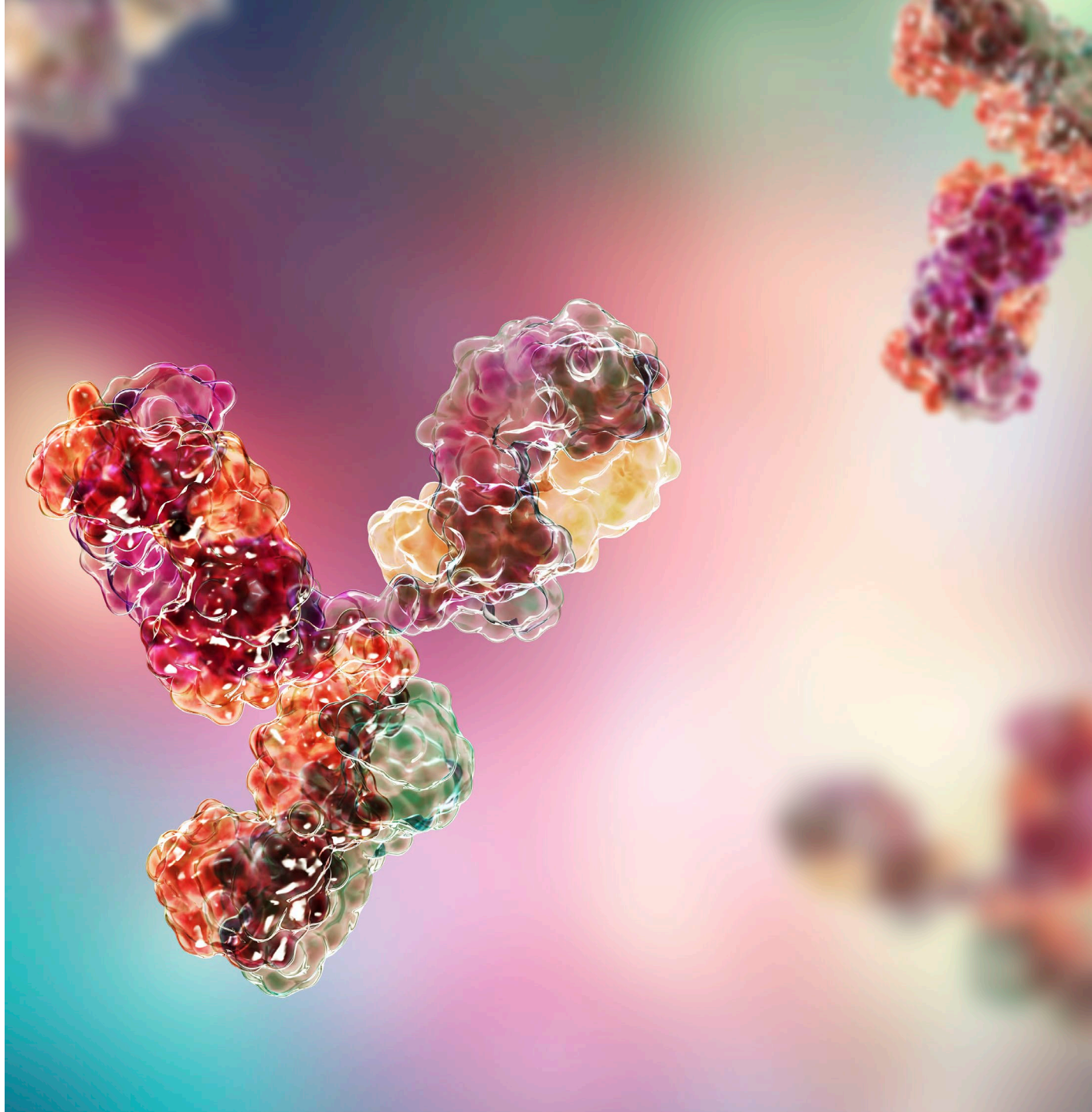
HANSA BIOPHARMA

ConfIdeS
US Phase 3 Pivotal Trial
Topline Results

September 25, 2025



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ConfIdeS Topline Results Conference Call Agenda

