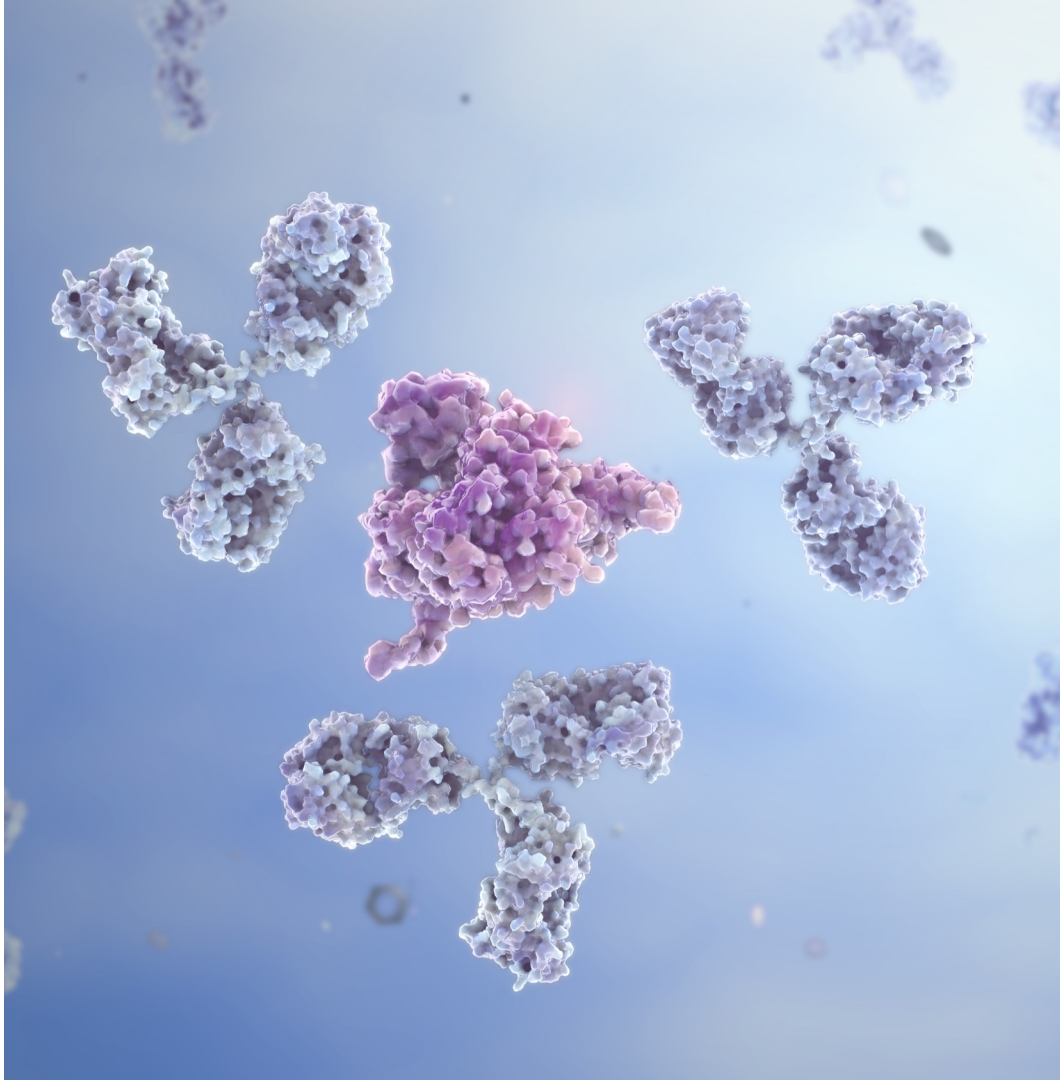
HANSA BIOPHARMA

Virtual event

Autoimmune Deep Dive

Guillain-Barré Syndrome

16 June 2025



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Speakers

Dr. David R. Cornblath

MD, Professor Emeritus, Neurology, Johns Hopkins University

Hitto Kaufmann

Chief R&D Officer, Hansa Biopharma

Dr. Simon Rinaldi

MRCP(Neuro), PhD, University of Oxford

Elisabeth Sonesson

VP, Global Franchise Lead Autoimmunity, Hansa Biopharma

Agenda

1 **Overview on Hansa**

Hitto Kaufmann, Chief R&D Officer

2 **Guillain-Barré Syndrome**

Dr David R. Cornblath, MD

3 **Results from the 15-HMedIdeS-09 single arm study**

Dr Simon Rinaldi, MRCP(Neuro), PhD

4 **Indirect analysis to IGOS real-world comparator group**

Elisabeth Sonesson, VP, Global Franchise Lead Autoimmunity

5 **Q&A**

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

FOCUS AREAS

DESENSITIZATION

- **Enabling Transplantation**
  First in class, paradigm shift for highly sensitized kidney transplant patients
- **Enabling Gene Therapy**
  Partnerships for pre-treatment to enable AAV gene therapy in patients with anti-AAV antibodies

