HANSA BIOPHARMA

Redeye Theme: Autoimmune and inflammatory disease

October 3, 2023

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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

A successful track record and a promising future…

A validated technology

- Commercial stage biotech company
- Approval in kidney transplantation (EU)
- Market Access in 13 European markets
- PoC in autoimmune diseases
- Three partnerships in gene therapy

Broad clinical pipeline

- Imlifidase being investigated in seven ongoing clinical programs in transplantation and autoimmune disease
- Planned clinical study in gene therapy
- Next generation IgG antibody-cleaving enzymes program in phase 1

Skilled and experienced team

- A high-performance organization with 20 years on average in life science
- Purpose driven culture
- Headquartered in Lund, Sweden with 162 employees (June 2023)
- Operations in both EU and the US

Financial position

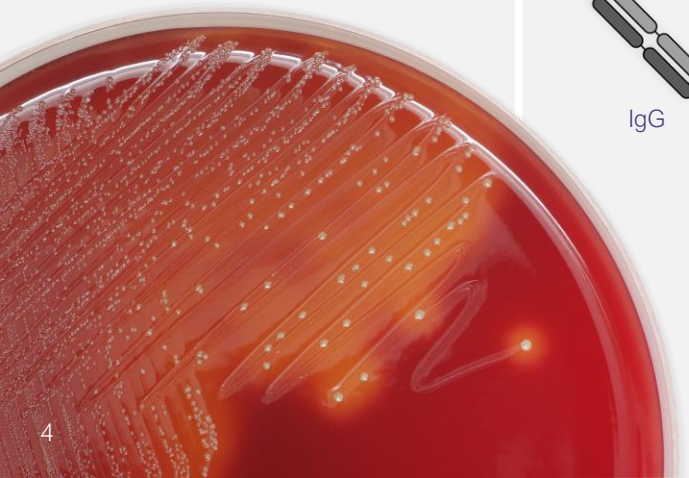
- Hansa is financed into 2025
- Market cap (USD): ~180m (Sep. 2023)
- Listed on Nasdaq Stockholm
- 20,000 shareholders
- Foreign ownership make up ~43%

Imlifidase

a novel approach to eliminate pathogenic IgG

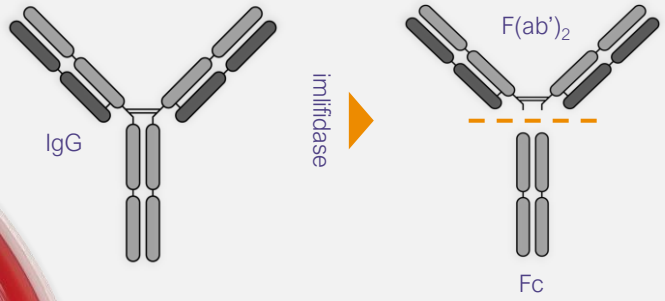
Origins from a bacteria *Streptococcus pyogenes*

