



Investor Presentation

William Blair KOL Expert event
Innovations in Organ Transplant
September 28, 2022

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Chief Operating Officer (COO)*

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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

145 employees June 2022
(~3x in 3 years)
Highly qualified team with 20 years on average in life science
Purpose driven culture

With current cash position Hansa is financed through 2024

FINANCIALS

SEK 617 in Cash and short term investments (USD ~60m) June 2022
SEK ~1.3bn (USD ~130m) post NovaQuest financing transaction carried out July 2022

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~300m

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



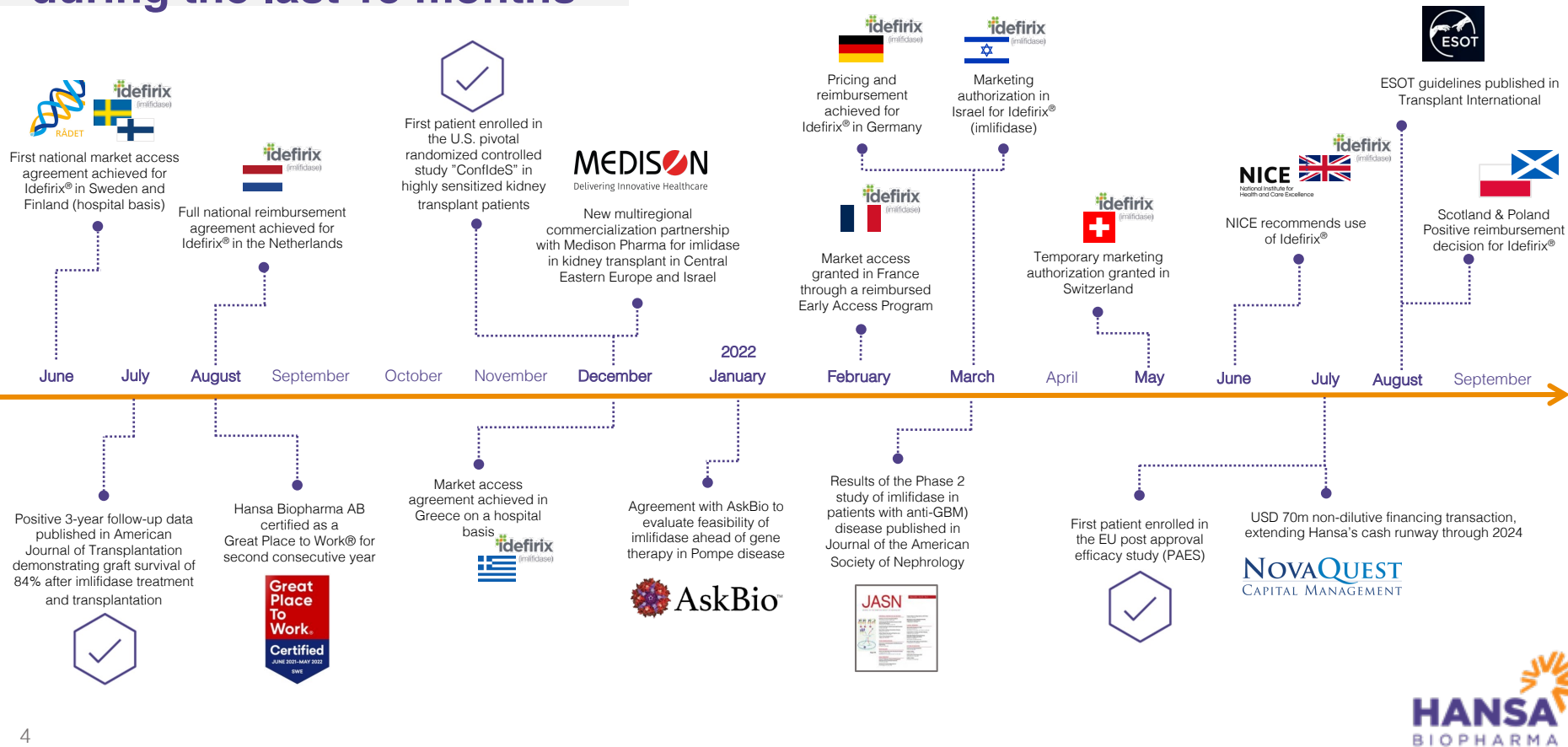
Patient*

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



Imlifidase

A novel approach to eliminate pathogenic IgG

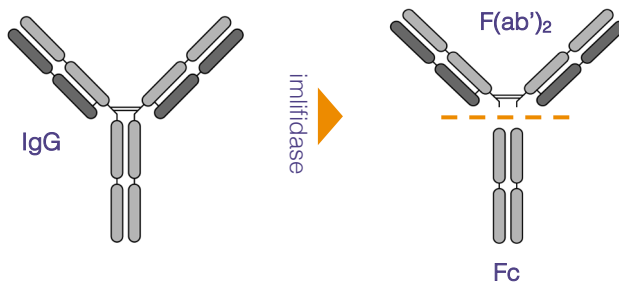
Origins from a bacteria *Streptococcus pyogenes*

