HANSA BIOPHARMA

KOL event with Citibank

San Francisco, September 12 , 2019

Forward-looking statement

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Hansa Biopharma's business, financial condition and results of operations. The terms "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 statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of Hansa Biopharma's strategy and its ability to further grow, risks associated with the development and/or approval of Hansa Biopharma's products candidates, ongoing clinical trials and expected trial results, the ability to commercialize imlifidase, 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.

No assurance can be given that such expectations will prove to have been correct. Hansa Biopharma disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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Today's agenda and presentations

Program

12:05pm	Welcome and short introduction
12:10pm	Business Update by Sören Tulstrup, President & CEO
12:30pm	Q&A/Break
12:35pm	Insights Medical Affairs by Vincenza Nigro, VP Medical Affairs
01:00pm	Q&A/Break
01:05pm	KOL presentation by Dr. Jordan and Dr. Huang, Cedar Sinai, LA Imlifidase for Deceased Donor Kidney Transplantation: The Cedars-Sinai Experience
01:40pm	Q&A
02:00pm	End of event

Business Update

by Sören Tulstrup, President & CEO

Continued progress on strategic agenda; Imlifidase highlighted at ATC

Highlights for the second quarter 2019

- Good progress on strategic agenda
  - Guillain Barré Syndrome (GBS) study started - expansion outside transplantation and into auto-immune diseases continues
  - Divestment of equity holding in Genovis
  - Advancement across pipeline
  - Expanding our presence in Europe and the U.S
- High level of excitement at the 2019 American Transplant Congress, with imlifidase highlighted in three presentations. Plenary abstract by Dr. Huang won the “People’s Choice Award”
- Advancing imlifidase toward commercialization for kidney transplantation in highly sensitized patients. MAA under review by EMA; complementary analysis being conducted in the U.S.
- All resolutions were passed at the AGM 2019
- Cash position stood at SEK 763m (~USD 80m) end of June 2019

Continued advancement toward commercialization

Imlifidase in kidney transplantation

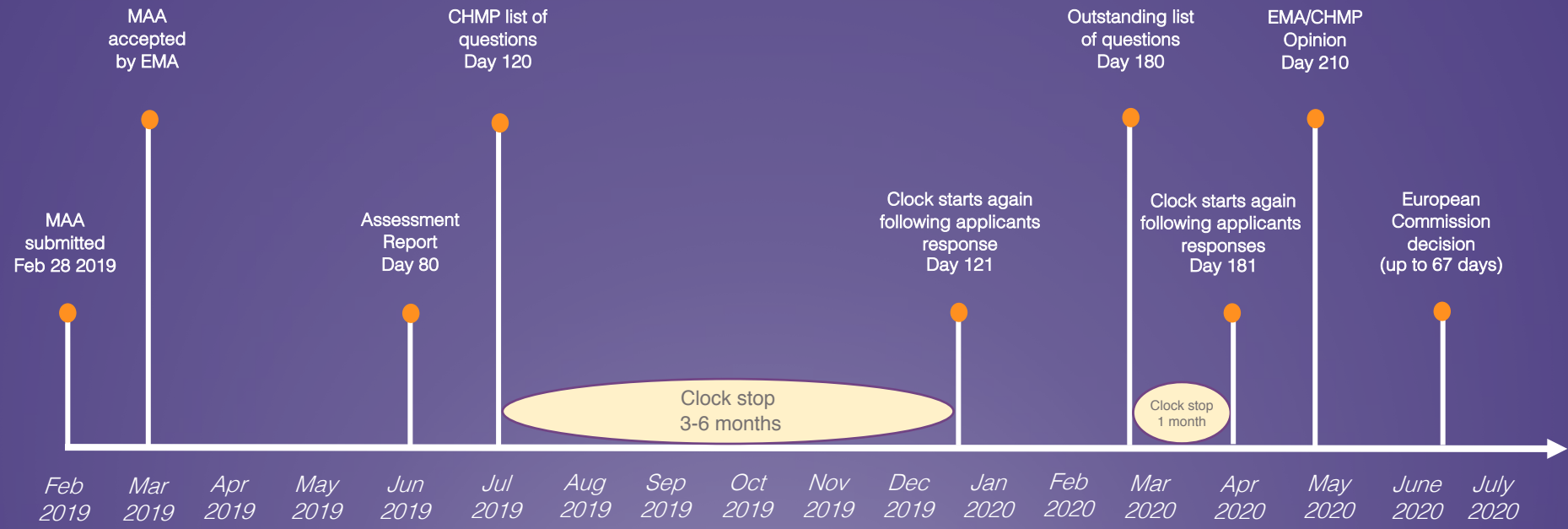
Europe (EMA)