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



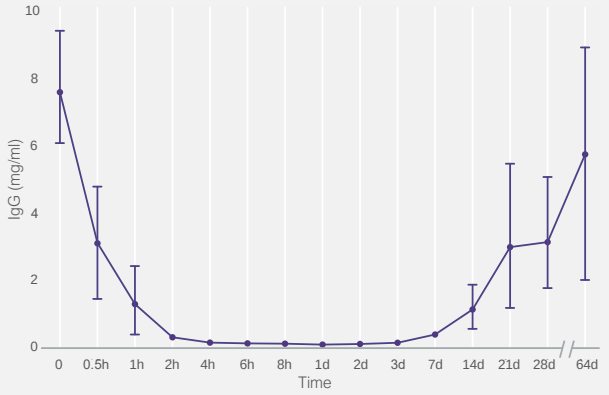
A unique IgG antibody-cleaving enzyme

- 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



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

Targeting rare IgG mediated diseases

Auto-immune diseases

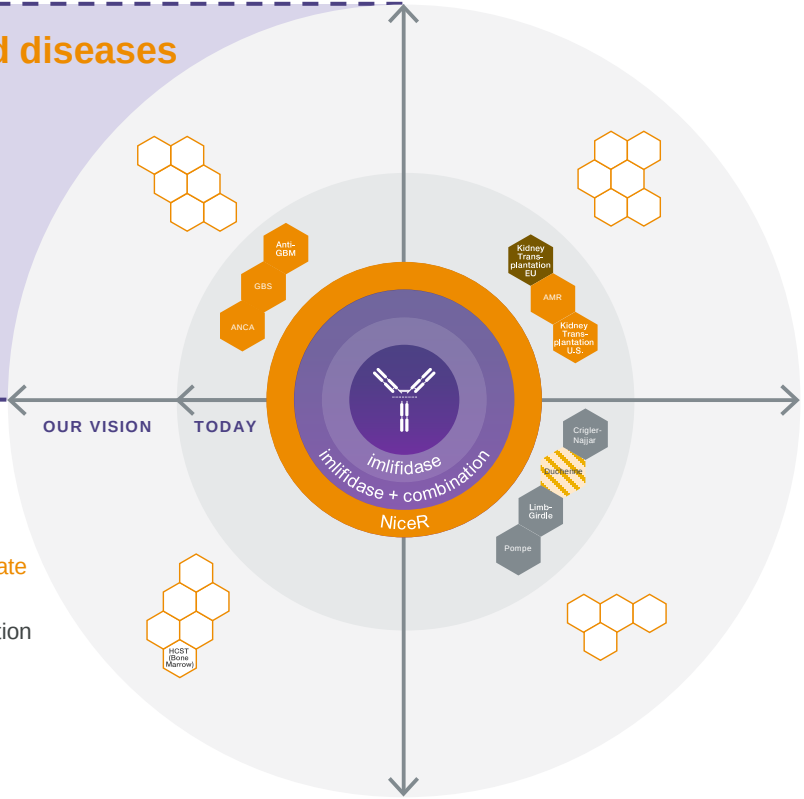
Anti-GBM disease paves the way for development in other autoimmune diseases

- Rapidly progressive glomerulonephritis
- Neurological disorders
- Skin and blood disorders

New therapies and oncology

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogenic stem cell (bone marrow) transplantation (HSCT)



Transplantation

Shaping a new standard for desensitization will help enable new indications in transplantations

- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types

Gene therapy

Exploring opportunities in gene therapy

- Encouraging preclinical data published in Nature
- Validation through collaborations with Sarepta, AskBio, and Genethon
- Wide indication landscape beyond

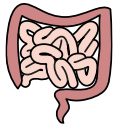
Regulatory approval (conditional) | Clinical development | Planned clinical trial | Partnership (preclinical development) | Preclinical development | Potential indications (currently not pursued)

Autoimmune attacks

A result of when the body's immune system by mistake damages its own tissue

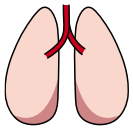
Blood
Autoimmune hemolytic anemia,
Immune thrombocytopenia

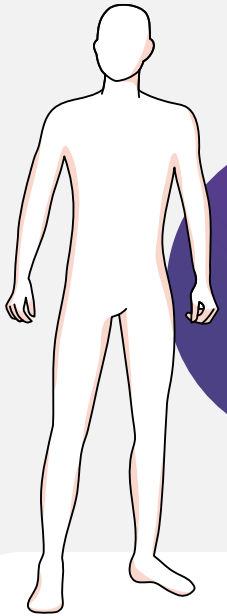
GI tract
Crohn's disease



Nerves
Guillain-Barré syndrome,
Myasthenia gravis

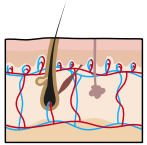
Lung
Wegner's granulomatosis





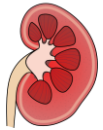
Over 100 different types of Autoimmune disorders

Skin
Psoriasis, Pemphigus

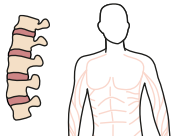


Brain
Multiple sclerosis,
Neuromyelitis optica

Thyroid
Hashimoto's disease,
Graves' disease



Kidney
Anti-GBM disease



Bone and muscle
Rheumatoid arthritis,
Dermatomyositis+ 32

Hansa's antibody cleaving enzyme technology

may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

Rapidly progressive glomerulonephritis

~1 000 patients*[1]

- Anti-GBM
- Lupus nephritis ~35 000*[2]
- ANCA-associated vasculitis ~325 000*[3]