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Introduction	**Renée Aguiar-Lucander** **CEO**
ConfIdeS Topline data	Richard Philipson CMO
Market opportunity	Maria Törnsén COO, President US
Next step Q&A and Close	Renée Aguiar-Lucander CEO

Novel, first-in-class IgG-cleaving enzyme from proprietary technology platform

What is IgG

- Immunoglobulin G (IgG): a protective antibody
- Autoimmune Disease: IgG becomes harmful and attacks the body's cells and tissues
- Gene Therapy / Transplantation: Antibodies prevent the delivery of therapy or procedure

Benefits / Opportunity of IgG Reduction

Rapid IgG reduction key to enable life saving treatments
Depletion of IgG antibodies can offer a solution for highly sensitized patient candidates for kidney transplantation

Targeted treatments enabling dosing of gene therapy for appropriate patients on label
Many late stage / commercial gene therapies are unable to provide access to all appropriate patients

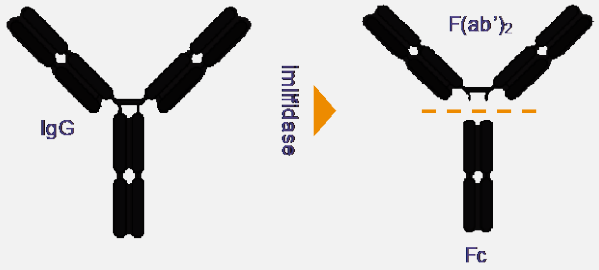
Orphan indication - Market opportunity
Significant unmet medical need for highly sensitized patients on waiting list – nothing approved today.

Hansa's IgG-cleaving Platform

Imlifidase – proprietary, first in class IgG cleaving enzyme

Rapid and targeted reduction of IgG to > 95% in 2-6 hours

Conditionally approved in EU for desensitization in kidney transplantation, with recent successful readout of US Phase 3 trial showing highly statistical significance for the primary endpoint of kidney function at 12 months.



Potential for addressing Autoimmune diseases
Anti-GBM Phase 3 readout expected Q4 2025. Potential to address IgG mediated autoimmune diseases supported by Phase 2 data. Second generation enzyme: targeting FDA meeting in Q1 2026 regarding plans for clinical development program.

Significant Unmet Medical Need

Over 800,000 people have End Stage Renal Disease (ESRD) in the US[1].

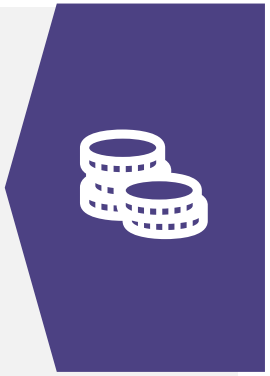
It is a medical condition in which kidneys no longer adequately filter waste products from the blood.

Kidney transplant is the treatment of choice for ESRD.

It provides higher quality of life, less societal impact, and lower mortality than chronic hemodialysis.[3]

65% of people in the US with ESRD are on dialysis.[1]

In 2020 Medicare spent over $30 billion on dialysis representing a significant cost to the US healthcare system.[2]



Every year there is a rise in adult candidates added to the kidney waitlist.

In fact, 12.4% of patients have been on the waitlist five years or longer and almost 16% have been on the waitlist for six years or more.[4]

1. Nation Institute of Health (NIH)
2. Axelrod DA, et al. An economic assessment of contemporary kidney transplant practice. Am J Transplant. 2018 May;18(5):1168-1176. doi: 10.1111/ajt.14702. Epub 2018 Mar 31. PMID: 29451350
3. Lentine et al. *Am J Transpl*. 2023 Feb; 23 (2): S1-S546
4. Kumar V et al. *Front Immunol*. 2021; 12: 1-5.