- MAA for imlifidase accepted end of Feb'19; regulatory review progressing
- Opinion from EMA expected within 210 working days, plus clock stops

U.S. (FDA)

- Conducting complementary transplantability analyses comparing imlifidase-treated patients and matched controls from U.S. transplant registry
- Upon completion of analyses, Hansa to request FDA meeting to determine U.S. regulatory path forward. Meeting expected in H2'19
- U.S. administration announced initiatives to increase transplant rate and quality of life for dialysis patients and also reduce expenditure to treat chronic and end-stage renal disease

EMA – The process towards approval



EMA/CHMP Assessment

- Evaluation of benefit and risks
- Assessment of Risk Management Plan
- Assessment of product information
- Assessment on need for post safety/efficacy studies
- Preparation of Risk Management Plan Summary

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Anti-GBM enrolling; AMR & GBS receives CTA approval. NiceR lead candidate selected

Advancement across our pipeline

Anti-Glomerular Basement Membrane Disease (Anti-GBM)

- 11 patients enrolled out of targeted 15. Adding more sites and expect the study to be fully enrolled by year-end

Antibody Mediated Rejection (AMR) in kidney transplant

- Phase 2 study with imlifidase in AMR received CTA approval in March'19. Recruitment of up to 30 patients initiated from eight sites in the U.S., Europe and Australia.
- Study is a randomized, open-label multi-center, active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in acute AMR

Guillain-Barré Syndrome (GBS)

- Phase 2 study with imlifidase in GBS received CTA in April'19

NiceR

- Lead candidate selected in next-generation program for repeat dosing
- Development of a GMP process initiated; preparations for toxicology studies are ongoing

New GBS study marks continued expansion outside transplantation

Initiation of GBS Phase 2 study in Europe

- Guillain Barré Syndrome (GBS) is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system affecting 1-2 in 100,000 people annually
- CTA approval obtained for Phase 2 study in GBS in April
- Recruitment of up to 30 patients initiated at ten clinics in France, U.K. and the Netherlands.
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS
- In 2018, the FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS

Broad pipeline in transplantation and auto-immune diseases

Candidate / Projecting	Indication	Research/ Preclinical	Phase 1[1]	Pivotal program/ Phase 2[2]	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	Kidney transplantation in highly sensitized patients				*)		MAA review by EMA Follow-up meeting with FDA
	Anti-GBM antibody disease						Complete enrolment
	Antibody mediated kidney transplant rejection (AMR)						Complete enrolment
	Guillain-Barré syndrome						Complete enrolment
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy						Research phase

Completed Ongoing

[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)

*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2. A confirmatory study would need to be executed in case of approval.

FDA: Discussion on path forward in the US is still ongoing.