RARE AUTOIMMUNE DISEASES

- **Anti-GBM and GBS**
  Clinical POC in two separate monophasic autoimmune disorders (anti GBM and GBS).
- **HNSA-5487**
  Next gen candidate with Phase 1b data shows promise of ability to re-dose

EU COMMERCIALIZATION

IDEFIRIX (imlifidase)

- **Conditional approval in Europe**
  for desensitization in kidney transplantation
- **Over 200 patients treated**
  utilization underscores clinical trial and real-world safety, tolerability and efficacy
- **Commercial-scale manufacturing**
  supports current and future launches

idefirix® (imlifidase)

KEY FACTS

- **Publicly traded on OMX NASDAQ Sweden**
  significant ownership from global biotech specialist investor
- **Strong IP portfolio**
  with coverage until the 2040s
- **Upcoming Catalysts in 2025**
  - US Phase 3 read out in 2H 2025 in Kidney Transplantation
  - Phase 3 read out in 2H 2025 in anti GBM
  - First clinical data in gene therapy (Sarepta Phase 1b)
  - US FDA BLA submission in kidney transplantation, subject to data

Two novel molecules focused on Autoimmune Disease and Desensitization in Gene Therapy and Transplantation

What is IgG

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

Benefits of IgG Reduction

Rapid IgG reduction key to halt disease progression
Depletion of IgG antibodies may halt disease progression and prevent organ damage

Safe, targeted treatments are needed
IgG driven diseases have limited, or no FDA approved treatments

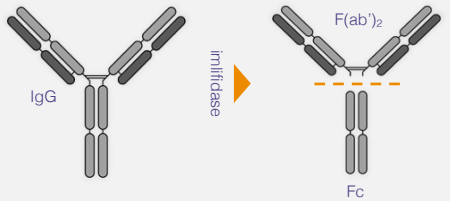
Market opportunity
Immune-mediated diseases are the largest field of research behind oncology

Hansa's IgG-cleaving Platform

Imlifidase – first gen, first in class IgG cleaving enzyme
Rapidly and effectively reduces IgG and inhibits its activity after one dose

Effectively and safely reduces IgG by > 95% in 2-6 hours

Conditionally approved in EU for desensitization in kidney transplantation, completed Phase 2 trials in Autoimmune disease (GBS, anti-GBM), ongoing clinical trials in Gene Therapy. Phase 3 readouts in kidney transplant and anti-GBM in 2H 2025



HNSA-5487 – next gen, IgG cleaving enzyme

Rapid and robust reduction in IgG with redosing potential

Targeting acute, or periodic exacerbations in Autoimmune diseases

Focused pipeline in Desensitization and Autoimmune Diseases

	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Partner	Upcoming Milestone
idefirix (imlifidase)	Desensitization Kidney Transplantation						2026: EU Ph 3 PAES data read out
	Desensitization Kidney Transplantation						2H 2025: ConfIdeS US Phase 3 data read out
	Desensitization Gene Therapy (Crigler Najjar)					GENETHON	2025: GNT-018-IDES complete enrolment
	Desensitization Gene Therapy (DMD)					SAREPTA	2025: SRP-9001-104 data read out
	Desensitization Gene Therapy (LGMD)					SAREPTA	Preclinical Research
	Autoimmune GBS						2025:15-HMedIdeS-09 data publication
	Autoimmune anti-GBM						2025: GOOD-IDES-02 data read out
	Autoimmune ANCA (Investigator Initiated Trial)[1]						2025: Complete enrolment

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

GUILLAIN-BARRE SYNDROME

David R. Cornblath, MD
Professor Emeritus, Neurology
Johns Hopkins University

Disclosures

- Consultant: Annexon Biosciences, Avilar Therapeutics, Boehringer Ingelheim, Dianthus Therapeutics, Grifols SA, Hansa Biopharma AB, Nuvig Pharma, Octapharma AG, Pfizer, Inc
- Data Safety Monitoring Board: Avidity Bio, Passage Bio, Vertex
- Technology Licensing: Worldwide Clinical Trials, Inc., Beijing 3E-Regenacy Pharmaceuticals Co., Ltd., Passage Bio, CMIC, MedImmune Ltd., Fundacion GELTAMO, RWS Life Sciences
- Scientific Advisory Board: Nervosave

GBS made simple

GBS is an antibody-mediated, auto-immune neuropathy in which complement fixing, IgG1/3 subclass, anti-ganglioside antibodies are induced through the mechanism of molecular mimicry with bacterial lipo-oliogosaccharides which may follow infections in susceptible individuals.