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



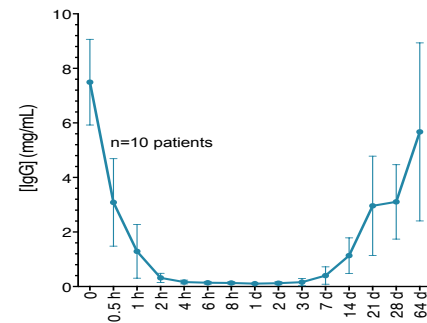
A unique IgG antibody-cleaving enzyme

- 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



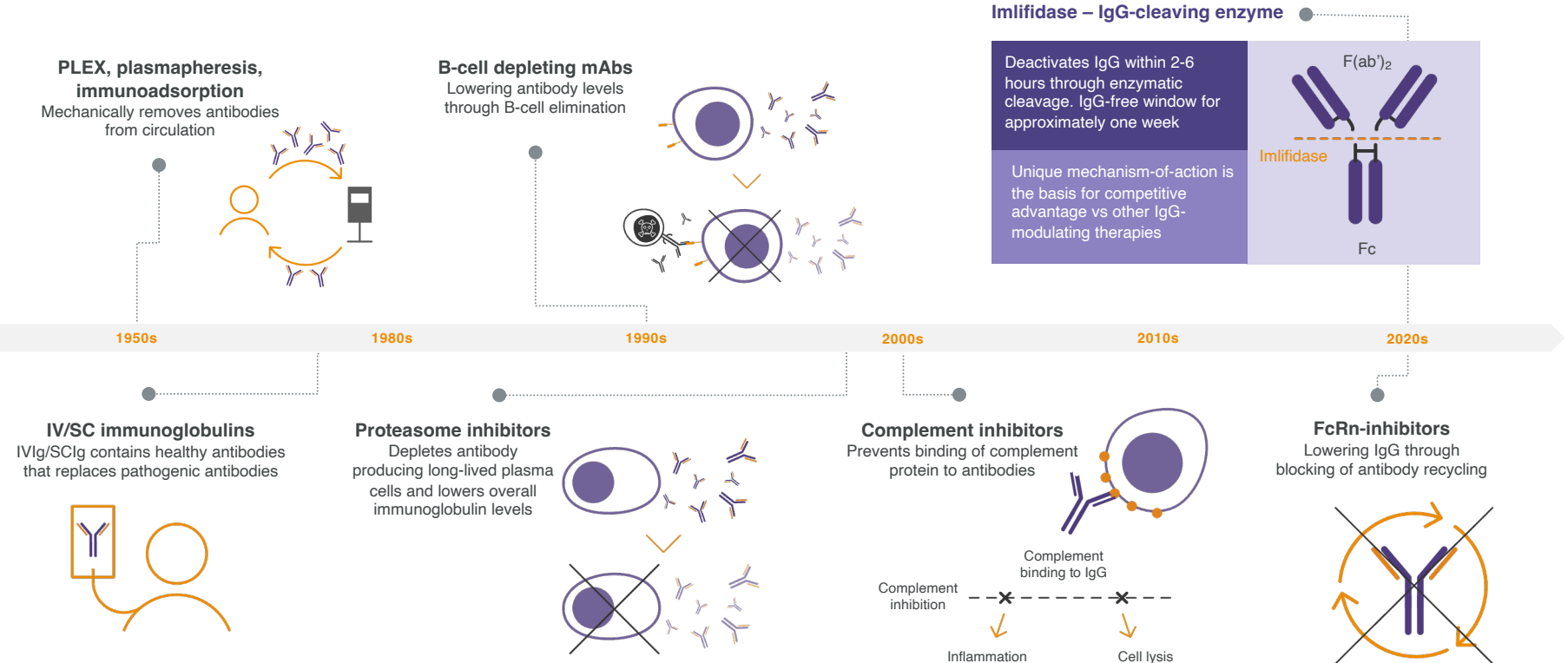
Inactivates IgG in 2-6 hours

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

