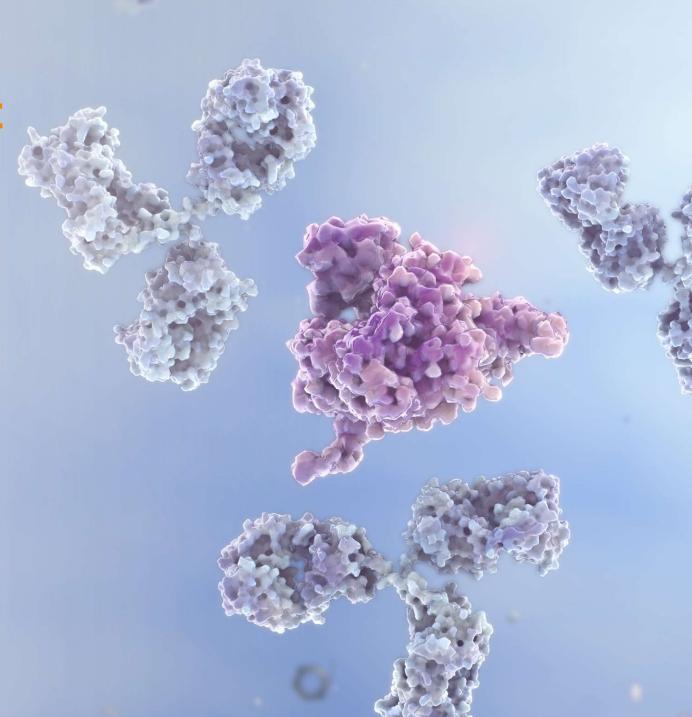
Interim Report

January - September 2025





Imlifidase successfully met primary endpoint in pivotal US Phase 3 ConfldeS trial in kidney transplantation

Business Update

- Year to date IDEFIRIX product sales totaled 143.6 MSEK and represented an increase of 29.1MSEK or 25.4% compared to the same period a year ago (114.5 MSEK). Year to date product sales represents approximately 102% of total full-year product sales achieved in 2024. Product sales in the third quarter of 2025 totaled 30.1 MSEK, compared to 39.8 MSEK for the same period in 2024.
- > At Hansa's Extraordinary General Meeting (EGM) on September 2, 2025, Elisabeth Björk, Natalie Berner and Michael Bologna were elected as new Board members. Anders Gersel Pedersen and Florian Reinaud resigned as members of the Board.
- Brian Gorman was appointed as Chief Legal Officer and Corporate Secretary, and Sandra Frithiof appointed as Chief Human Resources Officer. Gorman brings more than 20 years of international legal and governance experience while Frithiof has 25 years of experience in HR leadership across various industries.
- Subsequent Event(s): On October 1, 2025, Hansa successfully completed a directed share issue raising approximately 671.5 MSEK (approximately \$71.3M) before transaction costs with participation from both new and existing shareholders. Proceeds from the share issue will be used for general corporate purposes, including the filing of a Biologic License Application ("BLA") with the U.S. Food and Drug Administration ("FDA"), strengthening operational capacity in the U.S. ahead of potential U.S. commercial launch of imlifidase, subject to FDA approval, and a possible supplemental BLA filing for anti-GBM.

Financial Summary

Amounts in MSEK, unless otherwise stated	Q3 2025	Q3 2024	YTD 2025	YTD 2024
Revenue	30.8	48.7	146.3	139.0
- thereof: Product sales	30.1	39.8	143.6	114.5
SG&A expenses	(88.4)	(75.8)	(254.9)	(255.3)
R&D expenses	(70.2)	(79.6)	(230.3)	(274.3)
Loss from operations	(147.6)	(116.9)	(395.8)	(463.7)
Loss for the period	(148.3)	(103.8)	(364.2)	(530.3)
Net cash used in operations	(99.2)	(148.8)	(353.3)	(527.1)
Cash and short-term investments	252.1	553.5	252.1	553.5
EPS before and after dilution (SEK)	(1.75)	(1.53)	(4.90)	(8.67)
Number of outstanding shares	84,763,222	67,814,241	84,763,222	67,814,241
Weighted average number of shares before and after dilution	84,763,222	67,814,241	74,270,996	61,162,934
Number of employees at period end	133	135	133	135

Clinical Pipeline Update

- > **U.S. ConfideS trial:** Imlifidase successfully achieved its primary endpoint in the U.S. Phase 3 pivotal ConfideS (20-HMedIdeS-17) study in kidney transplantation. At 12 months, mean eGFR was 51.5 mL/min/1.73m² in the imlifidase arm compared to 19.3 mL/min/1.73m² in the control arm demonstrating a statistically significant and clinically meaningful difference of 32.2 mL/min/1.73m² (p<0.0001). Imlifidase was generally well tolerated with a safety profile consistent with previous clinical trial experience. Hansa expects to file a BLA submission with the FDA before year-end 2025.
- > SRP-9001-104 in Duchenne Muscular Dystrophy (DMD): Topline results were reported for three patients with DMD treated with imlifidase prior to administration of Sarepta's ELEVIDYS (delandistrogene moxeparvovec-rokl) in the trial. After a single dose of imlifidase, patients experienced a rapid reduction of IgG antibodies, to levels ≥95% less than baseline. In addition, pre-existing anti-AAV antibodies were reduced below a titre of 1:400, enabling treatment with ELEVIDYS. No new safety signals were observed in the trial. This first clinical data supports imlifidase ability to substantially reduce anti-AAV antibodies to allow administration of gene therapies.