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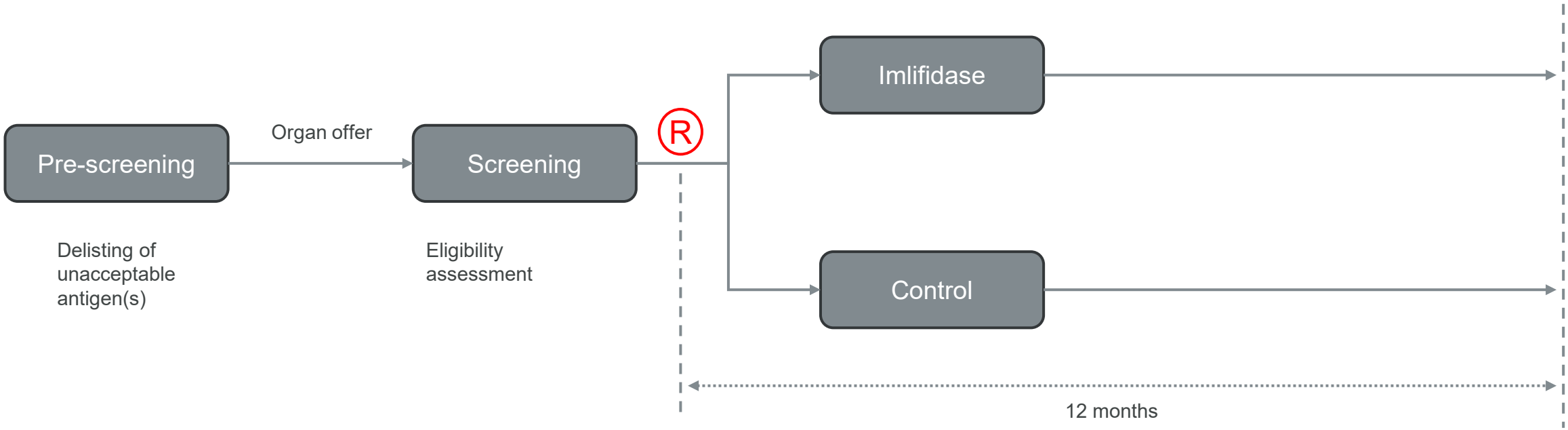
An open-label, controlled, randomized Phase 3 trial evaluating 12-month kidney function in highly sensitized (cPRA>99,9%) kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with standard of care

Renal function in highly sensitized patients 12 months after desensitization with imlifidase and transplantation of kidneys from deceased donors

Study Design

Study Design



Imlifidase arm: accept organ offer; if treatment results in xm-conversion from positive to negative, then proceed to transplant

Control arm: EITHER accept organ offer, use non-approved desensitisation* and proceed to transplant, OR reject organ offer and wait for more compatible organ offer(s) later in the 12-month follow-up period

* institution-specific desensitisation protocol may include any combination of PLEX, rituximab and other anti-CD20 antibodies, IVIg and eculizumab

Disposition & Demographics

Disposition and Demographics

Disposition n (%)	Imlifidase (N=32)	Control (N=32)	Total (N=64)
Randomized	**32 (100)**	**32 (100)**	**64 (100)**
Treated with imlifidase	**30 (93.8)**	**0 (0)**	**30 (46.9)**
Discontinued study	**2 (6.3)**	**4 (12.5)**	**6 (9.4)**
Completed study	**30 (93.8)**	**28 (87.5)**	**58 (90.6)**
Sex, n (%)			
Female	18 (56.3)	15 (46.9)	33 (51.6)
Male	14 (43.8)	17 (53.1)	31 (48.4)
Age, (years)			
Mean (SD)	45.8 (12.3)	44.7 (12.5)	45.3 (12.3)

Demographics and Baseline Characteristics

Treatment groups were balanced with respect to race and ethnicity, and representative of a highly sensitised waitlist population