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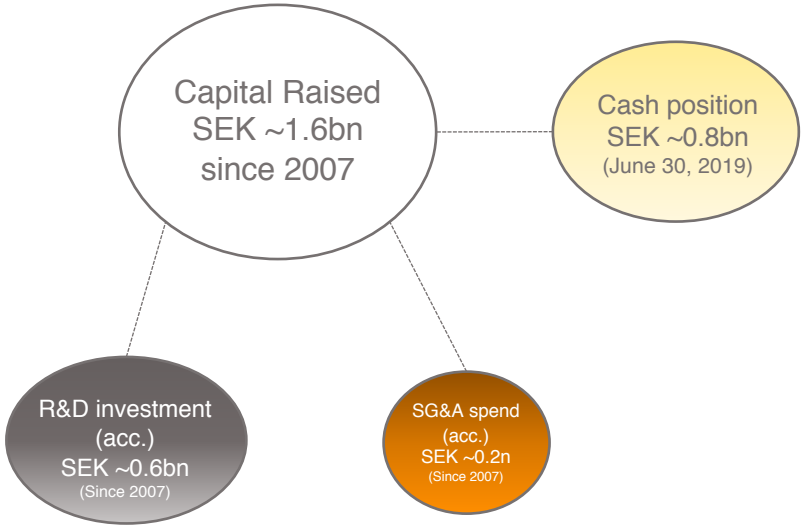
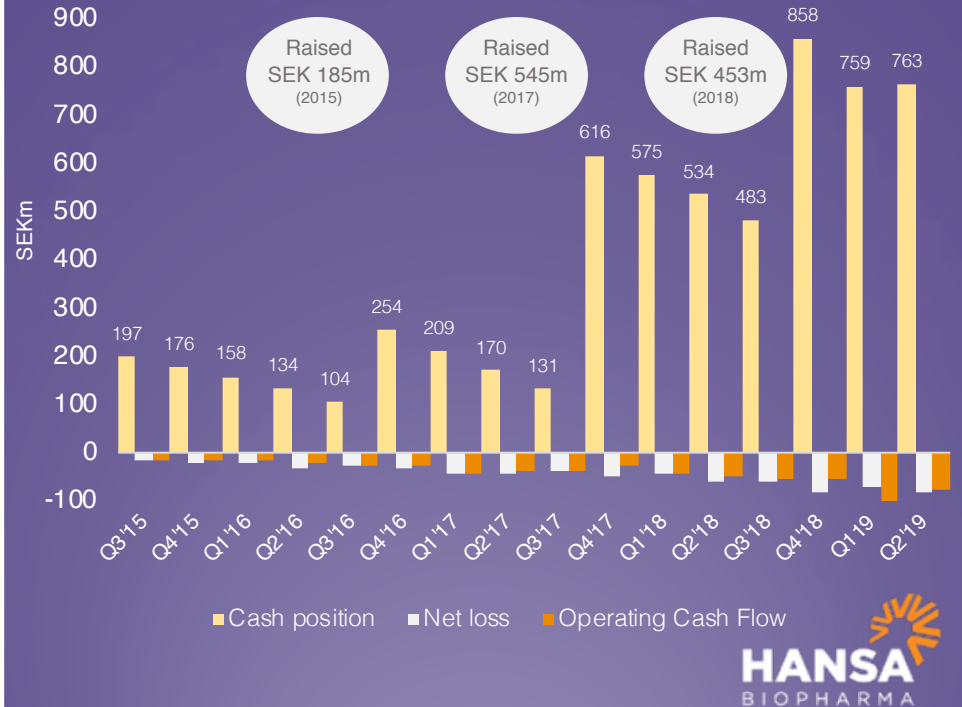
Hansa Biopharma is financed through 2020

