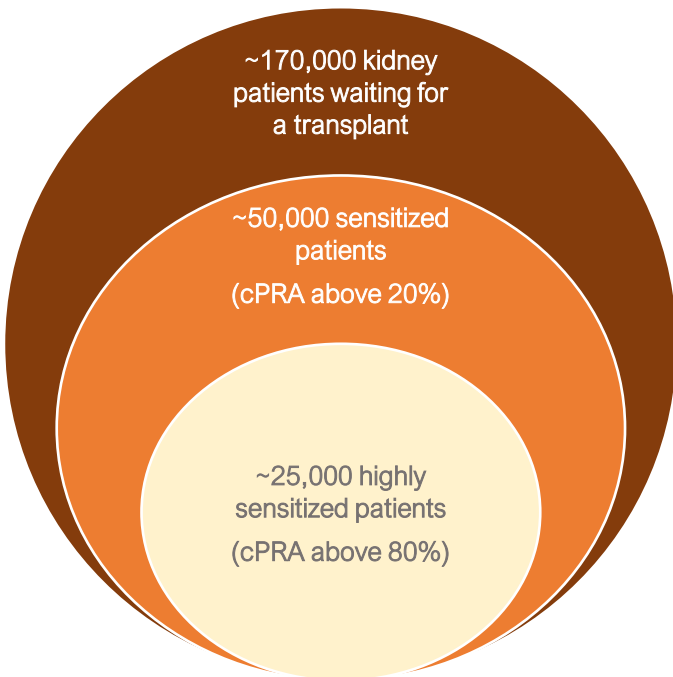


# The kidney transplantation landscape in Europe and the U.S.

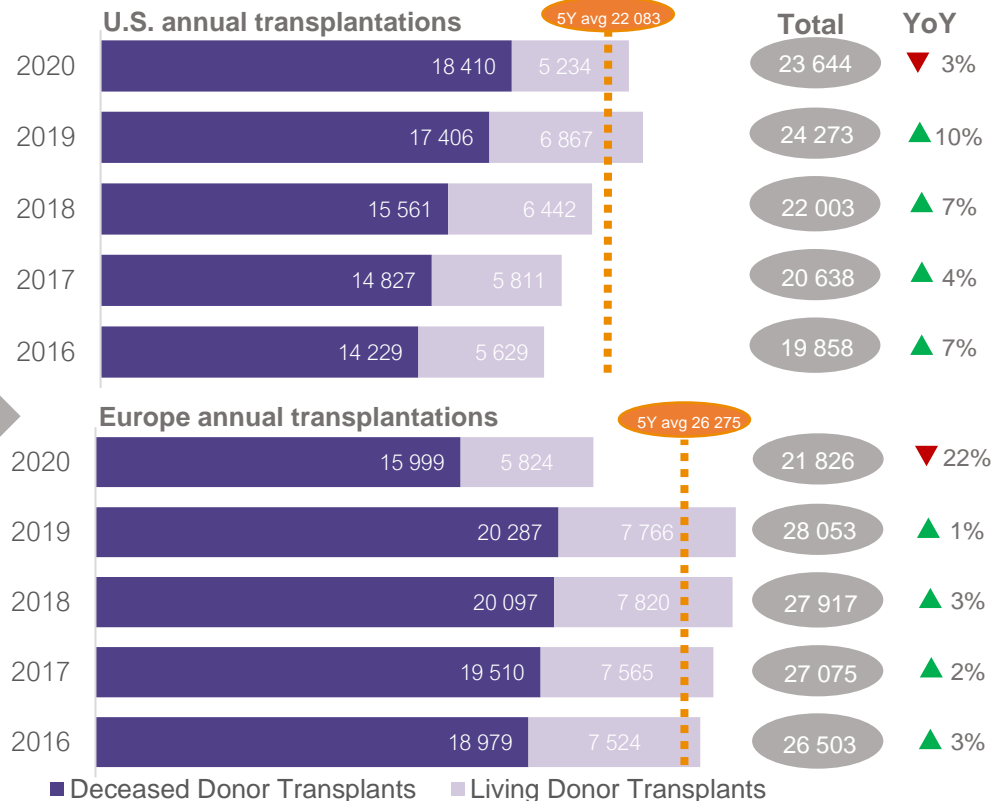
Up to 15% of patients waiting for a new kidney are highly sensitized