Upcoming Key Catalysts - Q4 2025 & H1 2026

Desensitization Gene Therapy

Phase 2 Interim Data Readout: Global trial in Crigler Najjar with Genethon (GNT-018-IDES)

Autoimmune Disease

Phase 3 Top Line Data Readout: Global anti-GBM trial (GOOD-IDES-02)

Desensitization Kidney Transplant

BLA filing with the FDA, requesting priority review



Successful Phase 3 Readout in Kidney Transplant

Renée Aguiar-Lucander CEO, Hansa Biopharma

A key milestone this quarter was the highly statistically significant outcome of the ConfldeS trial, where imlifidase met its primary endpoint of eGFR (estimated glomerular filtration rate) at 12 months in kidney transplantation, demonstrating a statistically significant (p < 0.0001) and clinically meaningful benefit for highly sensitized patients. This is the first time that imlifidase has been evaluated in a large, randomized and controlled trial and we are delighted with the results. It clearly underscores the unmet medical need for patients requiring an effective desensitization therapy and provides hope for patients who today face many years on dialysis and limited transplant options. Based on the strong data, we are targeting a Biologics License Application (BLA) submission to the FDA under the accelerated approval pathway before year-end 2025, where we will be requesting Priority Review. We hope to be able to present additional data from the phase 3 trial at the American Transplant Congress (ACT) in June of 2026.

Subject to an approval by the FDA, we plan to commercialise imlifidase in the US. In order to successfully launch in the US, we have assembled an experienced and seasoned senior team to lead this effort, and we will start to build out the infrastructure and resources required over the next several quarters.

In Europe, sales of IDEFIRIX were below expectations during the quarter, which reflects seasonality and the continued challenging situation in Germany, as previously noted in our Q2 report. We now have some further insight into this situation, and we believe that Germany unfortunately will provide limited opportunity for highly sensitized patients over the next several quarters, due to the requirement for new guidelines to be prepared, reviewed and implemented. There is also slow progress on achieving regional reimbursement in Spain, which is having an impact on sales.

Having had the opportunity to review the European commercial operation more in depth over the last 3-4 months, it has become apparent that there are several areas of improvement and investment which we believe will address some the key issues and enhance performance. We plan to implement many of these initiatives during Q4 and look forward to improved visibility and predictability in 2026. These initiatives in combination with the recent clinical results from the ConfldeS trial have the potential to significantly enhance the growth of the European business, the overall potential of which we believe is substantial.

In the third quarter, we reported the first results from a clinical trial sponsored by Sarepta, demonstrating that imlifidase pre-treatment in patients eligible for gene therapy significantly reduced anti-AAV antibodies to levels consistent with the label, thereby potentially enabling access to gene therapy for patients who would otherwise be ineligible. Additionally, the Genethon-sponsored Phase 2 trial (GNT-018-IDES) in Crigler–Najjar syndrome is ongoing, enrolling patients with pre-existing antibodies against AAV vectors. The study is evaluating the safety and efficacy of Genethon's gene therapy candidate, GNT-0003, following imlifidase pre-treatment. Highly encouraging data from the first treated patient was presented at the European Society of Gene & Cell Therapy (ESGCT) on October 10. In this study it was also observed that imlifidase pretreatment enabled dosing with the gene therapy in a patient who otherwise would have been excluded.

Since joining Hansa, I have led a comprehensive transformation of the company, including a strategic reorganization, the appointment of a new executive leadership team, and the establishment of a renewed vision and mission. These foundational changes have been instrumental in positioning Hansa for long-term growth and value creation. We have successfully addressed the company's capital structure by way of debt restructuring and raising of equity to strengthen our financial position and support the advancement of our strategic priorities. The positive data from the ConfldeS study provides an exciting launchpad from which we hope to drive significant future value and continue to support activities in both gene therapy and autoimmune diseases.

Looking ahead, we expect to report data from the GOOD-IDES-02 Phase 3 study in anti-GBM disease in Q4 2025. We look forward to sharing the results as we continue to address unmet medical needs and advance our pipeline in rare autoimmune disease.

An Extraordinary General Meeting was held on September 2nd, during which Elisabeth Björk, Natalie Berner, and Michael Bologna were elected to the Board of Directors. We welcome them to the Board and look forward to them sharing their insights and expertise to continue to support the business.

As a subsequent event, on October 1st, we successfully completed a directed share issue, raising approximately SEK 671.5 million (USD 71.5 million) in gross proceeds. The capital raise received strong support from both new and existing shareholders and was multiple times oversubscribed. Proceeds will be used for general corporate purposes, including preparations for a BLA submission to the FDA, expansion of operational capabilities in the U.S. ahead of a potential commercial launch of imlifidase (subject to approval), a possible supplemental BLA filing for anti-GBM disease, and other ongoing operational needs.

We are excited to continue our journey to address unmet medical needs for patients with serious immune mediated conditions and remain focused on creating sustainable value for all our stakeholders.

Imlifidase Commercial and Pipeline Update

Commercial Update

EU: Kidney transplantation in highly sensitized patients

The launch of IDEFIRIX continues to progress across European and international markets. Year-to-date product sales were 25% higher compared to the same period in 2024. Q3 2025 product sales were 24% lower than Q3 2024, due to fewer than expected kidney transplants, and lower orders, largely driven by the pause in the German Eurotransplant Prioritized Program and reimbursement challenges in Catalunya, one of the largest regions in Spain.

As mentioned in the Q2 report, the German Eurotransplant Prioritized Program has been paused, and as a result no product sales were reported in Germany during Q3. While physicians in Germany can continue prescribing IDEFIRIX under the standard Eurotransplant Kidney Allocation System (ETKAS), we expect that the pause of the prioritized program will continue to have a negative impact in the near- to mid-term.

IDEFIRIX is now reimbursed in 21 European and international countries, including UK and Switzerland, providing national reimbursement to over 90% of the European population. Efforts remain underway to secure reimbursement in key regions in large European markets, such as Catalunya in Spain where regional reimbursement has not been established.

Pipeline Update

Post Authorization Efficacy and Safety Study (PAES) - 20-HMedIdeS-19

Enrolment for the PAES trial was completed in Q1 2025 with top-line data expected in mid-2026. This study fulfils a key post-approval commitment under the European conditional marketing authorization for IDEFIRIX and is designed to support the transition to full marketing approval. The trial includes participation from 22 transplant centers, underscoring the continued clinical interest in and adoption of IDEFIRIX. Most participating sites have now established treatment protocols and gained direct experience in managing highly sensitized kidney transplant patients. The trial remains on track.

