



Conference Call
Presentation

Year-end report January – December 2023
Lund, February 2, 2024



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 enters 2024 in a strong position to successfully execute on our key priorities

1 Q4: Strong commercial performance

- ✓ **Strong revenue generation in Q4 2023**
 - SEK 43m in Idefirix product sales
 - Growth supported by U.K., Germany, and Spain
- ✓ **Commercial partnership with NewBridge**
 - Covering MENA in kidney transplantation
- ✓ **Market Access for Idefirix® in Slovenia**
- ✓ **Initiated restructuring program**
 - Will provide SEK 75-85m in annual savings

2 Pipeline: Encouraging read-outs across several indications

- ✓ **AMR:** Full data from AMR phase 2 study
- ✓ **GBS:** Positive high-level phase 2 data
- ✓ **Anti-GBM:** Positive momentum continues
- ✓ **HNSA-5487:** Encouraging high-level P1 data
- ✓ **Kidney Transplantation:**
 - ConfIdaS: Randomization completion mid-2024
 - Sustained positive outcomes out to year 5
- ✓ **SRP-9001-104 imlifidase in DMD:**
 - Initiation of phase 1 study mid-December 2023

Key strategic priorities



Commercialize Idefirix® in first indication and markets

1

- Successfully launch Idefirix® in Europe
- Secure FDA approval and launch Idefirix® in the U.S.
- Geographic expansion



Advance our ongoing clinical programs

2

- Achieve approval/usage of imlifidase in follow-on indications
- Broaden the Idefirix® label beyond kidney transplantation



Expand our IgG-cleaving enzyme technology

3

- Expand IgG-cleaving enzyme technology platform into gene therapy
- Develop next gen IgG-cleaving enzymes for repeat usage

Continued progress against our key launch metrics led by in-market growth

Market Development

7

-

Medical guidelines implemented on a national level in 7 countries



Market Access

14

9

Market access secured in 14 European markets, more recently in Slovenia

Patient Identification

28

6

Post Approval Study
~56% into completion

Transplant Center Readiness & Use

~50

25

~50 clinics are Idefirix
"ready" to treat patients

10

8

Ongoing HTA processes in 10 countries incl. Portugal and Switzerland

✓

Eurotransplant:

First patient treated in the ET desensitization program; 1st and 2nd wave patient assessment initiated in Q4'23

23

10

23 centers have treated patients overall; 14 centers have repeat usage

Major markets to support growth going forward France, U.K., Germany, Spain and Italy



Potential to disrupt transplantation care in the U.S. with imlifidase

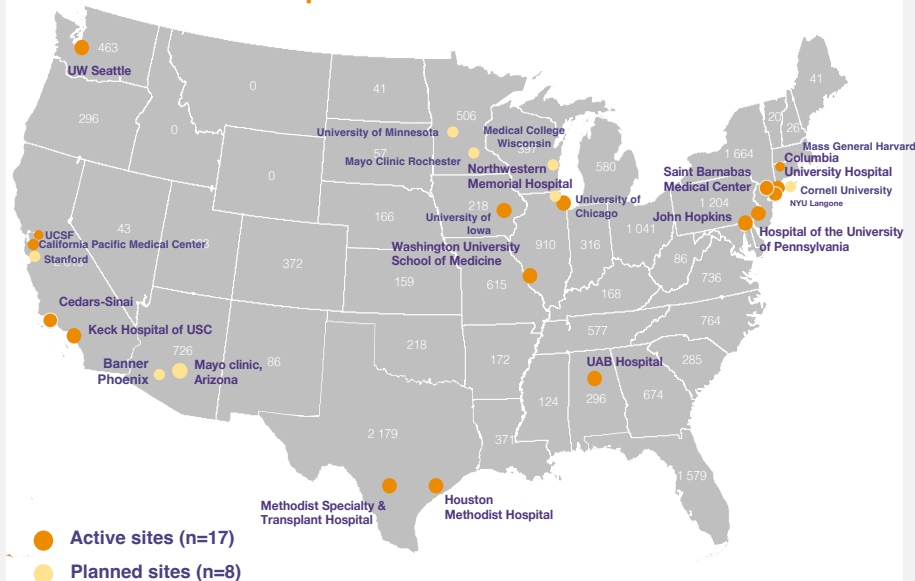
ConfideS phase 3 trial will further advance potential for imlifidase to address unmet need in desensitization