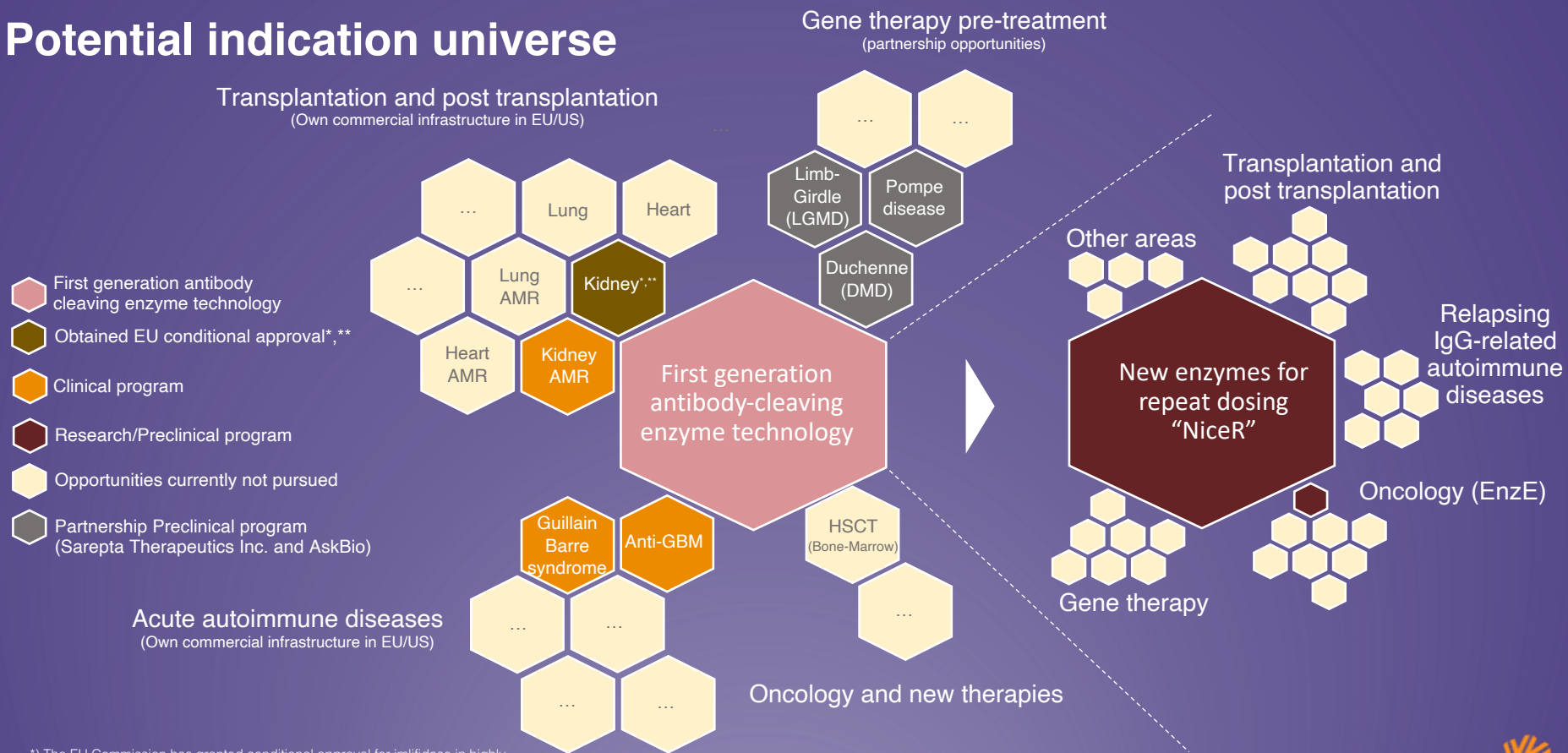


Development of IgG-modulating technologies

Mechanisms can be both complementary and competing



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

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

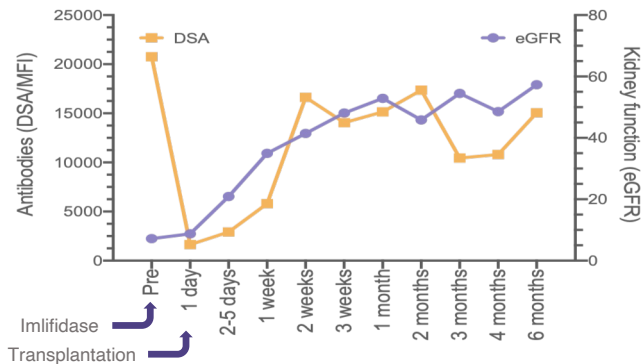
Actual patient has given consent to provide images