Demographic	Imlifidase (N=32)	Control (N=32)	Total (N=64)
Race, n (%)			
Asian	1 (3.1)	2 (6.3)	3 (4.7)
Black or African American	16 (50.0)	14 (43.8)	30 (46.9)
White	14 (43.8)	13 (40.6)	27 (42.2)
Other	0 (0)	2 (6.3)	2 (3.1)
Mixed	1 (3.1)	1 (3.1)	2 (3.1)
Ethnicity, n (%)			
Hispanic or Latino	4 (12.5)	5 (16.1)	9 (14.3)
Not Hispanic or Latino	28 (87.5)	26 (83.9)	54 (85.7)

Analysis Sets

Analysis set n (%)	Imlifidase (N=32)	Control (N=32)	Total (N=64)	Comment
Full analysis set (FAS)	32 (100)	32 (100)	64 (100)	All patients randomised
Safety analysis set (SAF)	30 (93.8)	32 (100)	62 (96.9)	Excludes patients who did not receive randomised imlifidase treatment

Efficacy Outcomes

	Imlifidase n	Control n	Imlifidase eGFR (mean)	Control eGFR (mean)	p-value
Primary endpoint eGFR at 12 months in FAS	32	32	51.5	19.3	<0.0001
Rank-based non-parametric analysis of eGFR at 12 months	32	32	50.0*	0*	0.0001
eGFR at 12 months in patients transplanted based on organ offer at randomization	27	3	59.3	23.1	0.0138

*Median

- At 12 months, mean eGFR was 51.5 mL/min/1.73m^2 in the imlifidase arm vs 19.3 mL/min/1.73m^2 in the control arm with a statistically significant and clinically meaningful difference of 32.2 mL/min/1.73m^2 ($p<0.0001$)
- A key secondary endpoint of dialysis dependency at 12 months was statistically significant ($p=0.0007$) in favor of imlifidase

Safety Outcomes in Imlifidase-Treated Patients

- Tolerability of imlifidase was good
  - There was a low incidence of infusion reactions, and no infusions were interrupted due to an infusion reaction
- Infections observed in imlifidase-treated patients were typically not related to treatment
- The AE and SAE profile of imlifidase reflected a population of patients undergoing kidney transplantation
  - Most SAEs were considered unrelated to imlifidase treatment

Conclusions

- The treatment arms were well-balanced at baseline, and the demographic characteristics reflected a highly sensitised, dialysis-dependent population wait-listed for transplantation
- Retention in the study was excellent; 58/64 patients (90.6%) completed the study
- The primary endpoint was statistically significant and showed a clinically relevant difference
  - At 12 months, mean eGFR was 51.5 mL/min/1.73m^2 in imlifidase arm vs 19.3 mL/min/1.73m^2 in the control arm ($p<0.0001$)
- The tolerability of imlifidase was good, and the safety profile was consistent with previous clinical trial experience, reflecting a population of patients undergoing kidney transplantation

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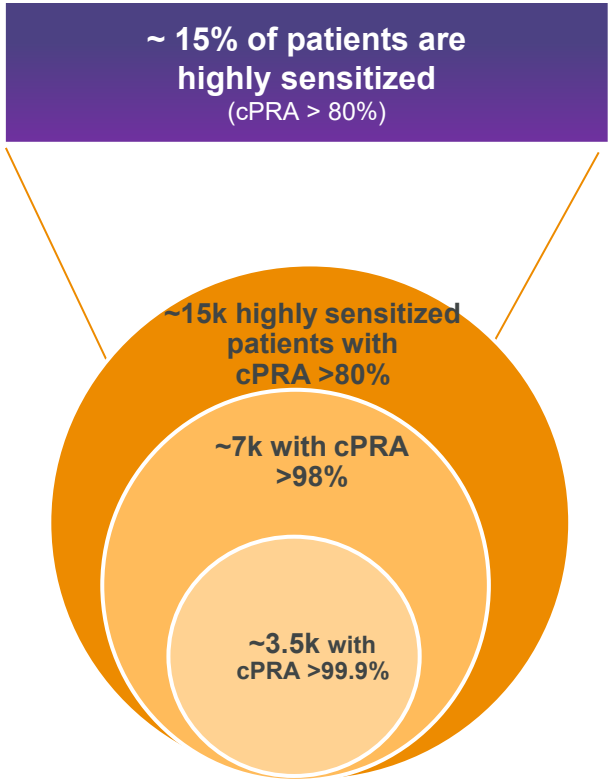
US represents a significant market opportunity