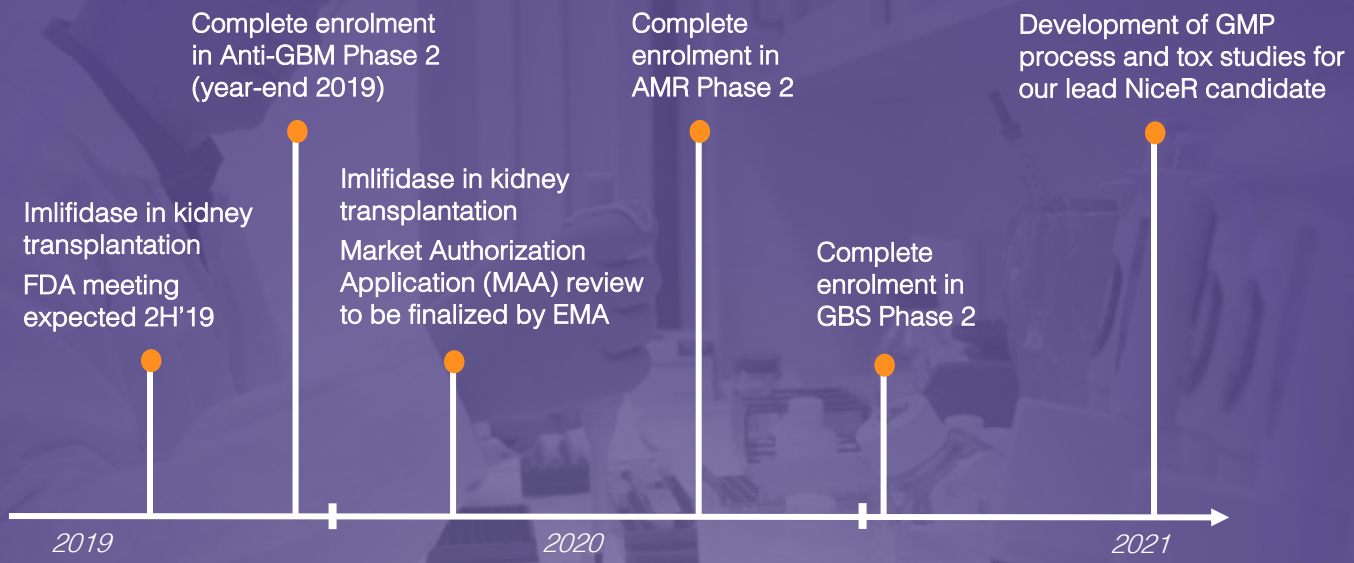
Significant capital raised since 2007



Solid cash position end of first half 2019



Milestones and near-term news flow

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Insights Medical Affairs

by Vincenza Nigro, VP Medical Affairs

Overview of the Landscape and Medical Affairs Focus

- **The growing problem** – Highly sensitized patients have extended organ wait times, which increases the risk of morbidity and mortality while on the waitlist
- **Allocation system have prioritized highly sensitized patients** – Some improvements in access but lengthy wait times and low transplant rates persist for some patients
- **Current methods of desensitization** – No FDA-approved desensitization options
- **Approach in DD setting** –Presents an opportunity to help standardize protocols and address the critical need for methods that are reliable and can be smoothly integrated into clinical practice in the Deceased Donor setting
- **Focus** – Guiding medically appropriate use of imlifidase in the transplant setting with a focus on “highly unlikely to be transplanted” (HUT) patients

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Opportunity

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Major challenge in kidney transplantation

- For patients with End Stage Renal Disease (ESRD), kidney transplant offers significant survival and quality-of-life advantages compared with dialysis[1-3]
- Approximately 1/3 of patients waiting for kidney transplantation are sensitized to donor tissues[6]
- 13% - 15% of patients on the transplantation waiting-list have been reported to be highly sensitized and is one of the biggest barrier to transplantation[4,5,7]

[a]Highly sensitized is defined as calculated PRA (cPRA) of at least 80%[7]

1. Orandi BJ, et al. *NEJM*. 2016;374:940-950. 2. Vo AA, et al. *Transplantation.* 2013;95:852-858. 3. Montgomery RA, et al. *N Engl J Med*. 2011;364:318-326. 4. Hansa Biopharma. Data on file 2019. 5. OPTN database. https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/#. Accessed 9.6.2019. 6. Iyer, H. S., et al. *Curr Opin Nephrol Hypertens.* 2013;22: 681-8. 7. Hart, A., et al. *Am J Transplant*, 2018; 18 Suppl 1: 18-113

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Why are DSAs a Problem?

- The presence of donor-specific anti-HLA antibodies (DSAs) and a positive cross match can be considered a contraindication to transplantation[1,2]

- Unapproved and lengthy resource intensive methods to desensitize patients[3]

Highly sensitized patients have extended waiting times for transplantation and are less likely to receive a transplant[4]

Increased waiting times are associated with higher morbidity and death[5]

1. Montgomery, R. A., and A. A. Zachary. *Pediatr Transplant. 2004;*8: 535-42. 2. Terasaki, P. I., and M. Ozawa. *Transplantation. 2005;*80: 1194-7. 3. Lipshutz GS et al. *JAMA Surgery*. 2011;146:453-458. 4. Stegall MD. Therapeutic options for sensitized patients in the era of KPD and KAS. ATC 2019 presentation. 5. Jackson KR, et al. *Am J Transplant*. 2019;19:1129-1138.

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In the US, changes in kidney allocation systems have facilitated access to transplantation for highly sensitized patients

- Transplantation rates of highly-sensitized candidates has improved with KAS, but not all have benefited[1]
- More than half (54%) of patients with cPRA >99.9% remain on kidney transplant lists for more than 5 years[1]
- Waitlisted patients with cPRA 100% were 2.2 times as likely to die or remain on the waiting list than receive a transplant in the post-KAS era[2]

1. Stegall MD. Therapeutic options for sensitized patients in the era of KPD and KAS. ATC 2019 presentation.
2. Schinstock C, Smith B, Bentall A, Stegall M. Presented at ATC 2018, Abs # B102.