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







Imlifidase enabled kidney transplantation in 46 highly sensitized patients during clinical trials

Pooled analysis from four Phase 2 trials

- Analysis included 46 patients
 - 50% had a cPRA of 100% (Average 99%)
 - 85% were crossmatch positive
 - 70% were retransplanted
- Donor Specific Antibody (DSA) levels rapidly decreased and all crossmatches were converted to negative, thus enabling transplantation in all patients
- At study completion, all patients alive and graft survival at 94% six months post transplantation



Study design of our four Phase 2 trials

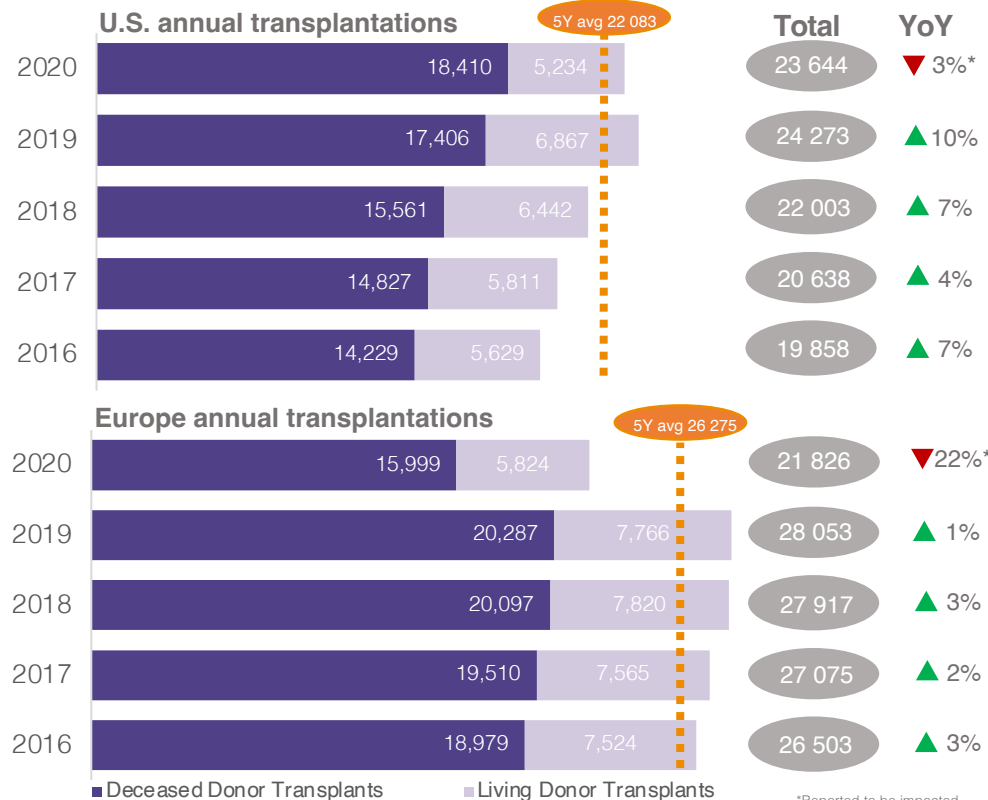
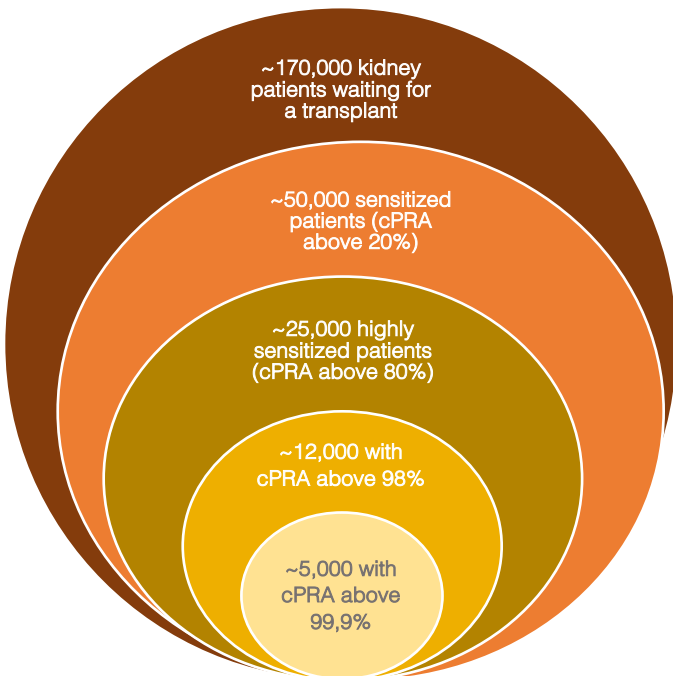
Study 02 Phase 2	Subjects	8 patients 
	Design	Single-center, single-arm, open-label
	Main objective	Efficacy defined as Imlifidase dosing scheme resulting in HLA antibody levels acceptable for transplantation, within 24 hours
Study 03 Phase 2	Subjects	10 patients 
	Design	Single-center, single-arm, open-label, no prior desensitization
	Main objective	Safety in the transplantation setting and efficacy defined as HLA antibody levels acceptable for transplantation
Study 04 Phase 2	Subjects	17 patients 
	Design	Investigator initiated, single-center, single-arm, open-label. All patients had prior desensitization with IVIG and/or PLEX
	Main objective	Safety in combination with Cedars Sinai's "standard protocol" for desensitization of highly sensitized patient
Study 06 Phase 2	Subjects	18 patients   
	Design	Multicenter, multinational, single-arm, open-label
	Main objective	Efficacy in creating a negative crossmatch test