U.S. ConfideS

Phase 3

- Continue enrollment beyond 64 patients
- Currently 104 patients screened and enrolled
- 40 out of 64 targeted patients randomized
- Expansion from 17 to 25 site to accelerate randomization
- Randomization expected to complete mid-2024
- BLA filing in 2025

Involved ConfideS sites cover more than 20% of total transplantation volumes in the U.S.¹



¹Organ Procurement & Transplantation Network, OPTN (2023)

Commercial partnership with NewBridge Pharmaceuticals expands market to Middle East & North Africa (MENA)

The MENA region will be the third region outside Europe where Idefirix is commercialized aimed at enabling kidney transplantation in highly sensitized kidney transplant patients

GCC Transplantation Key Facts

~1,500 kidney transplantations in 2022¹

It's estimated that 10-15% of patients waiting for a kidney offer are highly sensitized^{2,3}

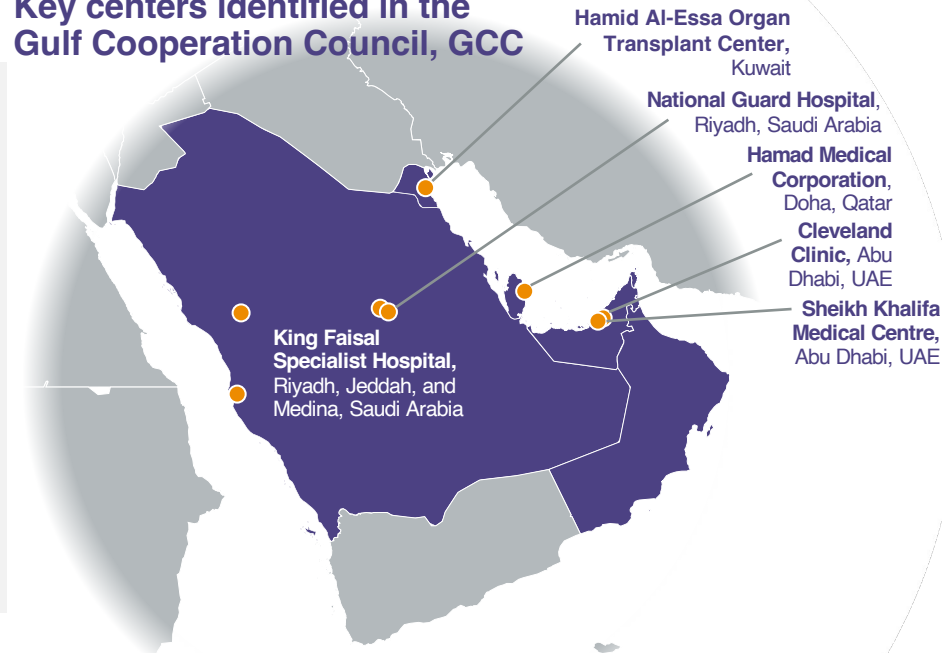
19% / 81% deceased vs living transplantations¹



NewBridge Pharmaceuticals,
HQ in Dubai, UAE

- A regional specialty company with a comprehensive pharmaceutical platform of services and expertise
- Established to in-license and commercialize U.S. FDA or EMA approved innovative therapeutics that address unmet medical needs the MENA regions