Neurological disorders

- Myasthenia gravis ~210 000*[4]
- NMO ~20 000*[7]
- CIDP ~55 000*[6]
- GBS

~10 000 patients*[5]

Skin disorders

<1 000 patients*[8]

- EBA
- Pemphigus vulgaris ~40 000*[9]

Blood disorders

~1 000* patients[13]

- AHA
- WAHA ~95 000*[11]
- APS ~350 000*[12]
- HIT 0.1–5% of patients receiving therapeutic dose of heparin[14]
- ITP ~75 000*[10]

■ Clinical programs

□ Potential autoimmune indications (currently not pursued)

*Total disease populations in EU & US, based on prevalence and population data

CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy
NMO: Neuromyelitis optica
EBA: Epidermolysis bullosa acquisita
ITP: Immune thrombocytopenia
WAHA: Warm antibody hemolytic anemia
APS: Antiphospholipid syndrome
AHA: acquired hemophilia A
HIT: Heparin-induced thrombocytopenia

[1]DeVrieze, B.W. and Hurley, J.A. *Goodpasture Syndrome*. StatPearls Publishing, Jan 2021. https://www.ncbi.nlm.nih.gov/books/NBK459291/ [accessed 2021-03-29]
[2]Patel, M et al. *The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK.* Arthritis & Rheumatism, 2006.
[3]Berti A, Cornec D, Crowson CS, Specks U, Matteson EL. *The Epidemiology of ANCA Associated Vasculitis in the U.S.: A 20 Year Population Based Study*. Arthritis Rheumatol. 2017;69.
[4]*Myasthenia Gravis.* National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/myasthenia-gravis/ [accessed 2021-03-29]
[5]*Guillain-Barré syndrome.* Orpha.net, https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Lng=GB&Expert=2103 [accessed 2021-03-29]
[6]*Chronic Inflammatory Demyelinating Polyneuropathy: Considerations for Diagnosis, Management, and Population Health.* The American Journal of Managed Care, https://www.ajmc.com/view/chronic-infammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health [accessed 2021-03-29]
[7]Marrie, R.A. *The Incidence and Prevalence of Neuromyelitis Optica.* International Journal of MS Care, 2013 Fall: 113-118
[8]Mehren, C.R. and Gniadecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011-10-05
[9]Wertenteil, S. et al. Prevalence *Estimates for Pemphigus in the United States.* JAMA Dermatol, May 2019: 627-629.
[10]*Immune Thrombocytopenia.* National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/immune-thrombocytopenia// [accessed 2021-03-29]
[11]*Warm Autoimmune Hemolytic Anemia.* National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/ [accessed 2021-03-29]
[12]Litvinova, E. et al. *Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria*. Frontiers in Immunology, 2018-12-14.
[13]NORD, Acquired Hemophilia [accessed 2022-10-17], available at https://rarediseases.org/rare-diseases/acquired-hemophilia/
[14]Hogan M, Berger JS. Heparin-induced thrombocytopenia (HIT): Review of incidence, diagnosis, and management. Vascular Medicine. 2020;25(2):160-173. doi:10.1177/1358863X19898253

Anti-GBM, a rare acute autoimmune disease

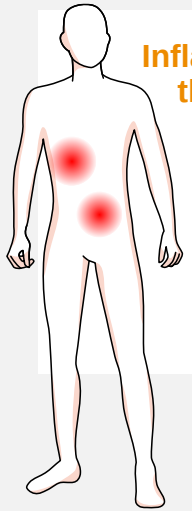
Incidences

1.6

in a million affected annually[1,2]

Standard of Care

- Plasma Exchange
- Cyclophosphamide (CYC)
- Glucocorticoids



Inflammation in the glomeruli

Early symptoms are unspecific…

…but can lead to rapid destruction of the kidney and/or the lung

Data published in JASN

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

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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 of 15) were dialysis independent. This is significantly higher compared with 18% (nine out of 50) in a historical control cohort (PolSKAN, Fisher's exact test). Eight serious adverse events (including one death) were reported, none assessed as probably or possibly related to the study drug.

Conclusions In this pilot study, the use of imlifidase was associated with a better outcome compared with earlier publications, without major safety issues, but the findings need to be confirmed in a randomized controlled trial.