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

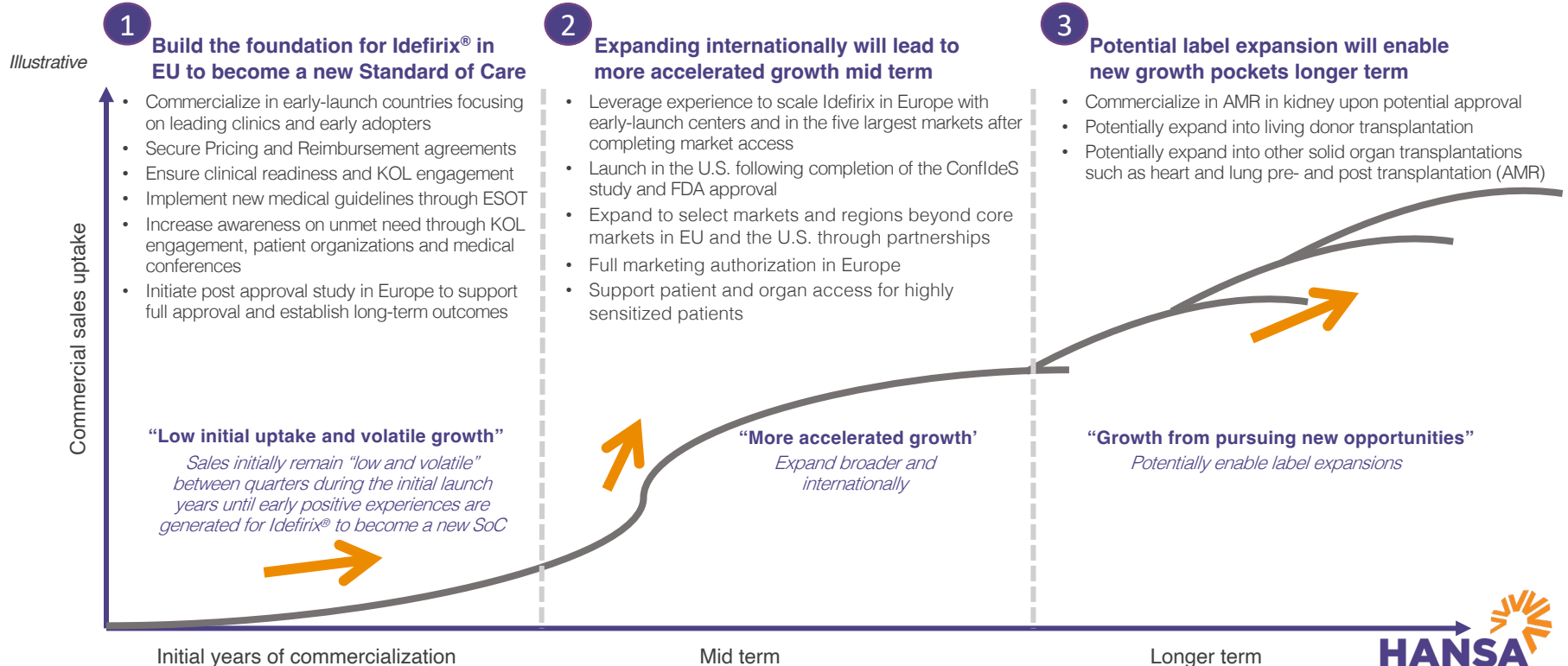
Breakdown of the kidney transplant waitlist in U.S. and EU