Significant Unmet Medical Need

Inability to match or effectively desensitize patients remains a barrier for transplantation in highly sensitized patients



US Transplant Waitlist

~100,000
on the wait list

~45,000
new additions to the wait list each year with highly sensitized representing 20%

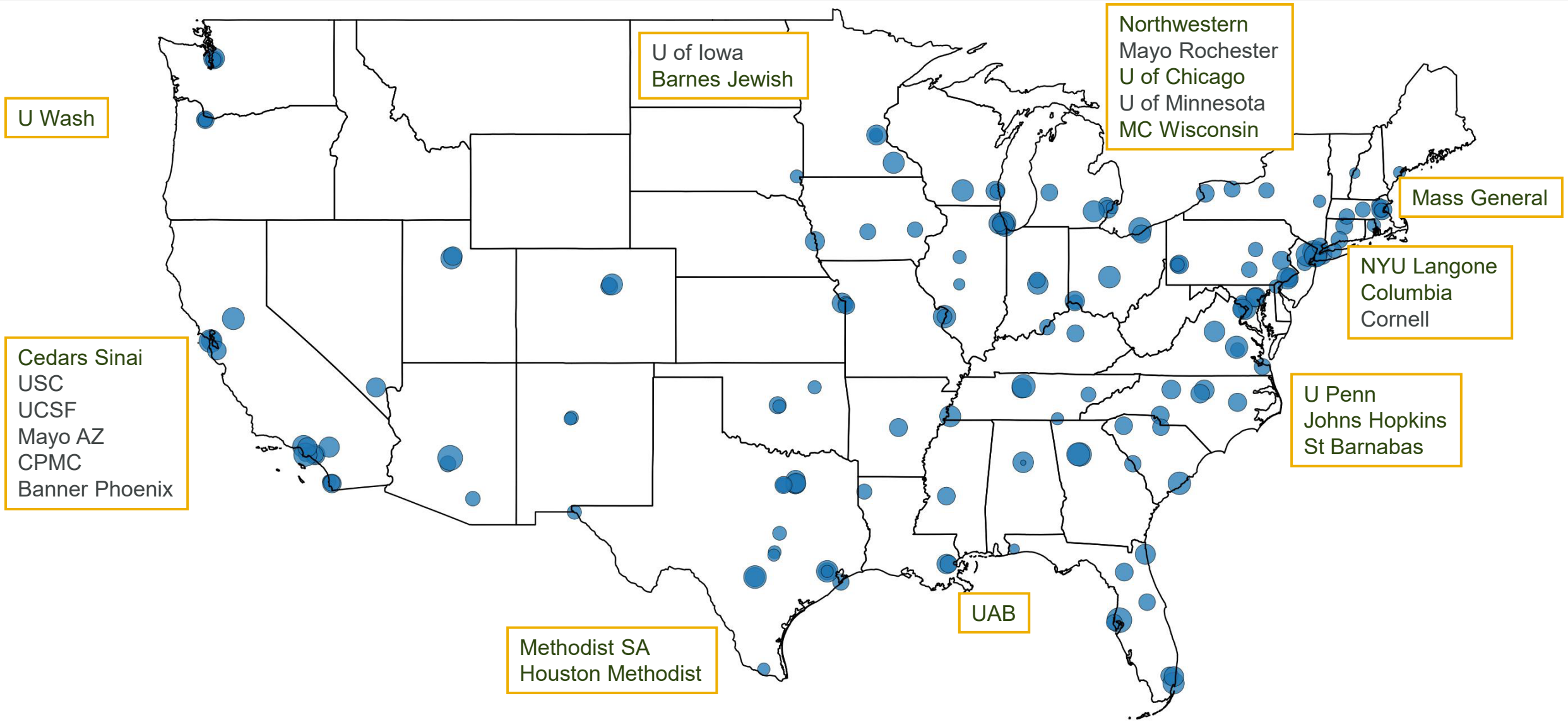
~10,000
die or become too sick to transplant, with highly sensitized representing 25%