ConfideS U.S. Phase 3 Trial - 20-HMedideS-17

Imlifidase successfully achieved its primary endpoint in the U.S.US Phase 3 pivotal ConfldeS trial in kidney transplantation. At 12 months, mean eGFR was 51.5 mL/min/1.73m² in the imlifidase arm compared to 19.3 mL/min/1.73m² in the control arm demonstrating a statistically significant and clinically meaningful difference of 32.2 mL/min/1.73m² (p<0.0001).

The trial was well conducted, with patient retention in excess of 90%. A key secondary endpoint-dialysis independence at 12 months-was also statistically significant in favour of

imlifidase (p=0.0007). Imlifidase was generally well tolerated with a safety profile consistent with previous clinical trial experience. Full results from the Phase 3 ConfldeS trial will be submitted for presentation at a medical congress in 2026.

Global Phase 3 anti-glomerular basement membrane (anti-GBM) Disease Trial - GOOD-IDES-02

Enrolment for the GOOD-IDES-02 Phase 3 trial has been completed with topline data expected later in Q4 2025. This open-label, controlled, randomized, multi-center study is evaluating renal function outcomes in patients with severe anti-GBM disease treated with imlifidase in combination with SoC versus SoC alone. The trial remains on track.

SRP-9001-104 Phase 1b Trial in Duchenne Muscular Dystrophy (DMD)

Sarepta's Phase 1b trial (SRP-9001-104) is evaluating the use of imlifidase as a pretreatment to Sarepta's gene therapy ELEVIDYS (delandistrogene moxeparvovec), in patients with DMD. Following a safety update for ELEVIDYS in March, several gene therapy trials—including SRP-9001-104—were temporarily halted at the request of EU reference member state authorities.

To date, three patients have been successfully treated with imlifidase. A single dose of imlifidase resulted in a rapid and profound reduction of IgG antibodies to levels below >95% of baseline. Pre-existing anti-AAV antibodies were reduced below the titre threshold of 1:400, enabling subsequent administration of ELEVIDYS. The combination treatment was well tolerated, with a safety profile consistent with prior experience and no new safety signals observed.

Twelve weeks following the gene therapy administration, transduction of the microdystrophin gene was confirmed in all three patients. Expression of micro-dystrophin was observed, although at levels lower than what was seen in other ELEVIDYS studies. Hansa and Sarepta plan to review the data and discuss next steps during Q4.

Genethon Phase 2 Trial in Crigler Najjar - GNT-018-IDES

In December 2024, Genethon and Hansa announced the initiation of GNT-018-IDES, a Phase 2 trial in patients with Crigler-Najjar syndrome who have pre-existing antibodies against adeno-associated virus (AAV) vectors. The study is evaluating the efficacy and safety of a single intravenous dose of Genethon's gene therapy, GNT-0003, following pretreatment with imlifidase in patients with severe Crigler-Najjar syndrome and pre-formed antibodies to AAV serotype 8 (AAV8). Due to protocol adjustments the enrolment will be completed 1H 2026, instead of 2025.

Subsequent Event: The feasibility and efficacy of a pre-treatment with imlifidase, enabling gene therapy in a patient with Crigler–Najjar syndrome and antibodies towards AAV 8 was presented at European Society of Gene & Cell Therapy (ESGCT), October 10th.

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabiopharma.com.



Focused Pipeline in Desensitization and Autoimmune Diseases

Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Partner	Upcoming Milestone
Desensitization Kid	Iney Transplantation					2026: EU PAES data read out
Desensitization Kid	Iney Transplantation					Q4 2025: BLA submission to FDA based on ConfldeS US Phase 3 data
Desensitization Ge	ene Therapy (Crigler N	lajjar)			GENETHON CURE THEOLOGY RANGONTON	1H 2026: complete enrolment
Desensitization Gen	e Therapy (DMD)				S A R E P T A	Discussions ongoing regarding next steps
Autoimmune GBS						1H 2026: data publication
Autoimmune anti-C	SBM					Q4 2025: Phase 3 data read out
Autoimmune ANC	\ Investigator Initiated	Trial (IIT) ¹				Recruitment phase concluded
Hansa 5487						Q4 2025: Indication to be communicated
	Desensitization Kico Desensitization Kico Desensitization Gen Desensitization Gen Autoimmune GBS Autoimmune anti-Co Autoimmune ANCA	Desensitization Kidney Transplantation Desensitization Kidney Transplantation Desensitization Gene Therapy (Crigler Notes to be a sensitization Gene Therapy (DMD) Autoimmune GBS Autoimmune anti-GBM Autoimmune ANCA Investigator Initiated	Desensitization Kidney Transplantation Desensitization Kidney Transplantation Desensitization Gene Therapy (Crigler Najjar) Desensitization Gene Therapy (DMD) Autoimmune GBS Autoimmune anti-GBM Autoimmune ANCA Investigator Initiated Trial (IIT)¹	Desensitization Kidney Transplantation Desensitization Kidney Transplantation Desensitization Gene Therapy (Crigler Najjar) Desensitization Gene Therapy (DMD) Autoimmune GBS Autoimmune anti-GBM Autoimmune ANCA Investigator Initiated Trial (IIT)¹	Desensitization Kidney Transplantation Desensitization Kidney Transplantation Desensitization Gene Therapy (Crigler Najjar) Desensitization Gene Therapy (DMD) Autoimmune GBS Autoimmune anti-GBM Autoimmune ANCA Investigator Initiated Trial (IIT)¹	Desensitization Kidney Transplantation Desensitization Kidney Transplantation Desensitization Gene Therapy (Crigler Najjar) Desensitization Gene Therapy (DMD) Autoimmune GBS Autoimmune anti-GBM Autoimmune ANCA Investigator Initiated Trial (IIT)¹

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabiopharma.com.