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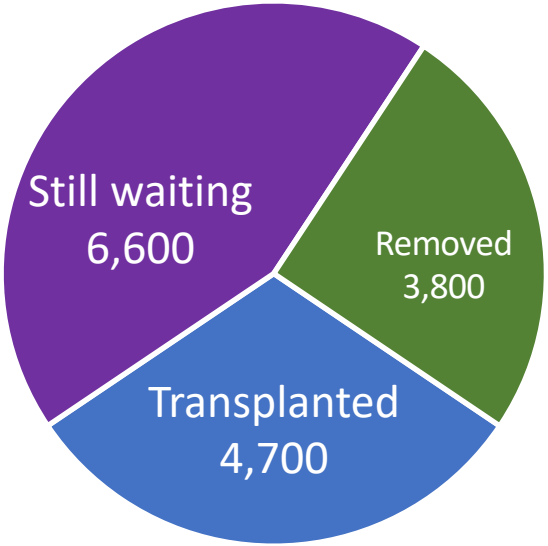
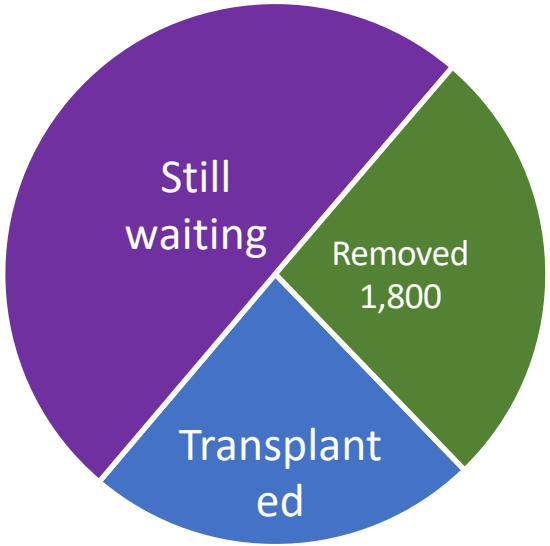
Hansa Unmet Need Focus: Highly Unlikely to be Transplanted (HUT) Patients

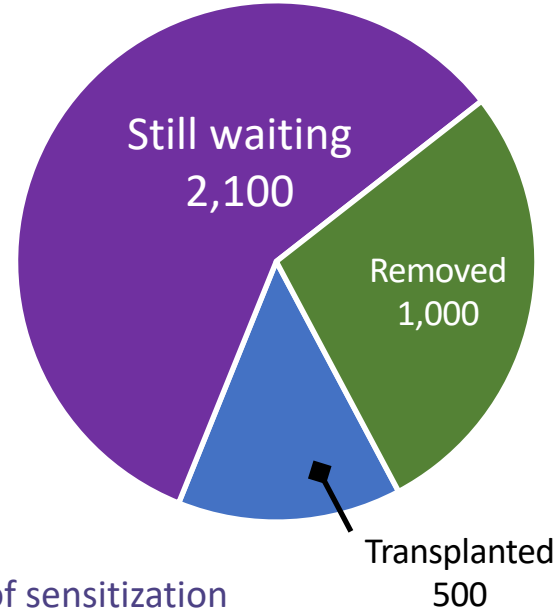
cPRA ≥95.0%
Total: 15,100



cPRA ≥99.5%
Total: 6,790



cPRA ≥99.9%
Total: 3,700



- Chances of receiving a transplant decreases with increasing levels of sensitization
- Patients with high immunologic risk are transplanted less frequently, with higher rates of removal from waitlist

US transplantation data. Based on UNOS database in the OPTN from 2010-2016.

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In EU, changes in kidney allocation systems have facilitated access to transplantation for highly sensitized patients

- Special allocation programs in Europe for HS patients:
  - Acceptable mismatch (AM) programs, allow for greater numbers of successful compatible transplants, compared with standard kidney allocation procedures[1]
  - Each allocation program has its own unique algorithm for prioritization

For example, in the UK –Median time to transplant for adult patients[2]

2½ years

Calculated Reaction Frequency	Number of patients registered	Waiting time (days) Median	95% CI
0-84%	7917	963	942 - 984
85-94%	344	1577	1487 - 1667
95-99%	377	2138	1870 – 2406
100%	164	2424	2072 – 2776
TOTAL	**8802**	**1016**	**995 - 1037**

6½ years

Country-specific programs prioritize highly sensitized patients, however highly sensitized patients still experience significantly longer waiting time

1. Heidt S, et al. *Am J Transplant*. 2019 Jun 2. doi: 10.1111/ajt.15486. [Epub ahead of print]. 2. NHS 2015 Kidney Allocation Task Force HLA Working Group slide presentation. http://slideplayer.com/slide/13542562/. Accessed 9.9.2019.