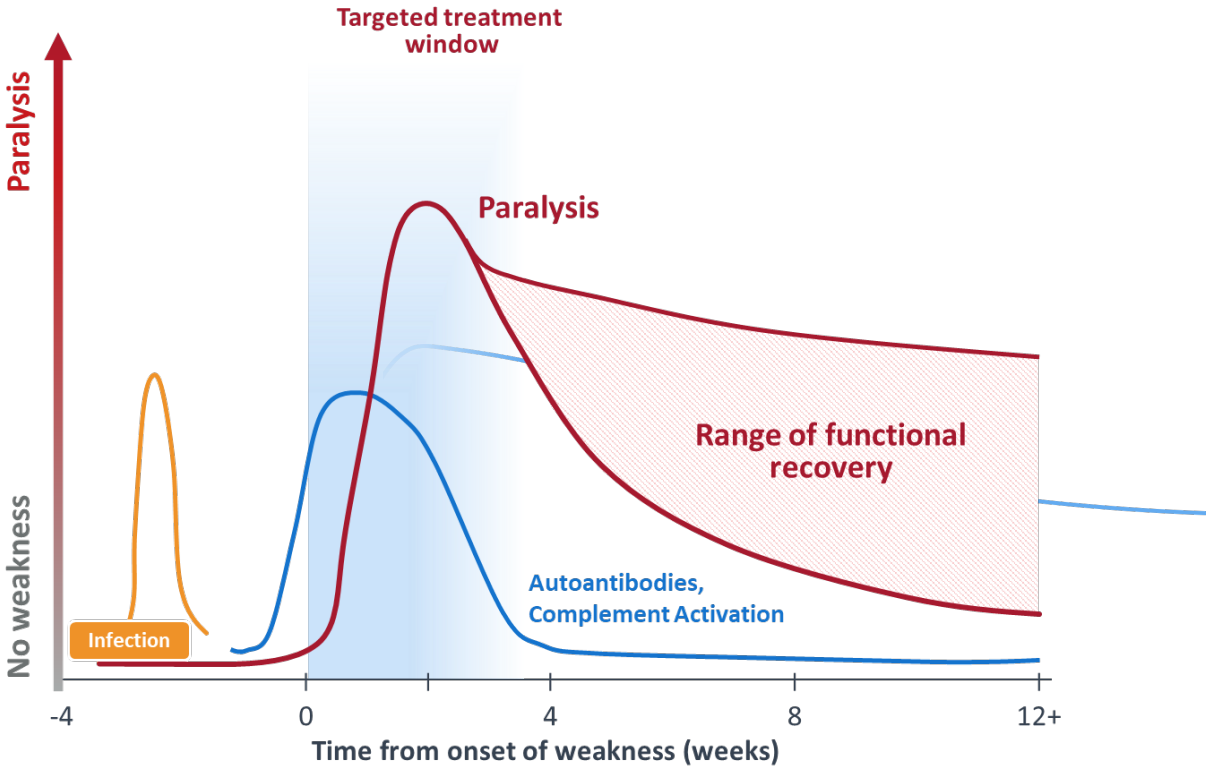
These antibodies are directed against epitopes present on peripheral nerves. The specificity of these antibodies largely determines the clinical spectrum (sensory-motor, pure motor, Miller Fisher syndrome, etc.).

GBS is “caused” by auto-antibodies which are contained in the IgG fraction of blood and “effected” at least partly by complement.

Current Treatments

- PLEX (plasma exchange) works by removing IgG and complement, as well as other components in the plasma.
- IVIg (intravenous immunoglobulin) works through several mechanisms including by interfering with “auto-antibodies” and complement.