European transplantation rates were negatively affected by COVID-19

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



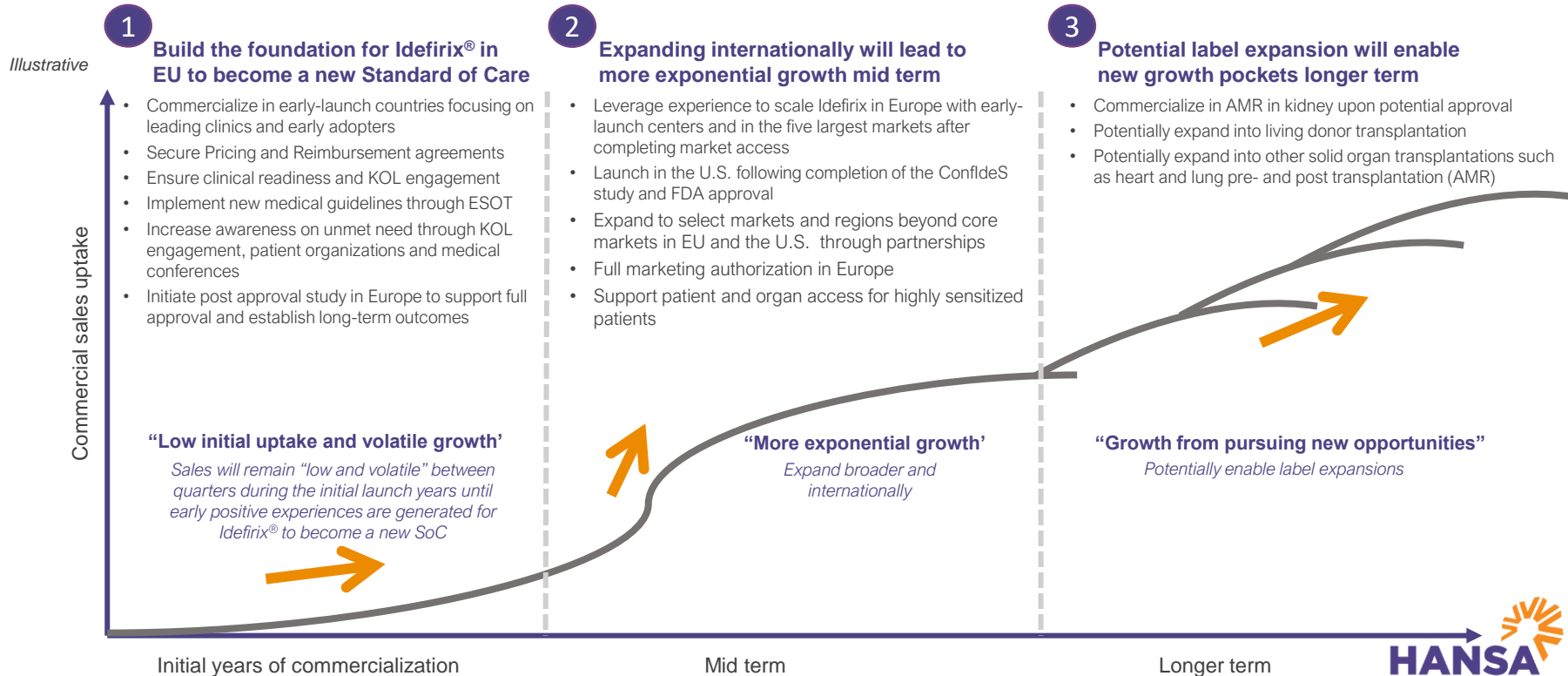
~50,000 transplants done annually in the U.S. and Europe





# Our center focused and sequenced launch process ("S"-shaped launch curve) will help build the foundation for Idefix® to become a new Standard of Care in transplantation