Hansa Biopharma Interim Report Q3 2025

¹ Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp <u>Enghard</u>, at Charité <u>Universitätsmedizin</u>, Berlin, Germany © 2025, Hansa Biopharma AB

Financial Review 2025: Third Quarter & Year to Date

Revenue

Revenue for the third quarter 2025 totaled 30.8 MSEK (2024: 48.7 MSEK) consisting of IDEFIRIX product sales of 30.1 MSEK (2024: 39.8 MSEK) and contract revenue of 0.7 MSEK (Q3 2024: 8.9 MSEK). The contract revenue in Q3 2025 was primarily related to the Axis-Shield agreement The corresponding contract revenue for the same period in 2024 reflected revenue from the Sarepta agreement and it was fully recognized in 2024.

For the nine months ended September 30, 2025, revenue totaled 146.3 MSEK (2024: 139.0 MSEK) including IDEFIRIX product sales of 143.6 MSEK (2024: 114.5 MSEK) and contract revenue of 2.7 MSEK (2024: 24.5 MSEK). Year to date product revenue increased by 29.1 MSEK or 25.48%.

Sales General & Administrative (SG&A) expenses

SG&A expenses for the third quarter 2025 totaled 88.4 MSEK (2024: 75.8 MSEK) and 254.9 MSEK for the nine-month period ended September 30, 2025 (2024: 255.3 MSEK). The year-over-year third quarter expense increase was 12.6 MSEK or ~16.6% and reflects increased costs associated with the expected U.S. market launch in mid-2026. Despite the third quarter increase in SG&A expenses, year to date expenses were slightly favorable to the same period a year ago.

For the nine-month period 2025, non-cash expenses for the Company's long-term incentive programs (LTIP) were included in SG&A and totaled 13.9 MSEK compared to 18.3 MSEK for the same period in 2024.

Research & Development (R&D) expenses

R&D expenses for the third quarter 2025 totaled 70.2 MSEK (2024: 79.6 MSEK) and 230.3 MSEK for the first nine months of 2025 (2024: 274.3 MSEK). Year-over-year third quarter R&D expenses were 9.4 MSEK or ~11.8% favorable compared to the prior year. For the nine months ended September 30, 2025, R&D expenses were 44.0 MSEK or 16.0% favorable compared to the same period a year ago. This favorable variance was driven by savings associated with the restructuring activities implemented in 2024, offset by continued investments in the U.S. Phase 3 ConfldeS study, EMA post-approval commitments, the ongoing Phase 3 study in anti-GBM and CMC development expense for HNSA-5487.

Non-cash expenses related to the Company's LTIP program were included in R&D expense and totaled 7.7 MSEK for the first nine months of 2025 compared to 7.9 MSEK during the same period in 2024.

Other operating income/expenses, net and finance income/expenses, net

Other operating income/expenses, net, primarily included gains or losses from foreign exchange rate fluctuations in operations. For the first nine months 2025, the Company recorded an income of 2.1 MSEK, and an expense of 3.1 MSEK in the first nine months of 2024. The change is primarily due to a strengthening in the exchange rate of the Swedish Krona against the primarily US dollar and Euro, affecting deferred revenue as well as accounts payable and receivable positions on the balance sheet.

Financial income/expenses, net, for the third quarter of 2025, totaled 0.0 MSEK (Q3 2024 income of 13.3 MSEK). For the first nine months of 2025, the income totaled 33.5 MSEK compared to an expense of 66.4 MSEK for the first nine months of 2024. The financial expenses, primarily driven by foreign exchange as the Swedish Krona exchange rate compared to the US dollar strengthened. This impacted the interest associated with the NovaQuest loan. The YTD 2025 financial expenses included non-cash

interest expense associated with the NovaQuest loan of 98.8 MSEK (9M 2024: 97.7 MSEK), a non-cash loss of 59,4 MSEK (9M 2024: 0.0) from the loan restructuring modification, favourable foreign exchange fluctuations associated with the NovaQuest loan to 157.1 MSEK (9M 2024 unfavorable: 56.2 MSEK), and other items (see Note 3).

Financial results

The loss from operations for the third quarter 2025 totaled 147.6 MSEK (2024: 116.9 MSEK) and 395.8 MSEK for the first nine months of 2025 (2024: 463.7 MSEK). The decrease in Hansa's operating loss for the first nine months of 2025 compared to the same period previous year was driven by lower overall expenses as well as increased sales.

The third quarter loss for the period totaled 148.3 MSEK (Q3 2024: 103.8 MSEK) and for the first nine months of 2025 the loss for the period totaled 364.2 MSEK (9M 2024: 530.3 MSEK).

Cash flow, cash and investments

Net cash used in operating activities for the third quarter 2025 totaled 99.2 MSEK (Q3 2024: 148.8 MSEK) and 353.3 MSEK for the first nine months of 2025 (9M 2024: 527.1 MSEK). The change for the first nine months, compared to the prior year, was driven by lower operating expenses and a positive change in working capital balance sheet accounts. The share issue completed during Q2 increased cash balances by 217.4 MSEK net of transaction costs.

Cash and cash equivalents totaled 252.1 MSEK at September 30, 2025, compared to 405.3 MSEK at December 31, 2024.

Parent Company

The parent company's revenue for the third quarter of 2025 totaled 30.8 MSEK (Q3 2024: 48.7 MSEK) and for the first nine months of 2025 to 146.3 (9M 2025: 139.0 MSEK). The third quarter 2025 the parent company loss for the period totaled 174.3 MSEK (Q3 2024: 134.0 MSEK) and for the first nine months of 2025 the loss for the period was 452.4 MSEK (9M 2024: 619.8 MSEK).

The parent company shareholders' equity at September 30, 2025, totaled 617.7 MSEK compared to 674.4 MSEK at December 31, 2024.