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Approach to Managing Desensitization Highly Sensitized Patients Vary Greatly - No Approved Standard

Intensity of desensitization regimen varies

Survey of physicians at 11 high-volume transplant centers

More intense

Desensitization regimens
Posttransplant induction only (Rabbit ATG + RTX)
Posttransplant IVIG + RTX only
Pretransplant IVIG + RTX—one round (Either low- or high-dose IVIG)
Pretransplant PLEX + IVIG followed by RTX— Several rounds depending on strength of DSA

"With regard to desensitization – "we've come a long way, but we haven't gotten very far"

- Intensity of desensitization depends on the magnitude of incompatibility between the donor organ and recipient
- Require weeks of treatment, limiting its use when awaiting a deceased donor kidney

Hansa Biopharma. Data on file 2019.

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Imlifidase MOA and Pooled Transplanted Patients Across Phase 2 Trials

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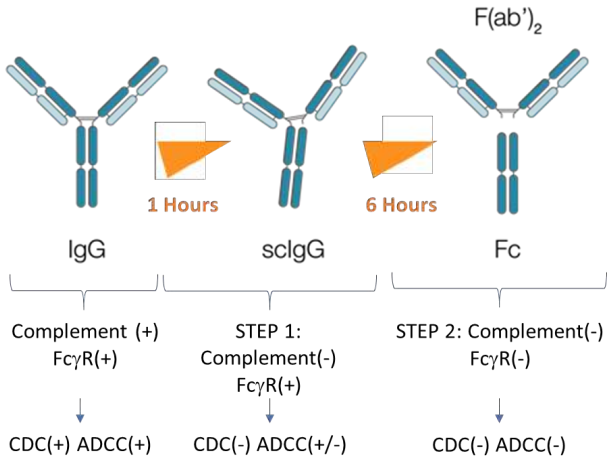
Imlifidase Mechanism of Action

- Imlifidase, an investigational enzyme that inhibits the IgG-mediated immune response by specifically and rapidly cleaving IgG antibodies, is given just prior to transplantation[1,2]

Imlifidase cleaves IgG in a 2-step process[1,2]



1. Winstedt L, el al. *PLOS ONE.* 2015;10(7):e0132011. doi:10.1371/journal.pone.0132011. 2. Ryan MF, et al. *Mol Immunol*. 2008;45:1837-1846.
3. Hansa Biopharma. Draft SMPC 2019. 4. Jordan SC, et al. *New Engl J Med*. 2017;377:442-453

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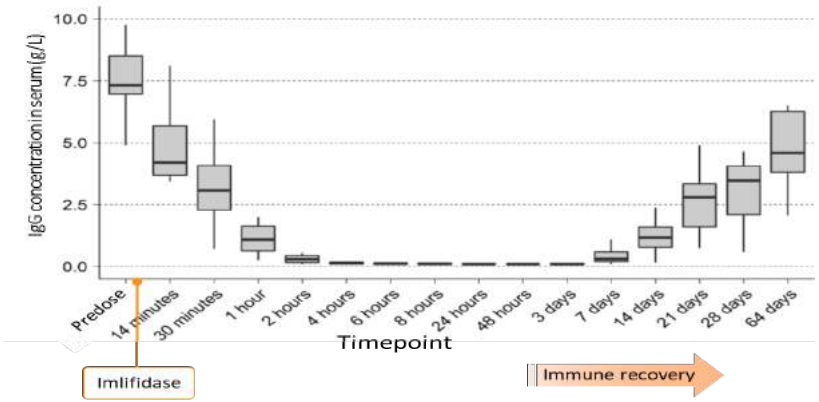
Imlifidase Mechanism of Action (continued)

- Complete inactivation of IgG occurs between 2-6 hours[1,2]
- IgG immune recovery begins within 7 days post-dose[3,4]

Predictable time course of IgG inactivation and recovery in highly-sensitized patients[3]