Clinical Trial registration number: EUDRACT 2016-004082-39 https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-001377-28/results

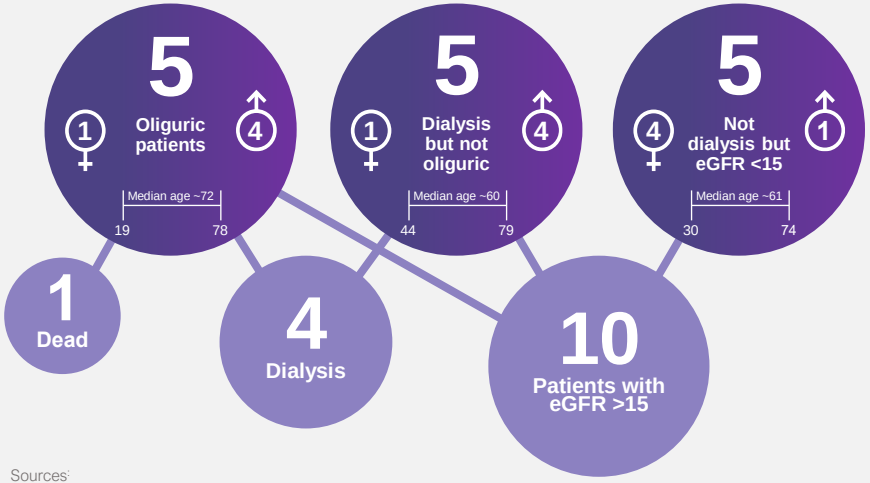
JASN 33: xxx–xxx, 2022 doi: https://doi.org/10.1681/ASN.2021111460

Kidney survival is poor in patients presenting with circulating anti-glomerular basement membrane (anti-GBM) antibodies and advanced kidney failure.[1,2] Most patients…

Received November 12, 2021. Accepted February 1, 2022

Results from Phase 2 study of imlifidase in anti-GBM disease published in Journal of American Society of Nephrology (JASN)[3]

10 out of 15 patients were dialysis independent after six months vs. the historical cohort[4], where only 18% had functioning kidney



Sources:

[1] Wang et al., J. Intern. Med., 2015
[2] Desai et al., Front. Endocrinol., 2019
[3] Uhlin et al. JASN (2022)
[4] 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

New pivotal phase 3 trial with imlifidase in 50 anti-GBM patients to evaluate kidney function after six months

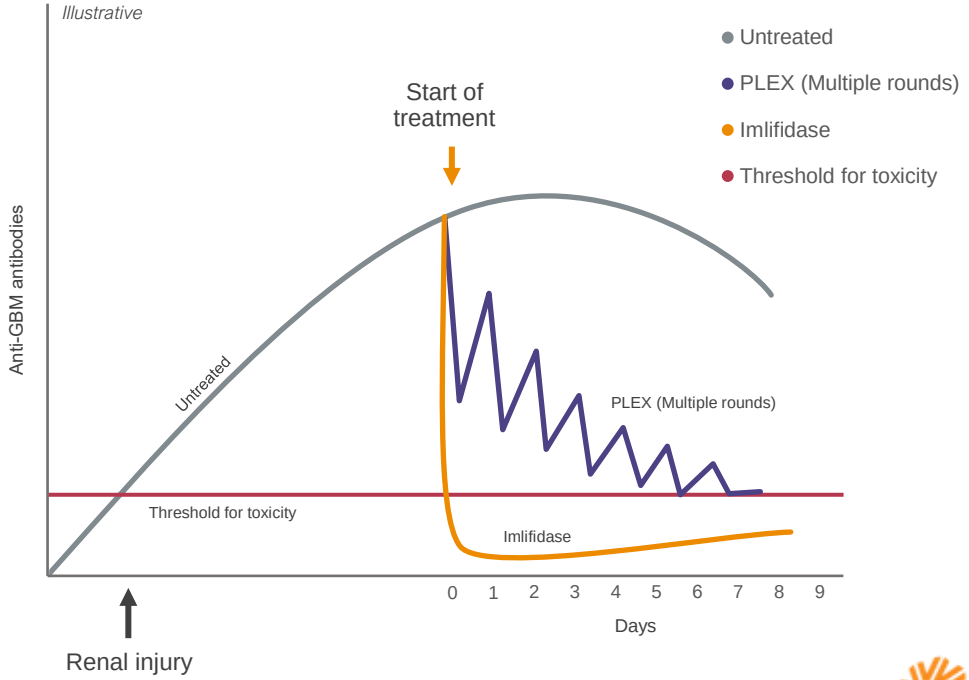
Study Design
- Open-label, controlled, randomised, multi-centre Phase 3 trial evaluating renal function in patients with severe anti-GBM disease imlifidase + SoC vs. SoC