Idefix® 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



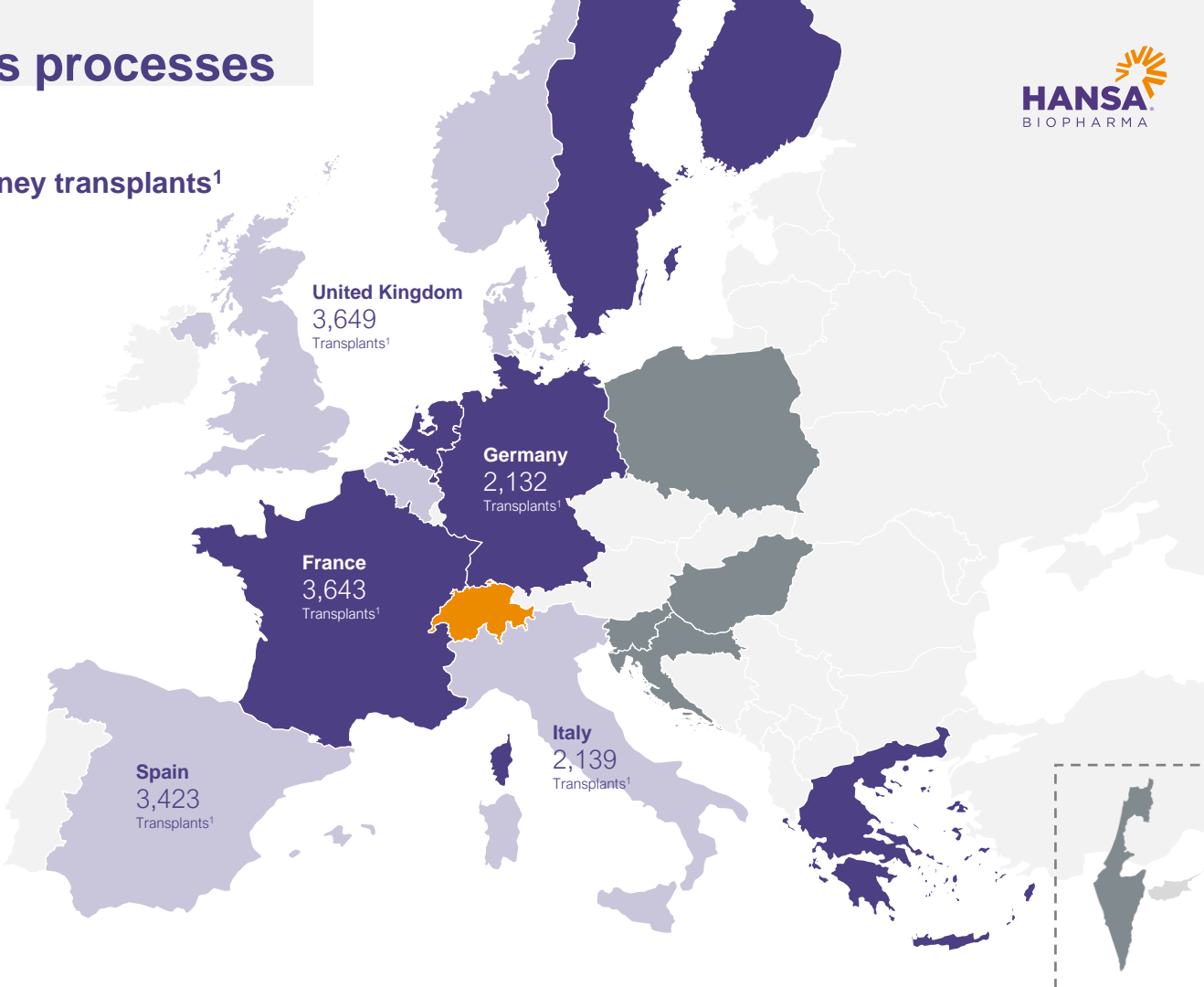


# Ongoing market access processes

EU4+UK represent ~15,000 annual kidney transplants<sup>1</sup>

Pricing and reimbursement obtained in France (early access), Germany, Sweden, Netherlands as well as Finland and Greece on a hospital basis; 10 clinics qualified as clinically ready

- Health Technology Assessments (HTA) dossiers filed
- Marketing Authorization Application submitted
- Pricing & reimbursement obtained
- Medison Pharma distribution partnership



<sup>1</sup>Annual kidney transplantations 2019 (pre COVID-19)  
<sup>\*</sup>Transplantation data is from Global Observatory on Donation and Transplantation, 2019  
<sup>\*\*</sup>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
- First patients enrolled at Columbia University, NYC