Key centers identified in the Gulf Cooperation Council, GCC



1. Transplant Observatory (2023), <https://www.transplant-observatory.org/export-database/>
2. EDQM. (2020). International figures on donation and Transplantation 2019
3. SRTR Database and individual assessments of allocation systems

Advancing HNSA 5487 – a high potential next-gen enzyme for repeat dosing

HNSA-5487



Engineered for lower immunogenicity



Short and long-term interval dosing



Broad range of indications
(prolonged or intermittent IgG-free window)

Broaden the IgG free window

Rapidly cleaves IgG and could potentially create a longer IgG-low period

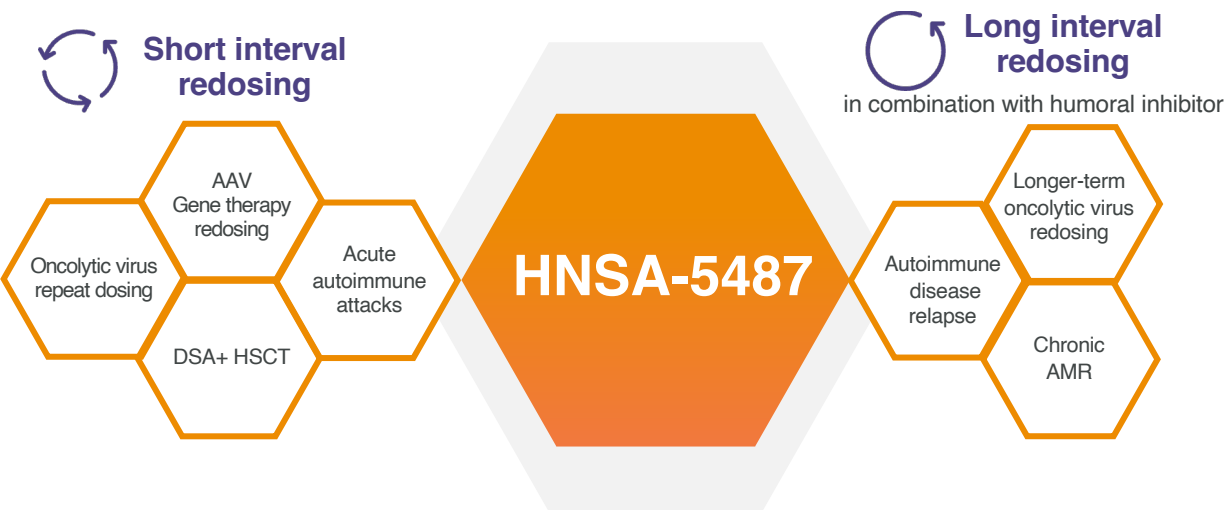
Address unmet need in autoimmune disease

Powerful 5487 IgG cleaving in combination with humoral inhibitor could result in greater control of disease in variety of autoimmune diseases

Enable re-dosing in gene therapy

Could provide solutions to enable re-dosing in AAV gene therapy and prolonged dosing of oncolytic viruses

Potential indication landscape for HNSA-5487 and reasons to believe



First in Human Study Results

- ✓ Administration was safe and well tolerated
- ✓ PD showed a fast and complete cleavage of IgG to F(ab')₂ and Fc-fragments with ascending doses; PK in line with expectations
- ✓ Further analysis around endpoints and immunogenicity to be completed in 2024 incl. selection of lead indication

Strong momentum across the pipeline in areas of high unmet need

Phase 1

HNSA-5487 (Lead from NiceR)



- Encouraging first read-out
- Ongoing collection of immunogenicity data in 2024

Pre-treatment Gene Therapy Duchenne



- Study site activated in Dec'23
- Dosing of first patient imminent

Phase 2

Antibody Mediated Rejection (AMR)



- Primary endpoint met
- Plans to publish in peer-reviewed journal

Guillain-Barré syndrome (GBS)



- Positive high-level data
- Further analysis in 2024 to contextualize efficacy data