*Reported to be impacted by the COVID-19 pandemic

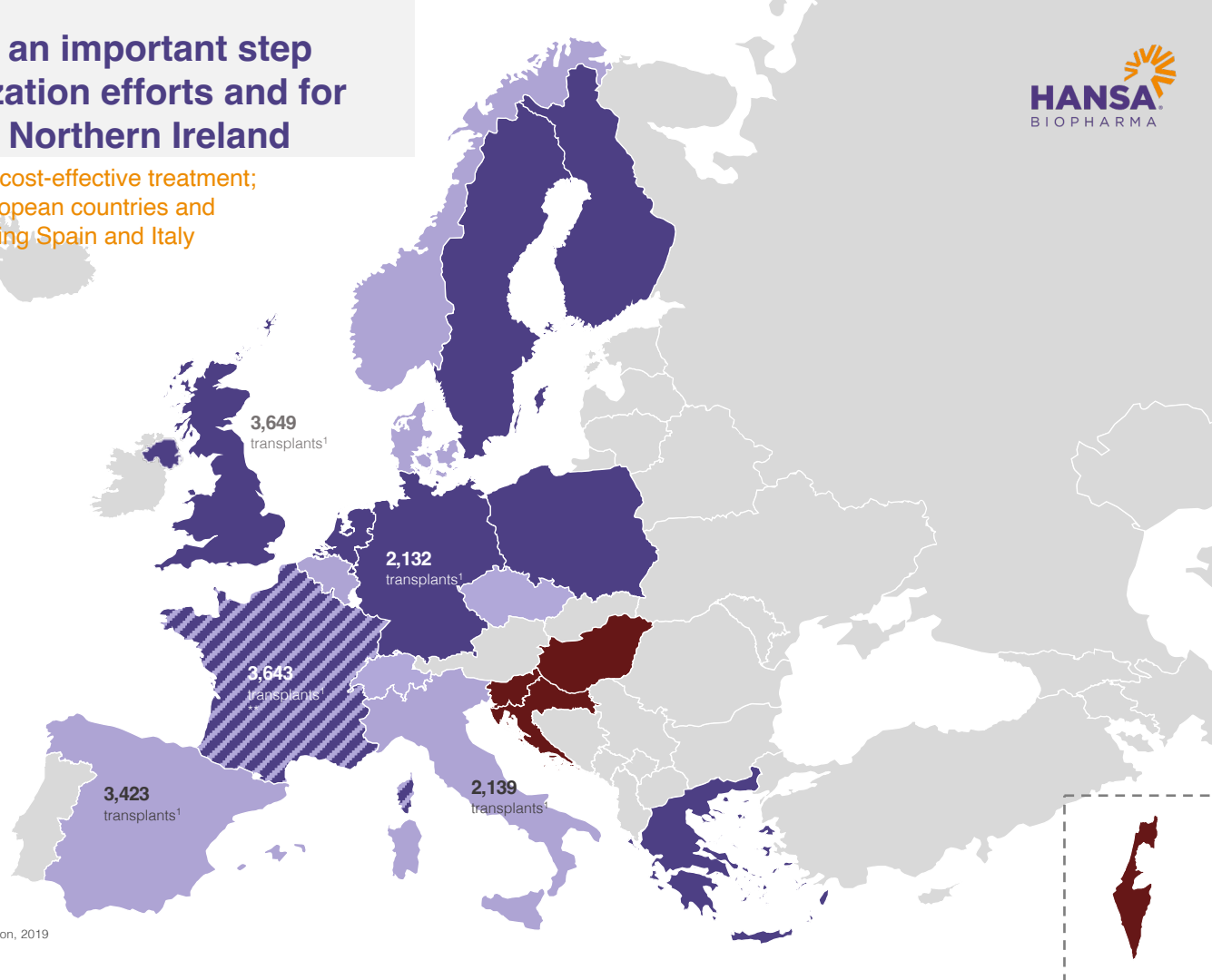
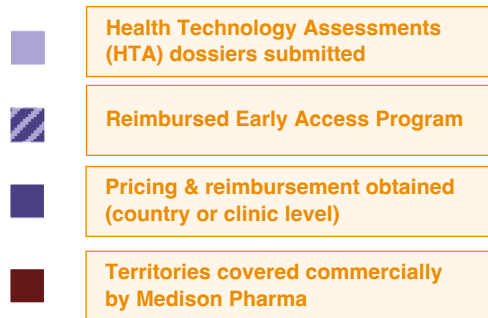
Our center focused and sequenced launch process will help build the foundation for Idefirix® to become a new Standard of Care in transplantation