Acute disease phase of GBS is short

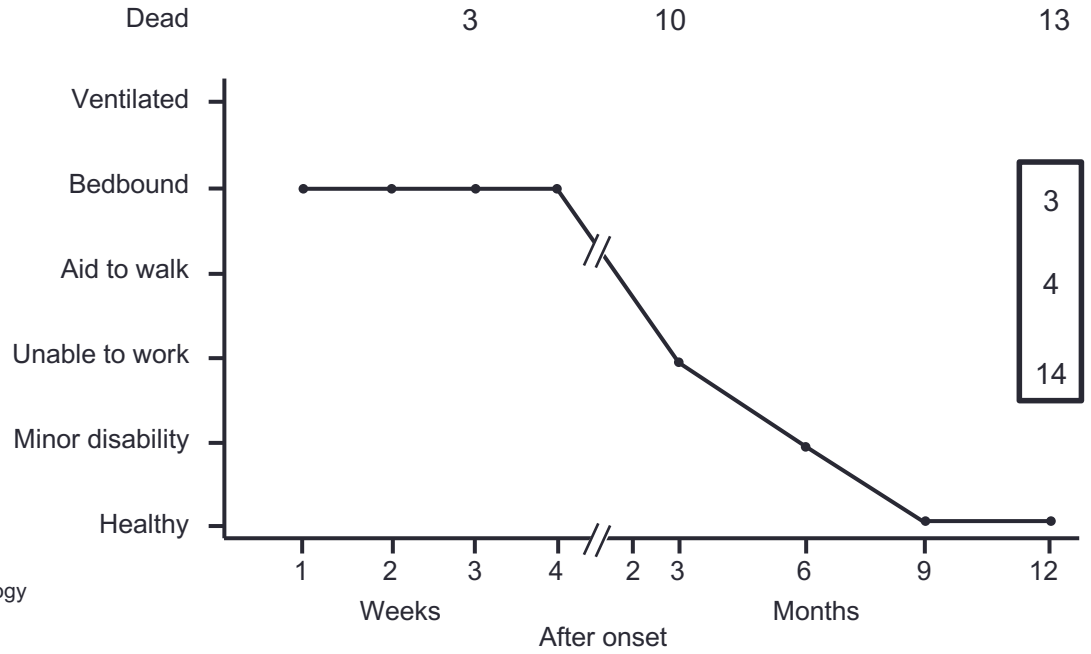


- GBS has an acute disease phase followed by spontaneous recovery
- Multiple mechanisms to target
- Target treatment window is likely within first 2 weeks

1. van den Berg B et al. *Nat Rev Neurol*. 2014;10(8):469-482. 2. Leonhard SE et al. *Nat Rev Neurol*. 2019;15(11):671-683.

Natural history of 100 patients with GBS from 1988

Graph adapted from:
Winer JB, Hughes RA, Osmond C. A prospective study of acute idiopathic neuropathy. I. Clinical features and their prognostic value. J Neurol Neurosurg Psychiatry 1988;51:605-12.



Richard A.C. Hughes
Emeritus Professor of Neurology at King's College London

In the 2000's:

3% – 7%
of patients still die as a result of the autoimmune attack.[1-3]

15-20%
of patients experience long-term impairments and reduced mobility.

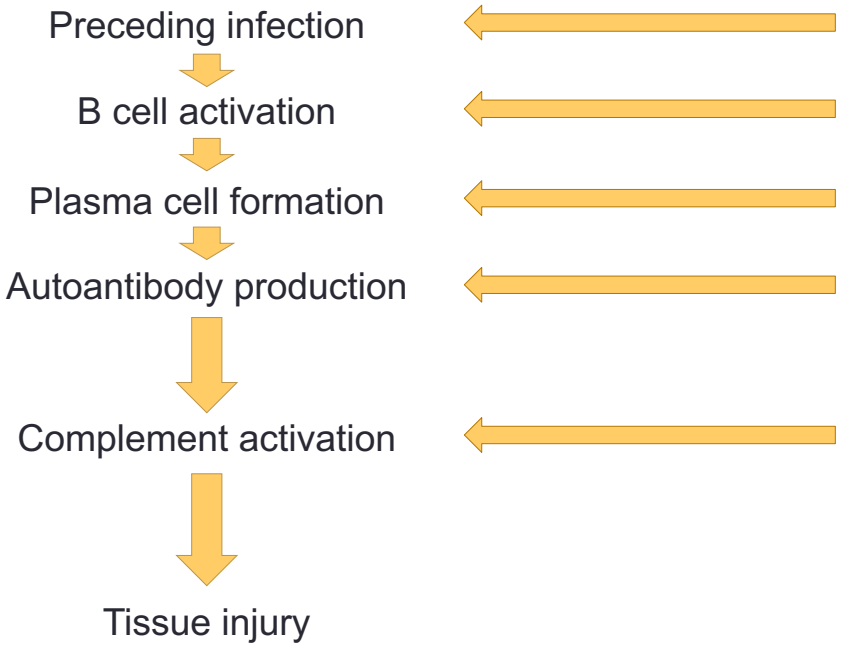
1. Fletcher DD, Lawn ND, Wolter TD, Wijdicks EF. Long-term outcome in patients with Guillain-Barre syndrome requiring mechanical ventilation. Neurology. 2000;54(12):2311–5.
2. Van den Berg B, Walgaard C, Drenthen J, Fokke C, Jacobs BC, van Doorn PA. Guillain-Barré syndrome: pathogenesis, diagnosis, treatment and prognosis. Nat Rev Neurol. 2014 Aug;10(8):469-82. doi: 10.1038/nrneurol.2014.121. Epub 2014 Jul 15. PMID: 25023340.
3. Leonhard SE, Papri N, Querol L, Rinaldi S, Shahrizaila N, Jacobs BC. Guillain-Barré syndrome. Nat Rev Dis Primers. 2024 Dec 19;10(1):97. doi: 10.1038/s41572-024-00580-4. PMID: 39702645.