ANCA-associated vasculitis



- 10 to be enrolled
- 1/3 into completion

• Patients enrolled
• Patients remaining

Phase 3

US ConfideS Study in kidney



- 104 patients enrolled;
- 40 of 64 patients randomized
- Randomization to complete mid'24

Post Approval Study in kidney



- 50 patients to be enrolled
- 56% into completion
- Study to complete by 2025

Anti-GBM disease



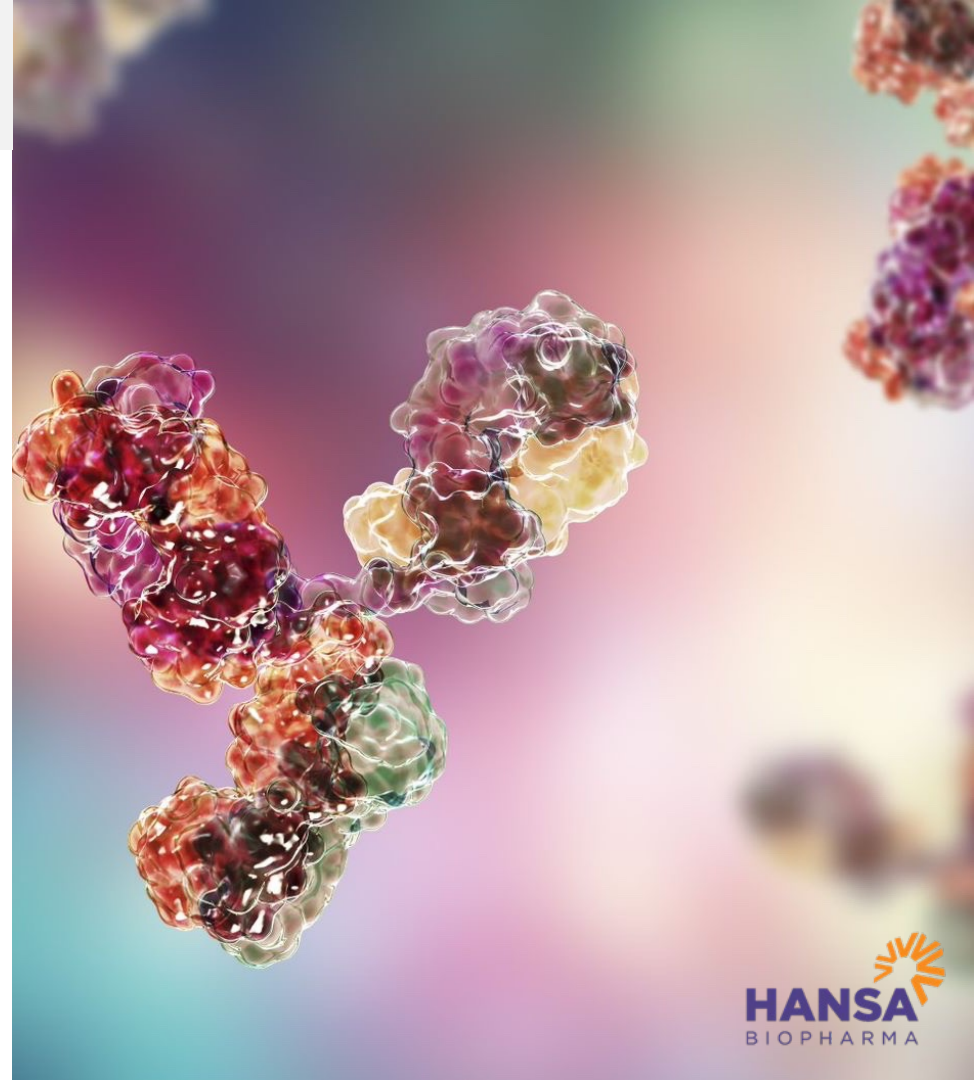
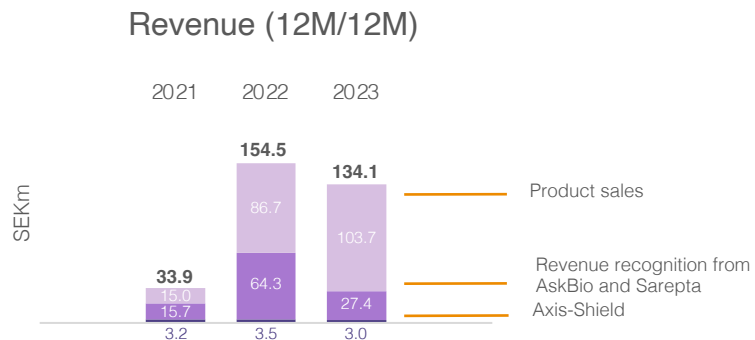
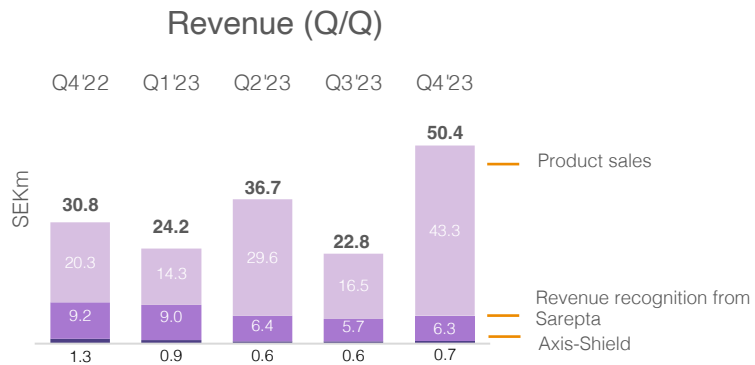
- 50 patients to be enrolled
- 36% into completion
- Complete enrollment in 2025