### 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

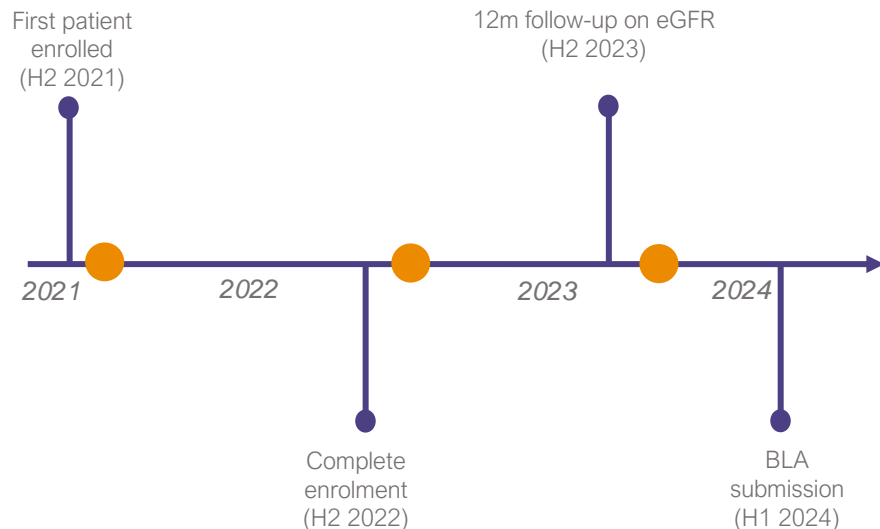
### Secondary endpoint

- Patient survival at 12 months

12-15 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
- Five clinics are open for recruitment as of February 2, 2022

## 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 [ClinicalTrials.gov](https://clinicaltrials.gov)



# 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 <sup>1,2</sup>						*	EU: Additional agreements around reimbursement from H2'21
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>							Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease <sup>3</sup>							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

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

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

<sup>3</sup> Investigator-initiated study by Märten 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