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



Recommendation by NICE is an important step forward for our commercialization efforts and for patients in England, Wales & Northern Ireland

NICE considers Idefirix® to be a clinically- and cost-effective treatment;
Market access has now been secured in 7 European countries and
procedures are ongoing in 11 countries, including Spain and Italy



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
- First patients enrolled at Columbia University, NYC
- More than half of patients enrolled across ten sites Mid- September

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

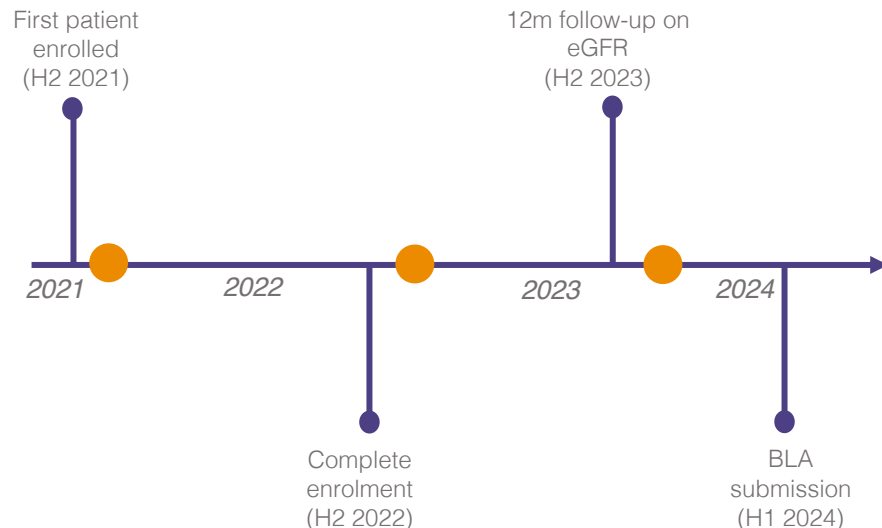
Secondary endpoint

- 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

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)

U.S. kidney transplantation landscape

Our ConfideS study is currently enrolling patients across ten 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

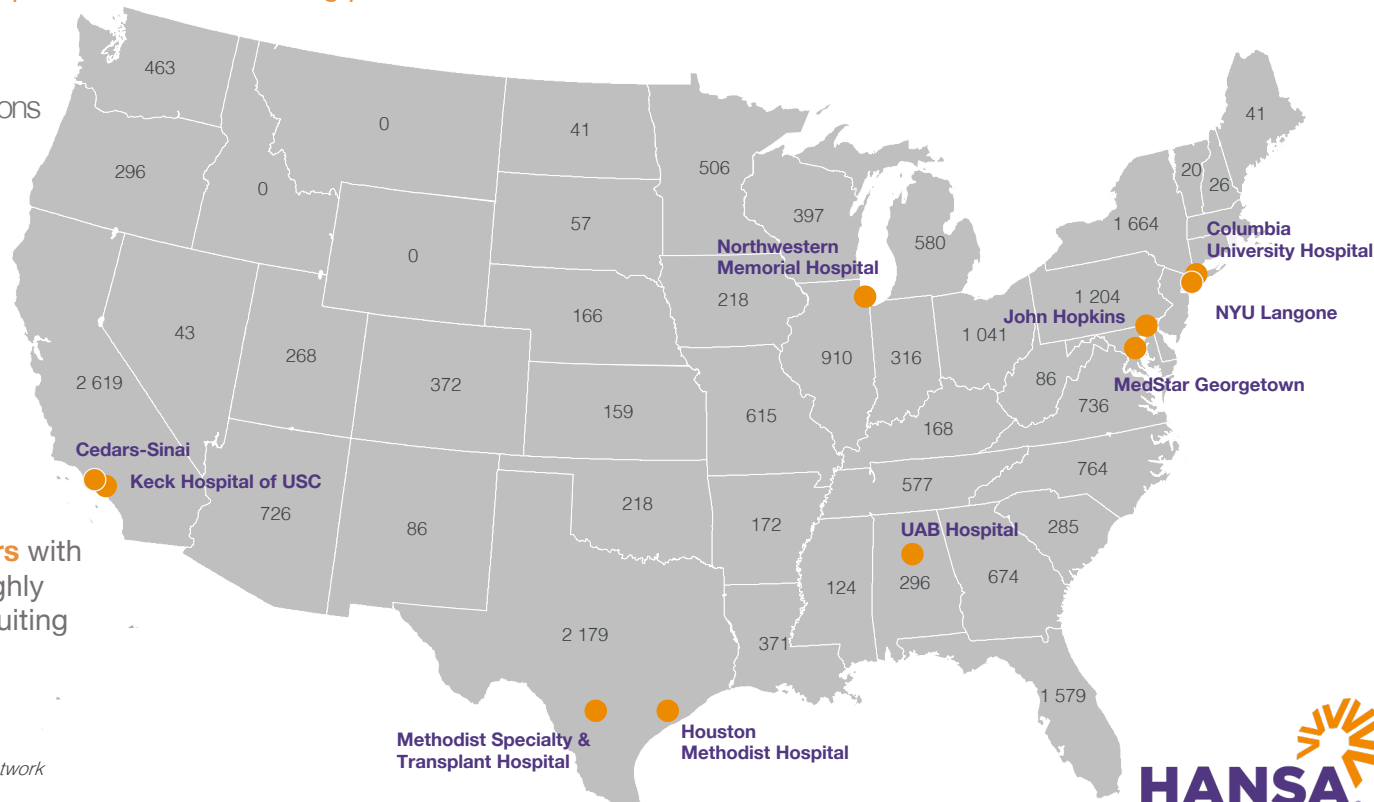
~90,000² waiting for a kidney transplant