• Patients enrolled
• Patients remaining

- Next generation enzymes
- Gene Therapy
- Autoimmune / Allograft
- Transplantation

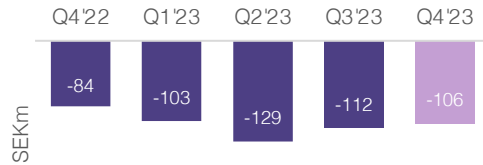
Strong revenue generation in Q4 2023, including SEK 43m in Idefirix product sales

Product sales improved +113% vs Q4 2022 and +163% vs Q3 2023; Growth driven by uptake in U.K., Spain, Germany

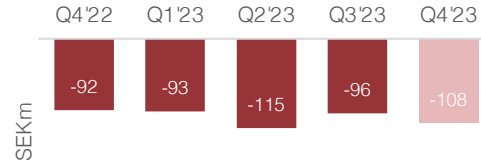


Continued investments in commercialization and R&D activities

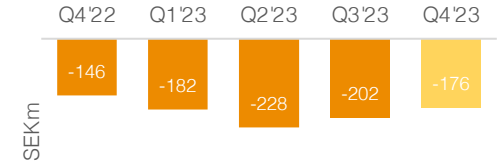
SG&A expenses (Q/Q)



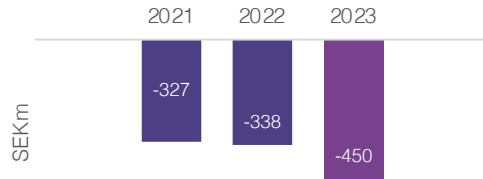
R&D expenses (Q/Q)



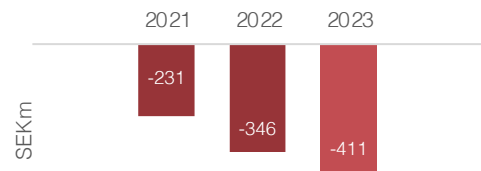
Operating loss (Q/Q)