The Group consists of the parent company, Hansa Biopharma AB, and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc., Hansa Biopharma Italy S.r.l. and Hansa Biopharma Australia PTY LTD. On September 30, 2025, Hansa Biopharma Inc. had fourteen employees, Hansa Biopharma Ltd nine employees and Hansa Biopharma S.r.l. three employees.

Financial Review 2025: Third Quarter & Year to Date (continued)

Long-term incentive programs

At Hansa Biopharma's previous Annual General Meetings, shareholders resolved to adopt various share-based LTIP programs. As of September 30, 2025, the Company incurred non-cash equity-based compensation expense under the following LTIP programs: 2020, 2021, 2022, 2023, 2024 and 2025.

The respective non-cash costs related to the ongoing LTIP programs are summarized in the table below. In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants. For further information on the different LTIP programs, please refer to Hansa Biopharma's 2024 Annual Report which can be found at www.hansabiopharma.com.

Ongoing programs	LTIP 2020	LTIP 2021	LTIP 2022	LTIP 2023	LTIP 2024	LTIP 2025
Maximum number of issuable shares*	633,776	71,500	58,500	625,658	1,179,404	7,472,356
Number of allocated outstanding share rights and options	487,520	55,000	45,000	486,893	917,824	4,501,250
Number of allocated outstanding warrants						1,688,250
Estimated total cost including social contributions for outstanding share rights and options, KSEK	25,863	15,473	8,047	14,068	30,025	60,985
Total cost per program, including social contributions as of September 30, 2025 YTD, KSEK	0	(14)	3,024	3,118	7,072	8,442
Total costs, including social contributions, as of Septembe	er 30, 2025 YTD,	, KSEK				21,642

Risks and uncertainties

Hansa's business is subject to a variety of external and internal factors that may significantly affect the Company's financial performance and position - many of which are partially or entirely beyond the Company's control. When evaluating the Company's prospects, it is important to consider these risks, alongside the potential for earnings growth in order to form a balanced and realistic assessment of the Company's expected development.

Since the fourth quarter 2022, Hansa has capitalized development costs related to IDEFIRIX following the conditional approval granted by the EMA (see Note 4). In 2023, based on conditional approval, the parent company also revalued the underlying intangible asset related to IDEFIRIX. Both the decision to

begin development costs and the revaluation of the intangible assets in the parent company were based on the assessment that Hansa is likely to obtain final EMA approval for the commercialization of IDEFIRIX. As part of the conditional approval, the EMA has required Hansa to conduct two clinical trials to support final approval:

- a) A five-year follow-up study of 46 patients previously treated with IDEFIRIX in a Phase II trial was performed. This follow-up clinical study was finalized and submitted to EMA in December 2023. In 2024, EMA finalized its review and the study was approved.
- b) A post-authorization efficacy and safety (PAES) study, involving 50 kidney transplant patients treated with IDEFIRIX with a reference group of 50 transplant patients receiving standard-of-care treatment without IDEFIRIX was completed in Q1 2025. Following the completion of the study, patients will be monitored for one year to assess the long-term effect of the drug. The objective of the follow up study is to determine whether outcomes in highly sensitized patients treated with IDEFIRIX are comparable to those receiving standard treatment. Hansa currently has no indication that the study would be unsuccessful.

Given that the follow-up study has been approved and there are no indications that the PAES study will be unsuccessful, Hansa considers the risk of not meeting EMA's conditions for final approval to be low.

Risk factors include, among others, uncertainties regarding clinical trials and regulatory approvals, collaborations and partnerships, intellectual property rights, reliance on key products, market dynamics and competition, manufacturing and supply chain challenges, pricing and reimbursement, as well as dependence on key persons and financial risks.

On October 1, 2025, Hansa completed a directed share issue raising gross proceeds of approximately 671.5 MSEK (approximately 71.3 MUSD) with participation from both new and existing shareholders. On a pro forma basis, with the completion of this capital raise and existing cash and cash equivalents at September 30, 2025 (252.1 MSEK) the Company has approximately 923.6 MSEK of cash. A detailed overview of the key risks and uncertainties facing Hansa can be found in the English version of the Company's 2024 Annual Report (pages 32-35).

On a regular basis, Hansa's Board of Directors and senior management review the development of these risks and uncertainties. No material changes from the presentation in the 2024 Annual Report have been identified as of the date of this quarterly report.

Financial Review 2025: Third Quarter & Year to Date (continued)

Other information

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Legal Disclaimer

This financial report includes statements that are forward-looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are developments within research programs. This is a translated version of the Swedish original.

Financial Calendar 2026

February 12, 2026 March 26, 2026 April 23, 2026 Full Year 2025 Report Annual and Sustainability Report for 2025 Interim Report for January – March 2026

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares September 30, 2025	84,763,222
Market Cap September 30, 2025	~2.22 BSEK (USD ~\$233M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of September 30, 2025

Shareholder Name	Number of Shares	Ownership %	
Redmile Group LLC	16,309,214	19.24%	
NovaQuest Capital Management LLC	6,398,981	7.55%	
Braidwell LP	4,128,105	4.87%	
Theodor Jeansson Jr.	3,520,000	4.15%	
Avanza Pension	3,112,198	3.67%	
Fourth Swedish National Pension Fund (AP4)	2,569,000	3.03%	
Hansa Biopharma AB	2,037,291	2.40%	
Handelsbanken Fonder	1,957,631	2.31%	
Thomas Olausson	1,917,000	2.26%	
Nexttobe AB	1,355,379	1.60%	
All other	41,458,799	45.99%	
Total Shares Outstanding	84,763,222	100.00%	

Source: Modular Finance compiled and processed data from various sources, including Euroclear, Morningstar, FactSet and the Swedish Financial Supervisory Authority (Finansinspektionen).

Hansa Biopharma had approximately 20,000 shareholders as of September 30, 2025.

Hansa Biopharma is a pioneering commercial-stage biopharmaseutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansablopharma.com.