10-15%³ of waitlisted patients are highly sensitized

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

2,542¹ combined annual kidney transplants

334¹ 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

3-year follow up demonstrate graft survival of 84% after imlifidase treatment and transplantation

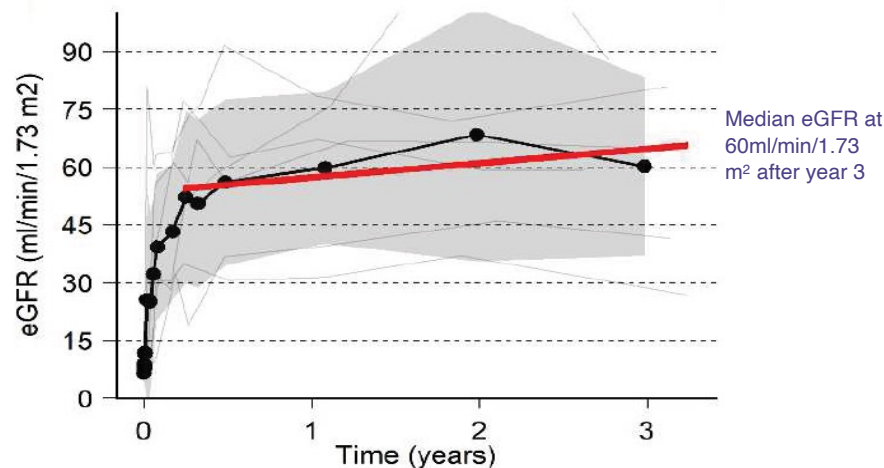
Data accepted for publication in the American Journal of Transplantation¹ [Link AJT article](#)

30 patients participating in follow-up study at year three

AMR frequency in line with other desensitization protocols

- Three-year follow-up data shows graft survival of 84% after imlifidase treatment and transplantation and a mean eGFR of 55 mL/min/1.73 m² (61 mL/min/m² for those without AMR)
- For a subgroup of patients (n=13) with cPRA of $\geq 99.9\%$ graft survival was 92% and improved kidney function for patients with a mean eGFR at 60mL/min/1.73 m² after year three
- 38% of the patients experienced active antibody mediated rejection episodes (AMR) within the first six months, which compares with 25-60% of patients in the literature for highly sensitized patients²
- Only two AMR episodes were reported beyond the first 6 months. All AMRs were treated with standard therapies and no graft losses were attributed to AMR
- Patient survival 90% (three deaths unrelated to imlifidase)
- Long-term safety profile indicates no increase in the rates of infection or malignancy
- Next milestone expected in 2023 on the 5-year follow-up data

Improved kidney function for patients with cPRA $\geq 99.9\%$



¹ American Journal of Transplantation - Outcomes at 3 years post-transplant in imlifidase-desensitized kidney transplant patients (AJT16754)

Link to AJT article <https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16754>

² Vo et al. 2013; Colvin 2007; Gloor et al. 2008; Haas et al. 2014; Jordan et al. 2010; Lefaucheur et al. 2010; Solez et al. 2007; Riella et al. 2014)