1. Winstedt L, el al. *PLOS ONE.* 2015;10(7):e0132011. doi:10.1371/journal.pone.0132011. 2. Ryan MF, et al. *Mol Immunol*. 2008;45:1837-1846.
3. Hansa Biopharma. Draft SMPC 2019. 4. Jordan SC, et al. *New Engl J Med*. 2017;377:442-453

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Patient and Graft Survival following Imlifidase of Pooled Transplanted Patients to be Presented at ESOT

	All patients (n=46)
6-month Graft Survival	93.5%
6-month Patient Survival	100%

At 6 months, all patients were alive; graft survival was 93% (43/46); three patients experienced graft loss unrelated to imlifidase.

2 grafts lost due to primary nonfunction
1 graft lost due to non-IgG mediated hyperacute rejection

1. Winstedt L, et al. Presented at ESOT 2019. Copenhagen

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Transplant Community Engagement

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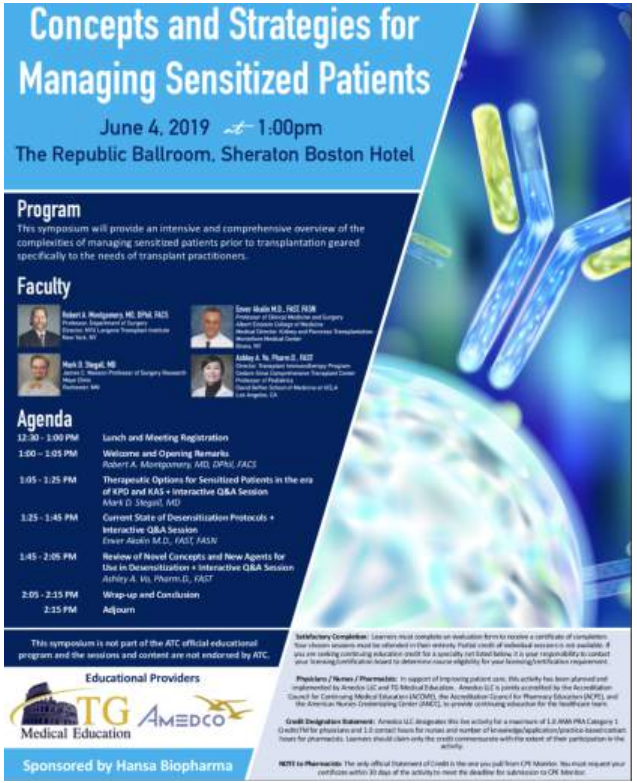
Hansa Biopharma Engaged with the Transplant Community



Dr. Huang, ATC's 2019 People's Choice Award Winner, received the highest ratings and accolades as the most impactful plenary for "Three-year Outcomes of the Highly Sensitized Kidney Transplant Recipients Desensitized with Imlifidase"

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Advisory Boards Steering Committee

Stanley C. Jordan, MD
Cedars-Sinai Medical
Center
Los Angeles, CA

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Director, Professor of Surgery
NYU Langone Transplant Institute
New York, NY

Kathryn J. Wood, DPhil
Emeritus Professor of Immunology
Nuffield Department of Surgical Sciences
University of Oxford
Oxford, England

Christophe Legendre, MD
Professor of Nephrology – Paris Descartes University
Head of Adult Nephrology and Transplantation Unit
Necker Hospital
Paris, France

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Insights from Advisors on Desensitization and HUT Target Population

- Patient segment with the highest unmet need are those with the lowest probability of receiving an organ offer; in the US this includes patients with cPRA >99.5%
- There may be an opportunity to help standardize protocols and streamline decision-making
- Critical need for desensitization methods that are reliable and can be smoothly integrated into clinical practice
- Opportunity to define how imlifidase can complement the KAS system to broaden organ access for highly sensitized patients, particularly for those with cPRA ≥99%

"These patients deserve a transplant"