The Board of Directors and the Chief Executive Officer affirm that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a fair view of the group's financial position and results. The interim report has been prepared in accordance with generally accepted accounting principles for the group and the parent company and gives a fair overview of the development of the group's and the parent company's operations, financial positions, and results.

Lund, Sweden, October 30, 2025

Peter Nicklin
Chairman of the Board

Hilary Malone Eva Nilsagård Board member Board member

Mats Blom Elisabeth Björk Board member Board member

Michael Bologna Jonas Wikström Board member Board member

Natalie Berner Board member

This report has been reviewed by the company's auditors.

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas — transplantation, autoimmune diseases, gene therapy and new therapies — where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabjopharma.com.

Hansa Biopharma Interim Report Q3 2025

Unaudited Condensed Financial Statements

Unaudited condensed consolidated statement of financial position

		Septem	Dec 31	
KSEK	Note	2025	2024	2024
ASSETS				
Non-current assets				
Intangible assets	4	265,440	174,844	197,333
Property and equipment	7	3,377	5,117	4,682
Right-of-use assets		8,152	15,058	13,198
Total non-current assets		276,969	195,019	215,213
6				
Current assets		2 520	4.076	2.640
Inventories		3,529	1,976	2,610
Trade receivables & unbilled revenues		165,793	144,645	144,965
Current receivables, non-interest bearing		42,742	45,491	32,574
Cash and cash equivalents		252,072	553,544	405,280
Total current assets		464,136	745,656	585,429
TOTAL ASSETS		741,105	940,675	800,642
EQUITY AND LIABILITIES				
Shareholders' equity		(560,744)	(319,959)	(589,833)
Non-current liabilities				
Long-term loan	3	774,695	942,950	1,064,645
Deferred tax liabilities		122	174	168
Provisions		6,923	4,701	4,259
Lease liabilities		971	8,624	6,678
Refund liabilities		99,459	-	59,038
Total non-current liabilities		882,170	956,449	1,134,788
Current liabilities				
Short-term loan		140,078	-	-
Tax liabilities		1,951	1,121	2,705
Lease liabilities		8,151	7,614	7,684
Current liabilities, non-interest bearing		63,604	51,617	55,491
Deferred revenue		13,986	20,552	16,334
Refund liabilities		65,152	132,499	64,484
Accrued expenses		126,757	90,782	108,989
Total current liabilities		419,679	304,185	255,687
TOTAL EQUITY AND LIABILITIES		741,105	940,675	800,642
		,		

Unaudited condensed consolidated statement of profit or loss and other comprehensive income (loss)

		Q	3	9М		
KSEK	Note	2025	2024	2025	2024	
Revenue	2	30,804	48,664	146,275	138,979	
Cost of revenue		(20,108)	(11,380)	(58,904)	(70,066)	
Sales, general and administration expenses		(88,413)	(75,819)	(254,927)	(255,276)	
Research and development expenses	4	(70,206)	(79,624)	(230,306)	(274,267)	
Other operating income/(expenses), net		311	1,231	2,066	(3,074)	
Loss from operations		(147,612)	(116,928)	(395,796)	(463,704)	
Financial income		10,279	5,784	145,938	16,990	
Financial expenses	3	(10,230)	7,474	(53,036)	(83,403)	
Non-cash loss on loan restructuring		-	-	(59,447)	-	
Loss before tax		(147,563)	(103,670)	(362,341)	(530,117)	
Tax		(693)	(126)	(1,872)	(201)	
Loss for the period		(148,256)	(103,796)	(364,213)	(530,318)	
Loss for the period attributable to owners of the pare	nt	(148,256)	(103,796)	(364,213)	(530,318)	
Loss per share, basic and diluted (SEK)		(1.75)	(1.53)	(4.90)	(8.67)	
Other comprehensive income/(loss)						
Items that have been, or may be reclassified to profit						
or loss for the period:						
Translation differences		(288)	(565)	(2,467)	167	
Other comprehensive income/(loss) for the period		(288)	(565)	(2,467)	167	
Total comprehensive loss		(148,544)	(104,361)	(366,680)	(530.151)	

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Unaudited condensed consolidated statement of changes in shareholders' equity

	January-Se	January-September		
KSEK	2025	2024	2024	
Opening balance of shareholders' equity	(589,833)	(167,876)	(167,876)	
Result for the period	(364,213)	(530,318)	(807,243)	
Translation reserve	(2,467)	167	1,350	
Net comprehensive loss	(366,680)	(530,151)	(805,893)	
Transactions with the group's owner				
Proceeds from new share issuance, net ¹	217,397	354,308	354,308	
Proceeds from restructuring of debt	141,472	-	-	
Long term incentive programs	18,515	23,760	29,629	
Long term incentive program option contribution ²	18,385	-	-	
Total transactions with the group's owner	395,769	378,068	383,937	
Closing balance of shareholders' equity	(560,744)	(319,959)	(589,833)	

¹ Total share issue cost 2025 amounted to SEK 14.703 KSEK, total share issue cost 2024 amounted to 17,845 KSEK.

Unaudited condensed consolidated statement of cash flow

	Q	3	9N	ı
KSEK	2025	2024	2025	2024
Cash Flows from Operating Activities				
Loss for the period	(148,254)	(103,796)	(364,211)	(530,318)
Adjustment for non-cash items ¹	32,657	(21,410)	(24,393)	74,347
Interest received and paid, net	(101)	(134)	(69)	758
Income taxes paid	(800)	(617)	(2,455)	(900)
Cash flow from operations before change in working capital	(116,498)	(125,957)	(391,128)	(456,113)
Changes in working capital	17,291	(22,844)	37,877	(70,971)
Net cash used in operating activities	(99,207)	(148,801)	(353,251)	(527,084)
Investing activities				
Acquisition of property and equipment	-	-	-	(116)
Cash flow from investing activities	-	-	-	(116)
Financing activities Proceeds from new share issue, net of transaction				
cost ²	-	-	217,397	354,308
Restructuring costs long-term loan	-	-	(9,530)	-
Payment of lease liabilities	(1,978)	(1,892)	(5,869)	(5,627)
Cash flow from financing activities	(1,978)	(1,892)	201,998	348,681
Net change in cash	(101,185)	(150,693)	(151,253)	(178,519)
Cash and cash equivalents at beginning of period	353,321	704,999	405,280	732,060
Currency exchange variance, cash and cash equivalents	(64)	(762)	(1,955)	3
Cash and cash equivalents, end of period	252,072	553,544	252,072	553,544

¹ Values are mainly costs of share-based incentive programs including social contributions and depreciation, partly offset by certain capitalized development costs (see further in Note 4).