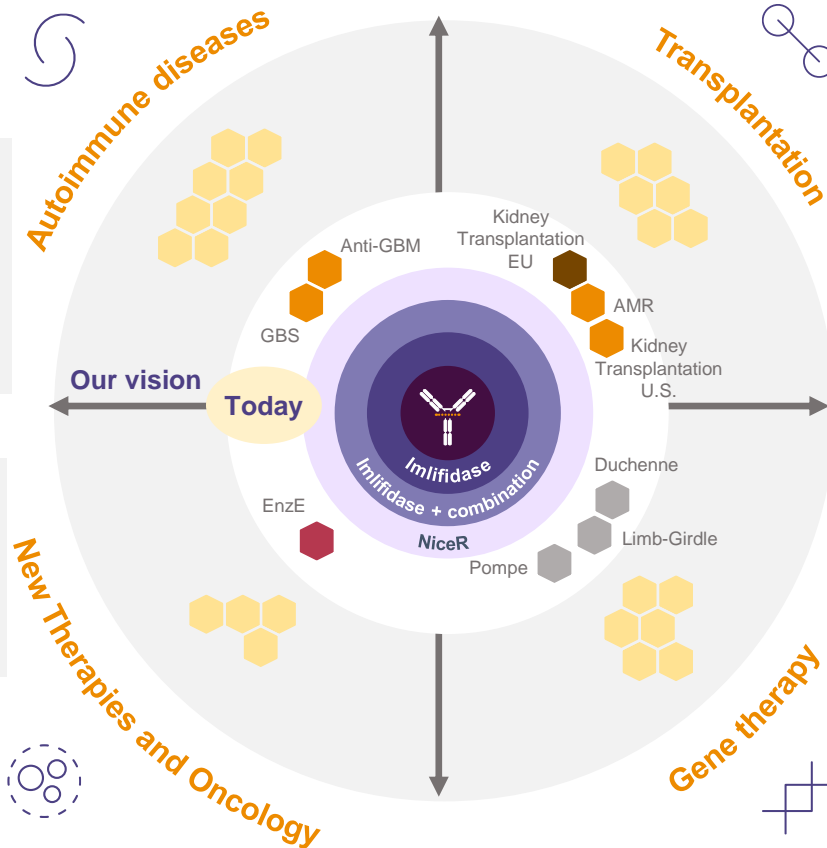
## Targeting rare IgG mediated diseases

### 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

- Allogenic 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

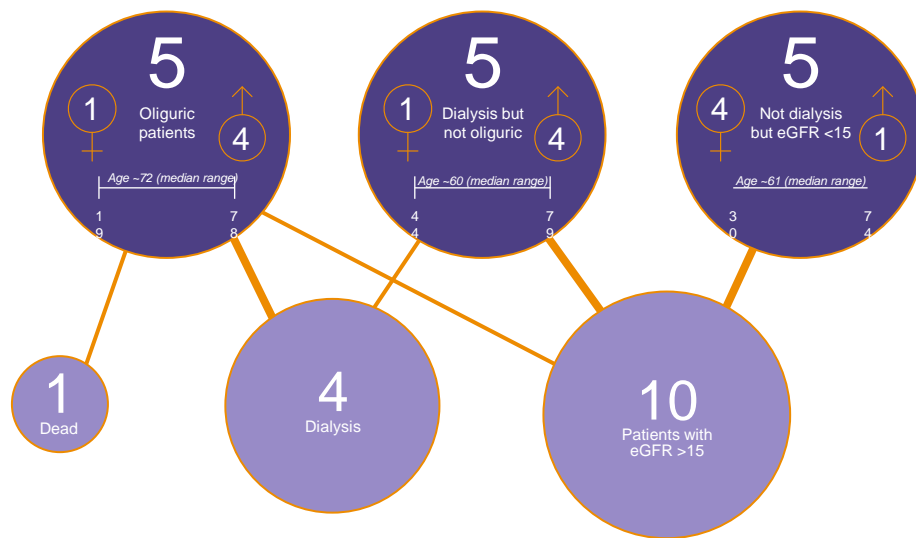


# Imlifidase treatment of anti-GBM disease highlighted in JASN (Journal of American Society of Nephrology)<sup>1</sup>

Encouraging phase 2 data marks an important milestone for Hansa Biopharma's IgG antibody cleaving technology platform outside transplantation

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

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



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

<sup>2</sup> 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



# Collaboration with AskBio to evaluate imlifidase in gene therapy targeting Pompe disease

Feasibility program to evaluate imlifidase as pre-treatment ahead of gene therapy in Pompe disease for patients with pre-existing neutralizing antibodies (NABs) to adeno-associated virus (AAV)



## Hansa's key resources and deliverables

- Imlifidase validated with positive clinical efficacy and safety data as well as European approval
- Significant know-how around antibody cleaving enzymes
- Clear path to U.S. approval (kidney transplant)
- Hansa supplies material and provides additional support



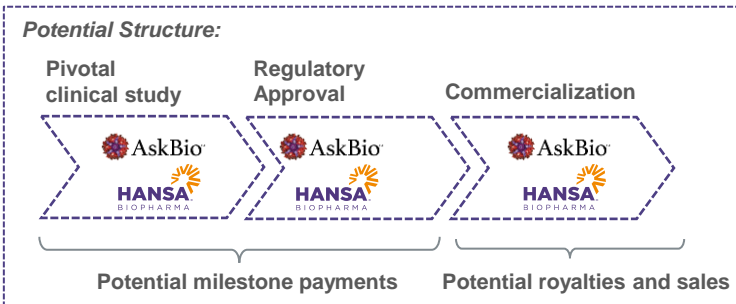
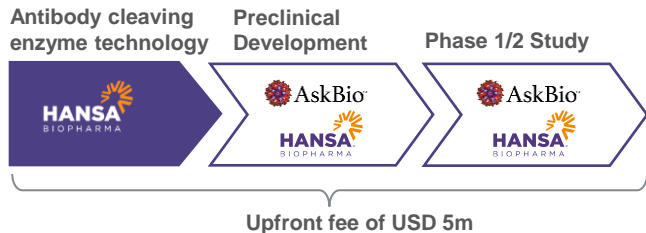
*Fully owned subsidiary of Bayer AG*

## AskBio's key resources and deliverables

- Early innovator in the Gene Therapy space with AAV platform and ongoing clinical stage Pompe disease program
- Conducts pre-clinical and clinical trials according to agreed plan

Current agreement scoped around a feasibility program which covers preclinical work and a Phase 1/2 study