Subjects
- 50 anti-GBM patients to be enrolled
- Patients will be followed for six months
- Recruitment at 30-40 clinics across US/UK/EU

Doses/Follow up time
- Dosage 0.25 mg/kg with 180 days follow up

Main Objectives
- Renal function is evaluated by estimated glomerular filtration rate (eGFR) at 6 months
- Dialysis need at 6 months

Status
- First patients enrolled in May 2023



1 Wang et al., J. Intern. Med., 2015
2 Desai et al., Front. Endocrinol., 2019

Guillain-Barré Syndrome (GBS) is an aggressive acute autoimmune attack on the peripheral nervous system

Incidences

1-2

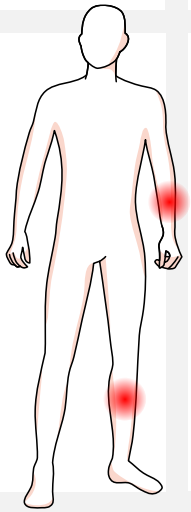
in 100,000 annually in 7 major markets

Standard of Care

- Intravenous immune globulin (IVIG) or
- Plasma Exchange (PLEX)

Indication

- Rapidly and progressively weakens extremities
- Triggered frequently by viral infections



High unmet need

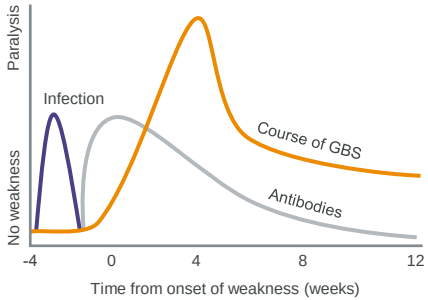
- 1/3 of hospitalized patients require mechanical ventilation
- Remaining long lasting symptoms in ca 40% of patients

FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS

Phase 2 study to evaluate safety and effectiveness of imlifidase in patients diagnosed with GBS

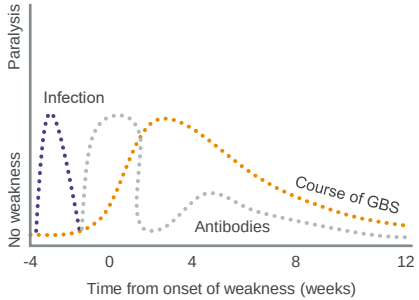
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



Study design: Study is an open-label, single arm, multi-center trial in 30 patients

Data read-out: Topline data expected H2'2023; Comparative efficacy analysis to a match cohort (IGOS data base at Erasmus, Rotterdam) expected 2024

Sources:

1) McGrogan et al. Neuroepidemiology 2009:32(2): 150-63.

New investigator-initiated phase 2 study in ANCA-associated vasculitis

- a group of autoimmune diseases characterized by inflammation of blood vessels with very few treatment options today

Incidences

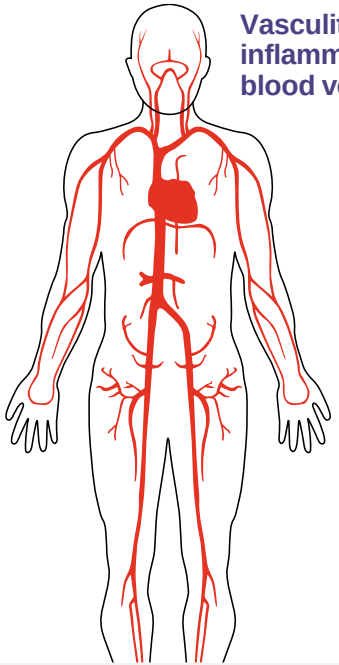
~3 in 100,000 annually across EU/US of which 8-36% are estimated to have Acute Respiratory Distress Syndrome due to pulmonary hemorrhage[1,2]