² In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants.

² Total share issue cost 2025 amounted to SEK 14,703 KSEK. Total share issue cost 2024 amounted to SEK 17,845 KSEK.

Parent Company - Unaudited condensed statement of financial position

		Septemb	er 30	December 31		
KSEK	Note	2025	2024	2024		
ASSETS						
Non-current assets						
Intangible assets	4	1,425,732	1,453,976	1,446,684		
•	4	3,377	1,433,976 5,117			
Property and equipment Right-of-use assets		•	15,058	4,682		
Investment in subsidiaries		8,152		13,198		
		38,891	34,593	34,194		
Total non-current assets		1,476,152	1,508,744	1,498,758		
Current assets						
Inventories		3,529	1,976	2,610		
Trade receivables & unbilled revenues		165,793	144,645	144,965		
Current receivables, non-interest bearing		41,440	45,203	31,160		
Cash and cash equivalents		243,392	534,273	385,103		
Total current assets		454,154	726,097	563,838		
_						
TOTAL ASSETS		1,930,306	2,234,841	2,062,596		
EQUITY AND LIABILITIES						
2201171112 21112111120						
Shareholders' equity		617,721	975,218	674,449		
Non-current liabilities						
Long-term loan	3	774,695	942,950	1,064,645		
Provisions		6,923	4,701	4,259		
Lease liabilities		971	8,624	6,678		
Refund liabilities		99,459	-	59,038		
Total non-current liabilities		882,048	956,275	1,134,620		
Current liabilities						
Short-term part of loan		140,078	-	-		
Tax liabilities		485	1,187	1,119		
Lease liabilities		8,151	7,614	7,684		
Liabilities, group companies		20,800	8,614	11,480		
Current liabilities, non-interest bearing		63,676	51,133	55,448		
Deferred revenue		13,986	20,552	16,334		
Refund liabilities		65,152	132,499	64,484		
Accrued expenses		118,209	81,749	96,978		
Total current liabilities		430,537	303,348	253,527		
TOTAL EQUITY AND LIABILITIES		1,930,306	2,234,841	2,062,596		

Parent Company – Unaudited condensed statement of profit or loss and other comprehensive income (loss)

		Q:	3	9	9М		
KSEK	Note	2025	2024	2025	2024		
Revenue	2	30,804	48,664	146,275	138,979		
Cost of revenue		(49,900)	(41,172)	(148,279)	(159,441)		
Sales, general and administration expenses		(88,277)	(76,032)	(259,265)	(253,217)		
Research and development expenses	4	(67,106)	(79,439)	(225,490)	(276,242)		
Other operating income/(expenses), net		(70)	910	1,244	(3,237)		
Loss from operations		(174,549)	(147,069)	(485,515)	(553,158)		
Financial income		10,279	5,785	145,938	16,981		
Financial expenses	3	(10,229)	7,462	(53,022)	(83,404)		
Non-cash loss on loan restructuring			-	(59,447)	-		
Loss before tax		(174,499)	(133,822)	(452,046)	(619,581)		
Income tax		235	(137)	(326)	(224)		
Loss for the period		(174,264)	(133,959)	(452,372)	(619,805)		
Other comprehensive loss for the period		_	-	-	-		
Total comprehensive loss for the period		(174,264)	(133,959)	(452,372)	(619,805)		

Parent Company – Unaudited condensed statement of changes in shareholders' equity

	Q3		Full year	
KSEK	2025	2024	2024	
Opening balance of shareholders' equity	674,449	1,216,945	1,216,945	
Result for the period	(452,372)	(619,805)	(926,376)	
Other comprehensive income/(loss) for the period	-	-	-	
Net comprehensive loss	(452,372)	(619,805)	(926,376)	
Proceeds from new share issuance, net ¹	217,397	354,308	354,308	
Proceeds from restructuring of debt	141,472	-	-	
Long term incentive programs	18,390	23,770	29,572	
Long term incentive program option contribution ²	18,385	-	-	
Total other transactions	395,644	378,078	383,880	
Closing balance of shareholders' equity	617,721	975,218	674,449	

¹ Total share issue cost 2025 amounted to SEK 14,703 KSEK. Total share issue cost 2024 amounted to SEK 17,845 KSEK.

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabjopharma.com.

 $^{^{2}}$ In the 2025 LTIP program, a number of Hansa employees invested their own capital to purchase warrants.

Financial Notes

Note 1 Basis of preparation and accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting, and recommendation RFR2 of the Swedish Reporting Board, Accounting for Legal entities. The same accounting principles have been used as in the latest annual report except for what is stated below. Hansa's Annual Report for 2024 was published on March 21, 2025, and is available at www.hansabiopharma.com. Disclosures in accordance with IAS 34.16A are as applicable in the notes or on the pages before the consolidated income statement.

Note 2 Revenue

Income per significant category of income	Q3		9M	
KSEK	2025	2024	2025	2024
Group				
Revenue				
Product sales	30,133	39,811	143,583	114,478
Contract revenue, Axis-Shield agreement	671	651	2,015	1,953
Cost reimbursement, Axis-Shield agreement	-	-	677	581
Contract revenue, Sarepta, AskBio agreement	-	8,202	-	21,967
	30,804	48,664	146,275	138,979
Parent Company				
Revenue				
Product sales	30,133	39,811	143,583	114,478
Contract revenue, Axis-Shield agreement	671	651	2,015	1,953
Cost reimbursement, Axis-Shield agreement	-	-	677	581
Contract revenue, Sarepta, AskBio agreement	-	8,202	-	21,967
	30,804	48,664	146,275	138,979

Note 3 Long-term loan

On July 18, 2022, the Company entered into a US \$70.0 million funding agreement with NovaQuest. The funding was accounted for as a liability and classified as debt because the Company has an unavoidable obligation to settle the agreement in cash. The debt will be accounted for over the life of the agreement.