Opportunities for Advancements in Treating GBS

Treatment for GBS has not changed in the last 30 years

- Based on disease mechanisms discovered since 1990, targeted immunotherapy treatments are now possible.
- The ideal treatment should have a rapid administration and onset of action given the 2-week treatment window.
- As disease mechanisms are same in all GBS subtypes, the clinical benefit of an early, targeted treatment would be across the entire disease spectrum.
- Targeted treatments should have minimal side-effects.

GBS pathogenesis and potential targeted therapies



(Avoid C. jejuni/Zika outbreaks)

B cell ablation

Plasma cell ablation

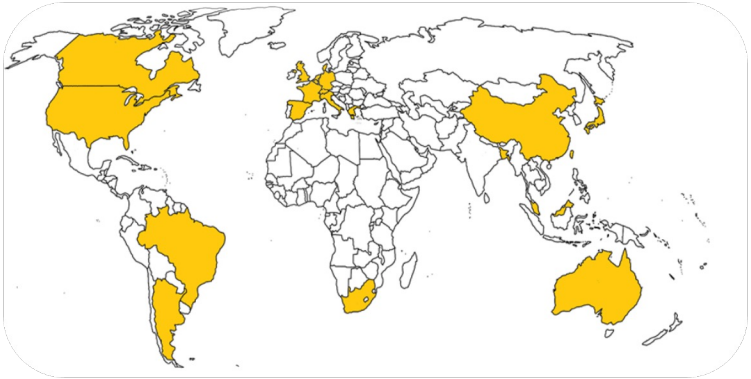
Antibody removal/destruction by imlifidase or anti-FcRn

Complement inhibition by anti-C1q,r,s, anti-C2, or anti-C5.

International GBS Outcome Study

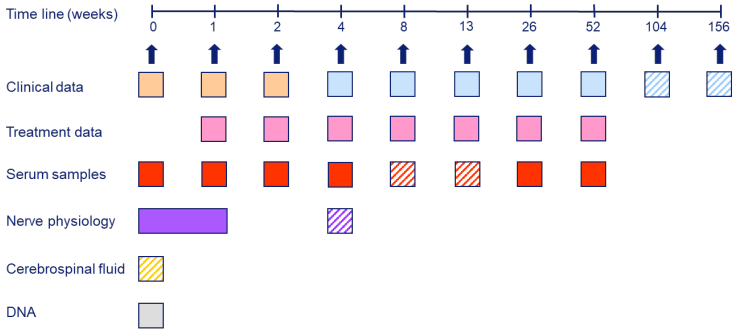
Observational prospective cohort study in GBS

2000 patients worldwide



- >160 hospitals
- Entire clinical spectrum of GBS

Follow-up 1-3 years



- Serial clinical and treatment data
- Electrophysiology, biosamples

Jacobs et al. J Peripher Nerv Syst 2017

IGOS

Overview of data currently available in IGOS-2000

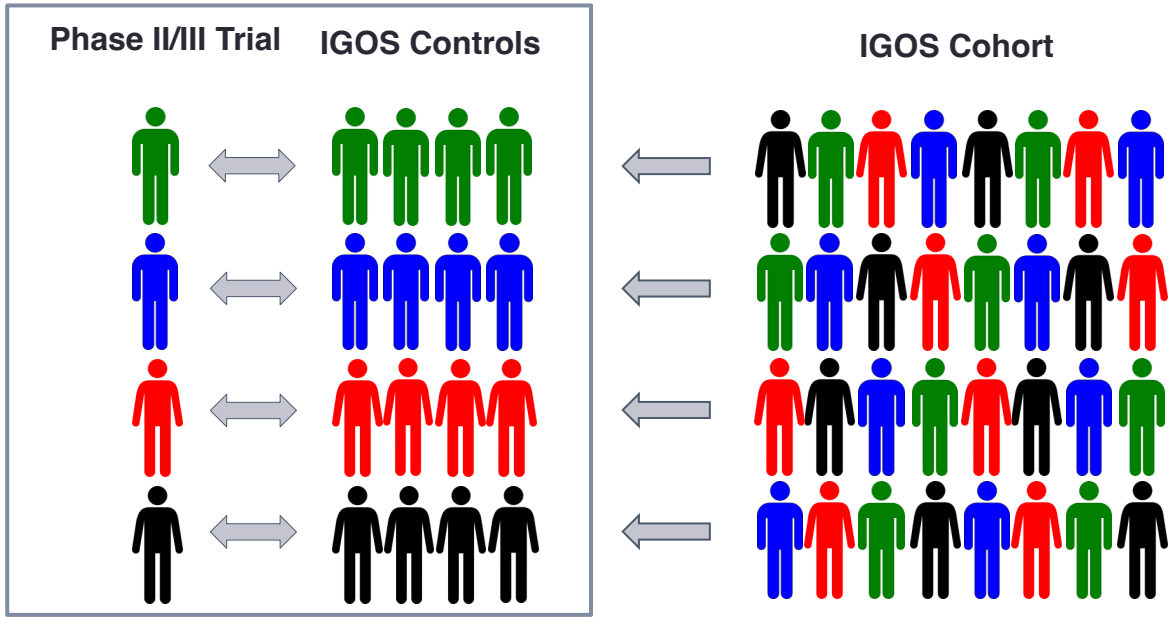
- **Clinical data:**
  - Demography, antecedent events, neurological examinations (MRC scores, cranial nerves, sensory deficits), GBS-DS and other clinical outcome measures, PROMS (I-RODS, FSS, pain (VAS)).
  - Key clinical diagnostic findings
  - Treatments and clinical response and courses