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Medical Affairs Focus

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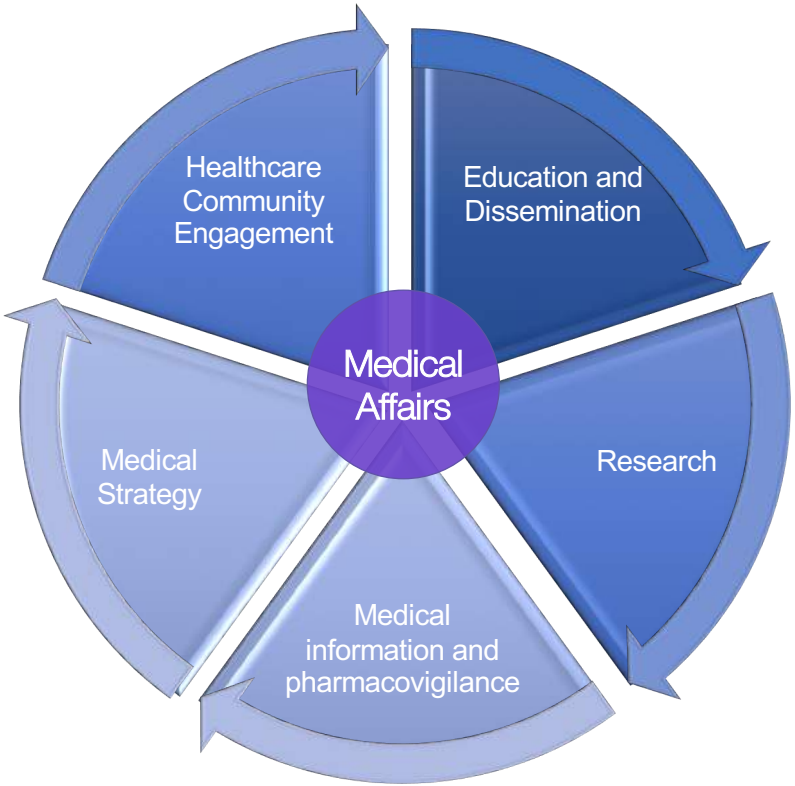
Introducing Medical Affairs



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Global Approach to Medical Affairs

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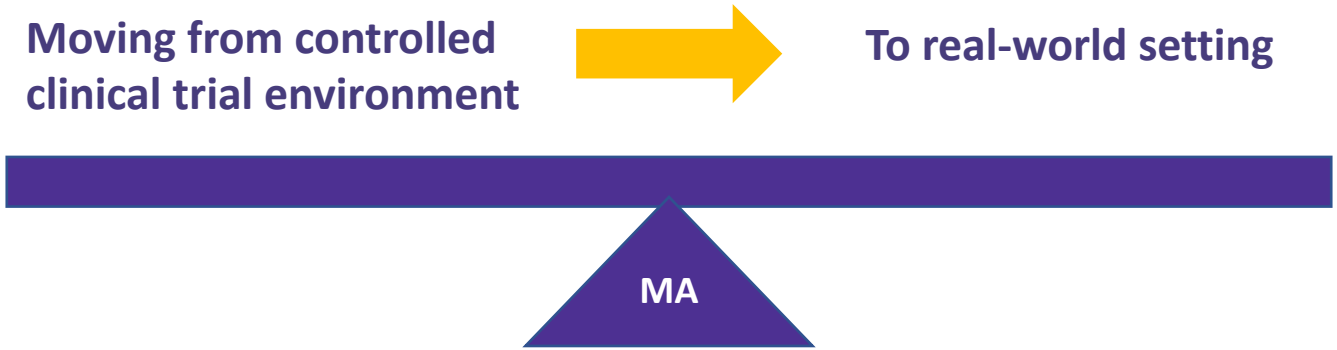
Medical Affairs Strategy:
Guide Medically Appropriate Use of Imlifidase



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MEDICAL AFFAIRS

Advance Desensitization in Kidney Transplantation

Medical Affairs Launch

MEDICAL AFFAIRS INITIATIVES

1. Understand Current Thinking
2. Community Engagement
3. Shape Practice
4. Launch Readiness

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Thank you!

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Imlifidase for Deceased Donor Kidney Transplantation: The Cedars-Sinai Experience

Dr. Edmund Huang,
M.D. FAST, Associate Professor of Medicine
Cedars-Sinai Medical Center
David Geffen School of Medicine, UCLA

Dr. Stanley Jordan,
M.D. Director Kidney Transplantation and Transplant Immunology at the Cedars-Sinai Medical Center in Los Angeles

Due to ATC rules the presentation from Dr. Edmund Huang and Dr. Jordan can be downloaded on the ATC website

https://atcmeeting.org/atc-ondemand

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