The net proceeds from the funding agreement totaled US \$69.2 million after the deduction of transaction costs.

In June 2025, Hansa and NovaQuest entered into agreements to restructure their existing debt agreement. As part of the restructuring, and in connection with the Directed Share Issue, Hansa offset approximately US \$14.875 million of its outstanding debt through the issuance of new shares at the same price as in the Directed Share Issue (the "First Tranche"). The First Tranche was resolved by the Company's Board of Directors under the authorization granted at the Annual General Meeting held on June 27, 2024, and with deviation from the shareholders' preferential rights.

On January 31, 2026, Hansa shall also pay NovaQuest US \$14.875 million (Second Tranche), either in ordinary shares or in cash, at the Company's discretion. If paid in shares, the subscription price will be the lower of (i) the subscription price in the Directed Share Issue or (ii) the volume-weighted average price (VWAP) of the Company's ordinary shares on Nasdaq Stockholm during the ten trading days immediately preceding the day before the resolution of the share issue.

NovaQuest has agreed to a lock-up for each share issue, restricting the sale or disposition of shares for a period of 180 calendar days from the respective issue date, subject to customary exceptions and the Company's prior written consent.

The remaining debt will be paid in three fixed cash payments scheduled for June 2027, June 2028 and January 2029. In addition, previously agreed approval-related payments will be eliminated. Under the restructured terms, total payments from Hansa to NovaQuest will be capped at US \$150.5 million an increase from the original agreement cap of US \$140.0 million. The NovaQuest debt restructuring actions were deemed to be non-substantive.

An updated version of the original security agreement entered into under the initial debt agreement remains in place under which the Company has granted NovaQuest a broad security interest in certain assets, proceeds and intellectual property rights related to imlifidase for use in kidney transplantation in highly sensitized patients and in the treatment of anti-GBM disease.

The new debt amendment resulted in modification of the original debt agreement. As a result, the debt was remeasured based on the net present value of the revised cash flows, discounted using a fair value effective interest rate. This remeasured amount was compared to the previous carrying value of the original debt, with any difference recognized as a gain or loss in the financial statements. Transaction costs incurred in connection with the new amendment were also recognized as part of a gain or loss calculation on the modification.

The Company records the difference between the principal and the total payments as interest expense over the term of the debt by applying the effective-interest-rate method. Based on the progress of the payments, the Company will recalculate the effective interest each reporting period until the debt obligation has been satisfied.

On September 30, 2025, the loan totaled 914.8 MSEK, including 391.3 MSEK in total accrued interest.

Note 4 Intangible assets – Internally-generated intangible assets

Expenditures related to research activities are recognized as expense in the period in which it is incurred. An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized only if all the following criteria have been demonstrated in accordance with IAS 38:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale:
- the intention to complete the intangible asset and use or sell it;

Financial Notes continued

- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible assets is the sum of the expenditures incurred from the date when the intangible asset first meets all the recognition criteria listed above. Development expenses, for which no internally-generated intangible asset can be identified, are expensed in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

The Company determined that IDEFIRIX and its conditional approval by EMA to enable kidney transplantation in highly sensitized patients met all the above criteria as of Q4 2022.

As of September 30, 2025, the total capitalized development expenses related to fulfilling the IDEFIRIX EMA post-approval commitments amount to 290.1 MSEK, with 90.4 MSEK capitalized during 2025. These capitalized development costs are subject to regular amortization over their useful life, which is projected to extend until the end of 2032. Total accumulated amortization at September 30, 2025 was 42.8 MSEK.

Glossary

Adeno-associated virus (AAV)

AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

Allogeneic hematopoietic stem cell transplantation

Allogeneic HSCT, also known as "bone-marrow" transplantation, involves transferring the stem cells from a healthy person (the donor) to the patient's body after high-intensity chemotherapy or radiation. The donated stem cells can come from either a related or an unrelated donor.

AMR

Antibody mediated transplant rejection.

Antibody

One type of protein produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM.

Anti-GBM disease (Goodpasture syndrome)

Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease

Diseases that occur when the body's immune system reacts against the body's own structures.

Biologics License Application (BLA)

A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

CD20

B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

Clinical studies

Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical phase 1

15

The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical phase 2

Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical phase 3

Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

DSA

Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

EMA

The European Medicines Agency (EMA) is an EU agency for the evaluation of medicinal products.

Enzyme

A protein that accelerates or starts a chemical reaction without itself being consumed.

ESO

The European Society for Organ Transplantation (ESOT) is an umbrella organisation which overlooks how transplantations are structured and streamlined.

FDA or US FDA

U.S. Food and Drug Administration.

Guillain-Barré syndrome

Guillain-Barré syndrome (GBS), is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

HBI

Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

HL

Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

laC

IgG, Immunoglobulin G, is the predominant type of antibody in

Imlifidase

Imiffidase, is the immunoglobulin G-degrading enzyme of Streptococcus pyogenes, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

IND

Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

INN

International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient.

In vitro

Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo

Term within biomedical science to indicate that experiments or observations are made in living organisms.

IVE

IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Marketing Authorization Application (MAA)

A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

Neutralizing Antibodies (NAbs)

NAb is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.

Pivotal trial

A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat life threatening or severely debilitating conditions.

Panel Reactive Antibody (PRA)

PRA is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development

Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

Randomized Control Trial (RCT)

RCT is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care.

Streptococcus pyogenes

A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

Standard of Care (SOC)

Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.

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