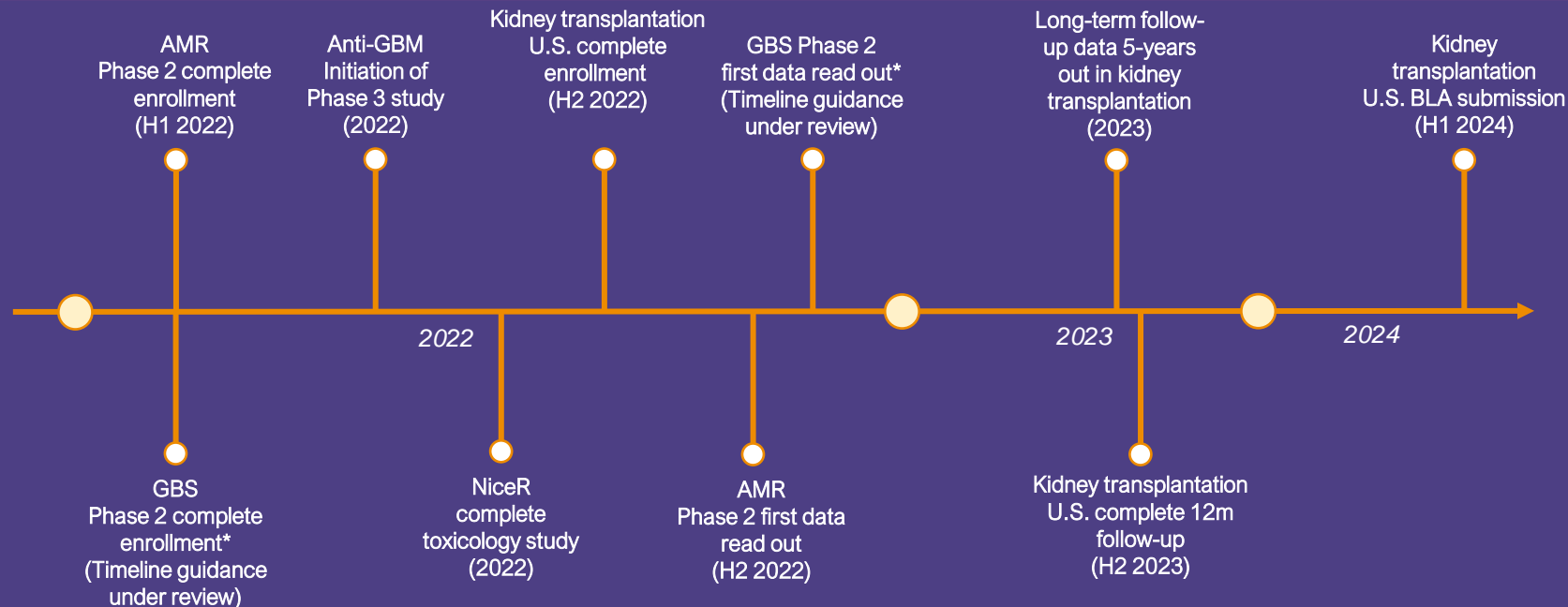
Exclusive option for AskBio to negotiate a potential full development and commercialization agreement





# 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.

\*GBS: Given the current difficulty of predicting enrollment due to the direct and indirect effects of the persistent and even escalating pandemic, Hansa expects to update its guidance for completion of enrollment in GBS in April 2022







# Corporate Contacts

Investor Relations and  
Corporate Communications

Visit our web site  
[www.hansabiopharma.com](http://www.hansabiopharma.com)



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## Calendar and events

April 21 2022

April 21 2022

April 27 2022

May 15 2022

May 16, 2022

June 16 2022

July 12, 2022

July 21 2022

Aug 9, 2022

Aug 10, 2022

Sept 7, 2022

Sept 7-8, 2022

Oct 20, 2022

Nov 23, 2022

Interim Report for January-March 2022

Kempen Life Sciences Conference 2022, Amsterdam

Redeye Orphan Drugs 2022, Stockholm

ABG ABGSC Life Science Summit 2022, Stockholm

European Midcap Event, Copenhagen

Annual General Meeting 2022

William Blair's Biotech Focus Conference 2022, New York

Half year 2022 report

BTIG Biotechnology Conference 2022, New York

Canaccord Annual Growth Conference, Boston

Pareto annual Healthcare Conference 2022, Stockholm

Citi's 17th Annual BioPharma Conference, Boston

Interim Report for January-September 2022

Økonomisk Ugebrev Life Science konference, Copenhagen