- **Key diagnostic investigations:**
  - CSF results (protein, cells, albumin)
  - Nerve electrophysiology results, automated subtype classification, serial recordings in subgroup

- **Biomarkers:**
  - Preceding infections (*C. jejuni*, EBV, CMV, HEV, *M. pneumonaie*)
  - IgM/IgG/IgA to glycolipids (>400 antibody reactivities, glyco-array Glasgow) and others (ongoing)
  - Serum albumin, IgG, NfL and proteomics (testing ongoing)
  - GWAS data (Illumina) (data analysis ongoing)

New treatments for GBS can compare their results to the IGOS cohort for Go/No Go decisions

Matching Adjusted Indirect Comparison and Propensity Matching



15-HMedIdeS-09

An open-label, single arm, multi-centre, phase II study investigating safety, tolerability, efficacy, pharmacodynamics and pharmacokinetics of imlifidase (IdeS) in patients with Guillain-Barré Syndrome (GBS)

Overview of trial design and results

A/Prof Simon Rinaldi

Overview of the Phase 2 trial design (15-HMedIdeS-09)

- Open-label, single arm, multi-centre trial (UK, France, NL) of imlifidase followed by SoC IVIg
- 30 patients with severe GBS* included (GBS DS ≥3, unable to walk 10m unassisted, within 10 days of onset)
- Single dose of 0.25 mg/kg imlifidase on day 1
- SoC IVIg started on day 3
- Assessment of efficacy using multiple measures
  - Disability (GBS DS / iRODS), strength (MRC SS), requirement/duration of mechanical ventilation/ICU

* diagnosed according to NINDS criteria

15-HMedIdeS-09 patient demographics

		15-HMedIdeS-09, N=27 n (%)
Median Age		60
Female Gender		13 (48)
Baseline GBS DS	3 4 5	6 (22) 20 (74) 1 (4)
Baseline MRC sum score	N Median Mean (SD)	27 42 39 (14)
Mean days from onset of weakness to start of treatment (SD)		4.5 (1.8)
Cranial nerve involvement at baseline		12 (44)
Presence of diarrhea (<4 wks prior to screening)		15 (56)

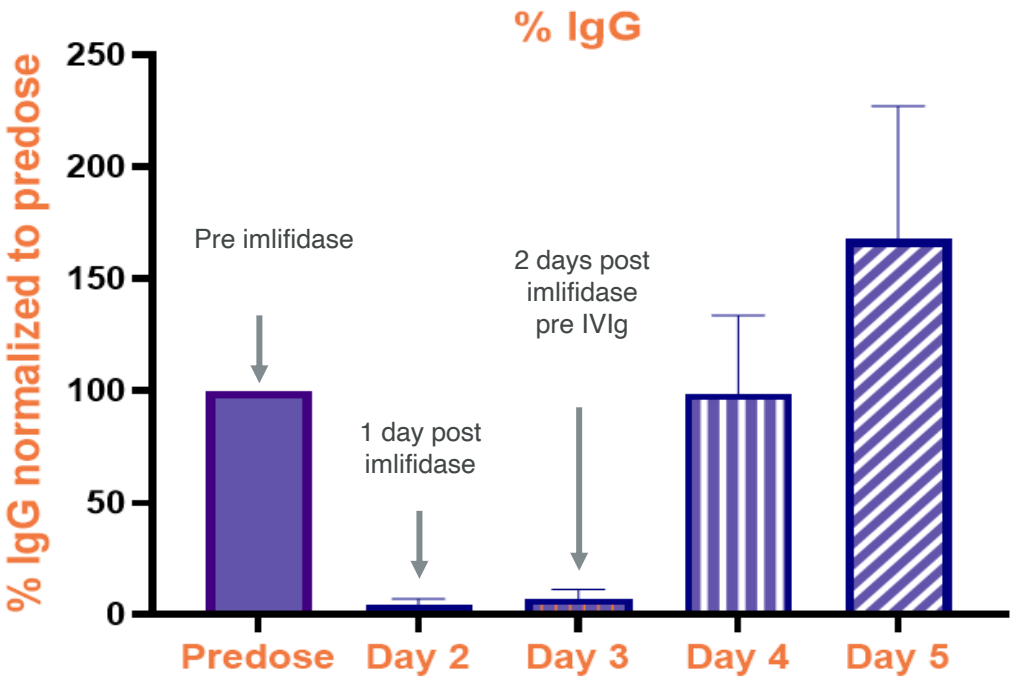
✓ During the trial, 3 patients were re-diagnosed with other conditions*, leaving 27 patients with confirmed severe GBS (GBS disability score 3-5) eligible for efficacy evaluation