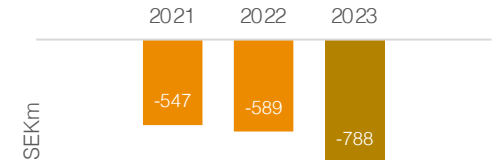
SG&A expenses (12M/12M)



R&D expenses (12M/12M)

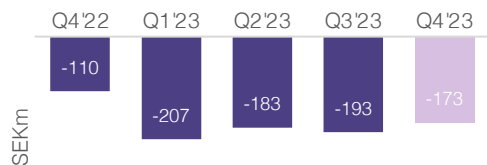


Operating loss (12M/12M)

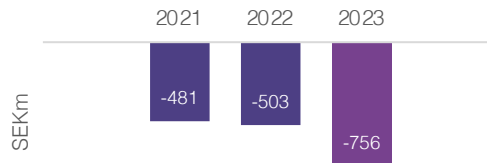


With current cash position and projected burn-rate, Hansa's operations are financed into 2025

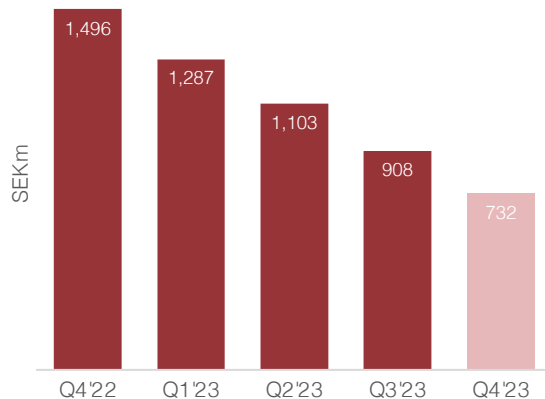
Operating cash flow (Q/Q)



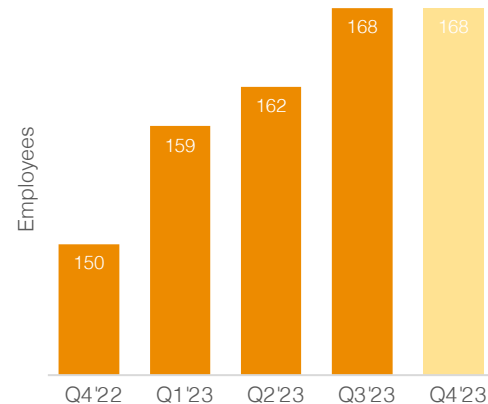
Operating cash flow (12M/12M)



Cash & short-term investments (Q/Q)



Number of employees (Q/Q)



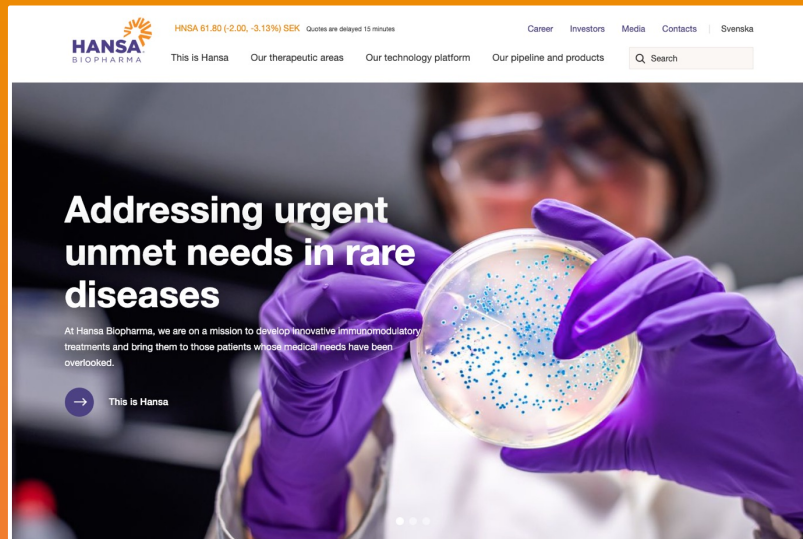
2023 achievements and upcoming milestones 2024/25