Standard of Care

- Current protocol is Immunosuppression and Intensive support care

Indication

- Causes damage to small blood vessels in the body resulting in inflammation and damage to organs, such as the kidneys, lungs etc.[3]
- Progress of the disease results in end stage kidney disease in 25 percent of patients[5]
- Most severe cases involving lungs lead to respiratory failure[4]
- Few treatment options today



Vasculitis means inflammation of blood vessels

The investigator-initiated trial (IIT) is sponsored by Charité Universitätsmedizin, Berlin

Study design

- Single arm, single center, phase 2 study with the primary objective to evaluate efficacy and safety on top of SoC
- 10 patients with severe ANCA-associated vasculitis and Acute Respiratory Distress Syndrome will be treated with imlifidase on top of SoC
- First patient treated Q2 2023
- Trial led by Dr. Adrian Schreiber and Dr. Philipp Enghard at Charité

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2. Rathmann J, et al. RMD Open. 2023;9:e002949.
3. Falk RJ, Jennette JC. The New England journal of medicine. 1988;318(25):1651-7.
4. Flossmann O, et al. Annals of the rheumatic diseases. 2011;70(3):488-94.
5. Booth AD, et al. American journal of kidney diseases. 2003;41(4):776-84.

Positive topline data from the imlifidase phase 2 study in antibody mediated rejection (AMR) episodes post kidney transplantation

Incidences

Acute AMR episodes occur in

5-7%

of annual kidney transplants[1]
(2,500-3,500 patients across US/EU)

Standard of Care

- Intravenous immune globulin (IVIg) or
- Plasma Exchange (PLEX) or
- Steroids

High unmet need

- AMR is one of the most challenging adverse events after kidney transplantation leading to graft dysfunction and loss
- There is no approved treatment for AMR

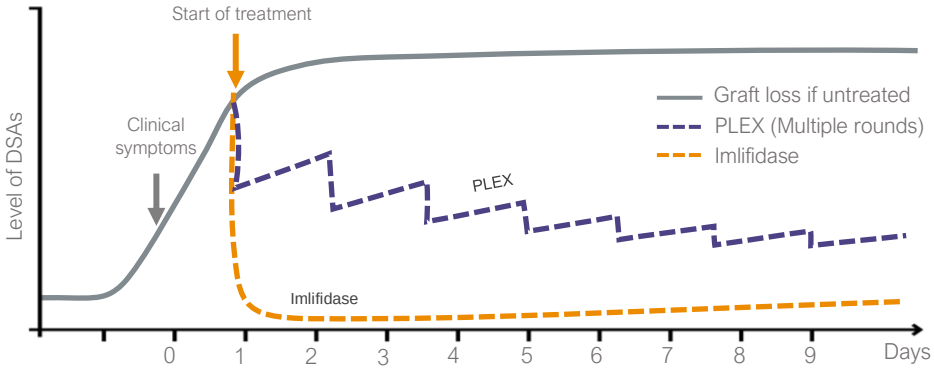
Phase 2 study design

30 patients with active or chronic active AMR episodes post kidney transplantation have been enrolled and randomized 2:1 to imlifidase vs. SoC

Full data read out from phase 2 study expected to be published in H2'23

Top-line data readout from phase 2 trial demonstrates a significant superior capacity of imlifidase to rapidly reduce levels of DSAs vs. PLEX (SoC) in the five days following the start of the treatment

Potential with imlifidase vs. PLEX in AMR
Illustrative



[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.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Calendar and events

Oct 5, 2023	Cowen non-deal road show, U.S.
Oct 12, 2023	Redeye: Afterwork, Malmö
Oct 18, 2023	**Interim Report for January-September 2023**
Nov 21, 2023	SEB Healthcare Seminar 2023, Stockholm
Nov 23, 2023	Redeye Life Science Day, Stockholm
Dec 6, 2023	Carlsquare Life Science Investor Day, Stockholm
Dec 14, 2023	Redeye Investor Forum, Gothenburg
Jan 8, 2024	JPM Week, SF
Feb 2, 2024	**Full-year Report for January-December 2023**
Feb 28, 2024	Ökonomisk Ugebrev Life Science Event, Copenhagen
Mar 20, 2024	**Annual Report 2023**
Apr 17, 2024	**Interim Report January-March 2024**
July 17, 2024	**Half-year Report January-June 2024**
Oct 23, 2024	**Interim Report for January-September 2024**