GBS DS

0 Healthy
1 Minor sx, able to run
2 Unable to run
3 Unable to walk 10m without help
4 Bedridden / chair bound
5 Requiring mechanical ventilation
6 Dead

* CIDP, encephalomyelitis and combined central and peripheral demyelination

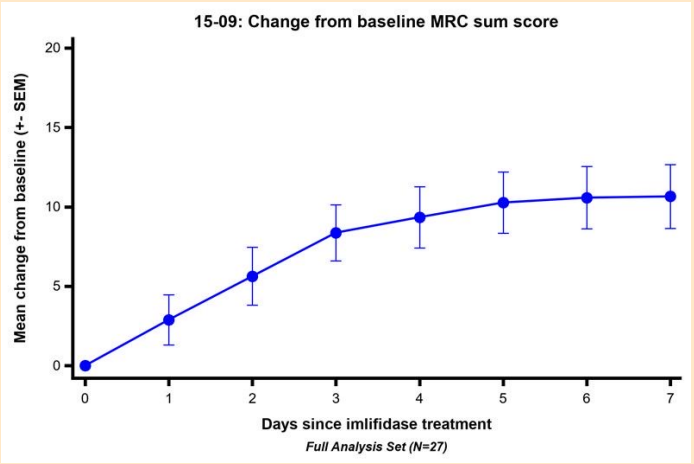
Total IgG was rapidly reduced by imlifidase and restored with IVIg treatment

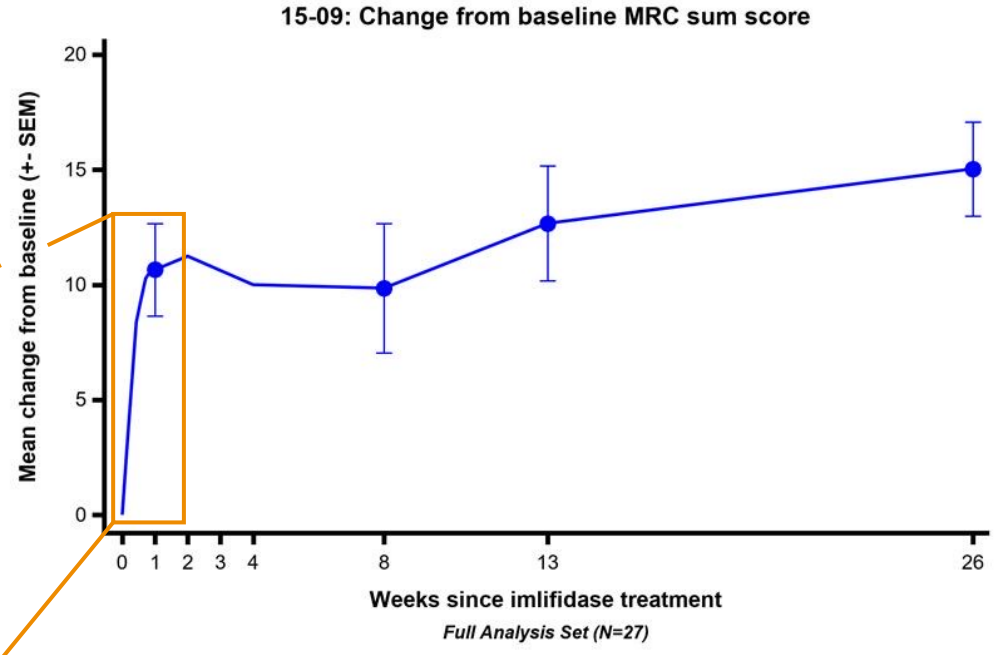


- ✓ Imlifidase rapidly reduces total IgG
- ✓ Standard of care IVIg is initiated 48 h after imlifidase and IgG levels return to normal