2023	2024	2025
Q4 2023		
<ul style="list-style-type: none"> ✓ HNSA-5487 (Lead NiceR candidate): High-level data readout from Phase 1 ✓ Long-term follow-up (Kidney tx): 5-year data readout ✓ GBS Phase 2: First data readout ✓ AMR Phase 2: Full data readout ✓ Sarepta DMD pre-treatment Phase 1b: Commence clinical study 	<ul style="list-style-type: none"> - GBS Phase 2: Outcome of comparative efficacy analysis - Genethon Crigler-Najjar Phase 1/2: Initiate clinical study with imlifidase prior to GNT-0003 - HNSA-5487 (Lead NiceR candidate): Further analysis around endpoints to be completed in 2024 incl. lead indication - U.S. ConfideS (Kidney tx) Phase 3: Complete randomization - Sarepta imlifidase in phase 1b in DMD: First high level data read-out from phase 1b 	<ul style="list-style-type: none"> - U.S. ConfideS (Kidney tx) Phase 3: BLA submission - Anti-GBM disease Phase 3: Complete enrolment

Q&A

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

Visit our website
hansabiopharma.com



Broad clinical pipeline in transplantation, autoimmune diseases, and gene therapy

Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Partner	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients ^{1,2}	Completed	Completed	Completed	Planned	Completed	Ongoing		EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	U.S. "ConfIdes": Kidney transplantation in highly sensitized patients ^{1,2}	Completed	Completed	Completed	Ongoing				Completion of randomization (64 patients) mid 2024
	GOOD-IDES-02: Anti-GBM antibody disease	Completed	Completed	Completed	Ongoing				Complete enrollment (50 patients)
	16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)	Completed	Completed	Completed					Publication in peer-reviewed journal
	15-HMedIdes-09: Guillain-Barré Syndrome (GBS)	Completed	Completed	Ongoing					Comparative efficacy analysis 2024
	Investigator-initiated trial in ANCA-associated vasculitis ³	Completed	Completed	Ongoing					Complete enrollment (10 patients)
	SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)	Completed	Phase 1b					Sarepta Therapeutics	First patient treated in clinical study
	Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)	Ongoing						Sarepta Therapeutics	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease	Ongoing						AskBio	Preclinical research
	Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome	Ongoing						Genethon	Commence clinical study
HNSA-5487	NICE-01 phase 1: HNSA-5487 – Lead candidate from the NiceR program	Completed	Ongoing						Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication

Completed
 Ongoing
 Planned
 Post approval study running in parallel with commercial launch

¹ Results from the Phase 1 study have been published, Winstedt et 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)

³ Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

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Calendar and events

Feb 6, 2024 Aktiespararna, Falkenberg

Feb 8, 2024 Frankfurt MidCap Seminar, Frankfurt

Feb 14, 2024 Redeye Cell Therapy & Growth Day, Stockholm

Feb 28, 2024 Ökonomisk Ugebrev Life Science Event, Copenhagen

March 4-5, 2024 TD Cowen Healthcare Conference, Boston

March 6, 2024 Life Sciencedagen, Sahlgrenska Universitetssjukhuset Gothenburg

Mar 20, 2024 Annual Report 2023

April 8-11, 2024 Needham Healthcare Conference (virtual)

April 16-17, 2024 Van Lanschot Kempen Life Science Conference, Amsterdam

Apr 18, 2024 Interim Report for January-March 2024

June 27, 2024 2024 Annual General Meeting

July 18, 2024 Half-year Report January-June 2024

Oct 24, 2024 Interim Report for January-September 2024