up to 7 years
median time on waitlist for highly sensitized patients

~27,000
transplants each year with diseased donor representing 80%

Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization

The US transplant market is highly concentrated



Robust commercialization strategy established

Concentrated Market

~200 adult transplant centers

100 Centers › **~80%** of transplant volume

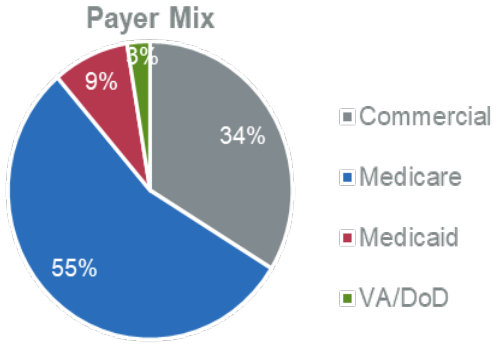
50 Centers › **~50%** of transplant volume

25 Centers in ConfIdeS › **~25%** of transplant volume

Significant clinical experience creates foundation for commercial launch

Pricing and Reimbursement

~55%
paid by Medicare



Kidney transplants are in-patient care covered by DRG codes

NTAP can be applied for in 2026; precedence exists from other new therapies

Pricing research will inform US price

Experienced US Team

Medical Affairs
Field team with multiple years in the transplant market; SVP Medical Affairs has recent nephrology launch experience

Market Access
VP Market Access with recent launch experience in nephrology and multiple other US launches

Analytical Capabilities
Inhouse expertise with recent US launch experience in nephrology

Field Team
Expect to hire a field team of ~20FTE

NTAP= New Technology Add on Payment

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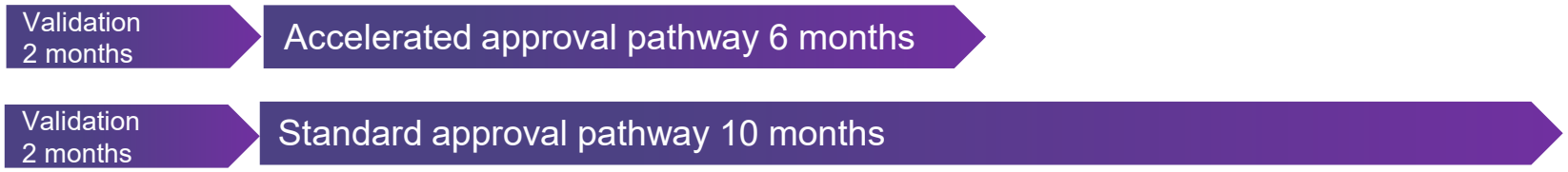
Next Steps

A Biologic License Application (BLA) under the accelerated approval pathway to the US Food and Drug Administration (FDA) remain on track



The FDA instituted its **Accelerated Approval Program** to allow **for earlier approval** of **drugs that treat serious conditions**, and **fill an unmet medical need based on a surrogate endpoint**.

Filing targeted for end of 2025 with the division of Rheumatology and Transplant medicine under CDER.

Targeting disclosure of additional Phase 3 results at the American Transplant Congress (ATC) in June 2026.

Q&A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