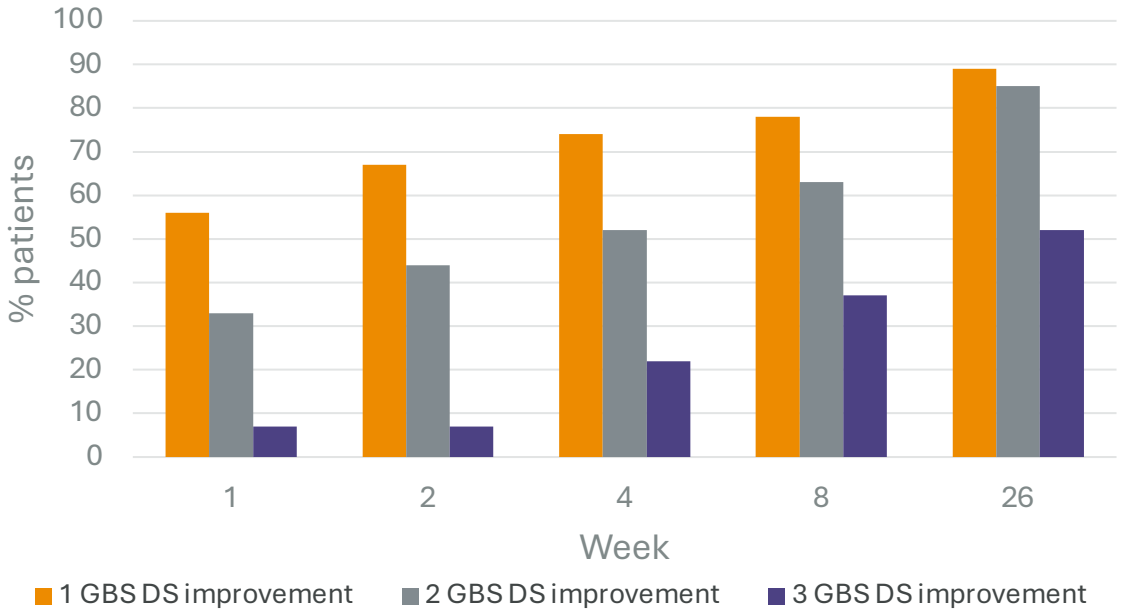
Mean change in MRC sum score over time in patients treated with imlifidase in combination with IVIg

- ✓ MRC sum scores increased early following imlifidase dosing
- ✓ Mean baseline MRC sum score: 39 points
- ✓ Mean MRC Sum score improvement at one week in muscle strength: 10.7 points
- ✓ Continued improvement throughout the follow up period



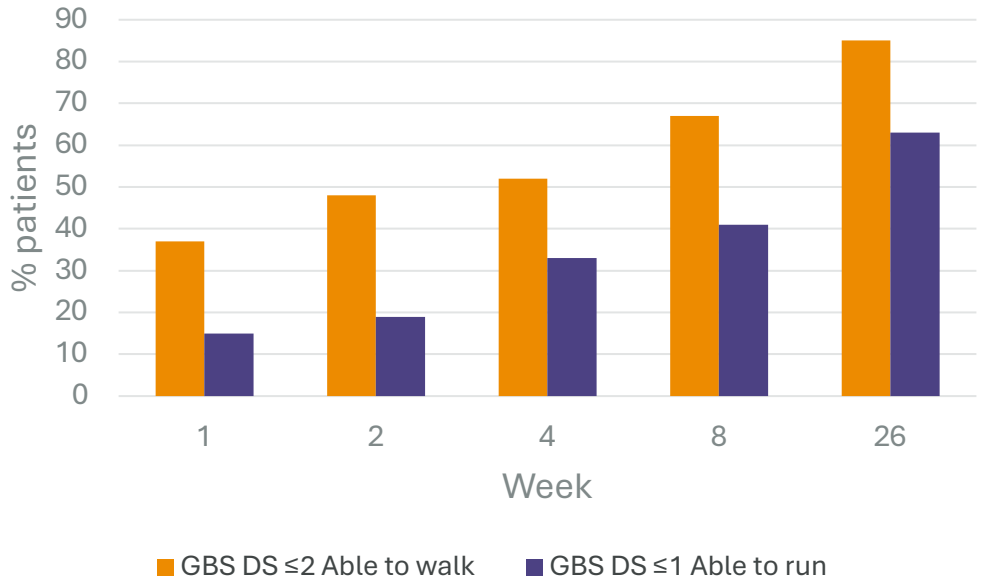


Improvement in GBS DS with at least 1, 2 and 3 grades over time in patients treated with imlifidase followed by IVIg



- ✓ Fast improvement of the functional status was observed
- ✓ Already at 1 week 56% of patients had improved by at least 1 grade in GBS DS
- ✓ Continued improvement in GBS symptoms over time was observed

Proportion of patients treated with imlifidase in combination with IVIg that are able to walk and run over time



- ✓ At 1 week, 10 patients (37%) were able to walk independently, and 4 patients (15%) were able to run
- ✓ At 4 weeks,14 patients (52%) were able walk independently and 9 patients (33%) were able to run
- ✓ At 6 months 23 patients (85%) were able to walk independently, and 18 patients (63%) were able to run

Rapid overall improvement in functional status

- Fast return to independently walking; median time to independently walk was **16 days**
- Improvement by at least one grade on GBS disability score at median time of **6 days**

Safety

- The administration of imlifidase followed by IVIg to patients diagnosed with severe GBS was safe and well tolerated
- Treatment emergent AEs (TEAEs) occurring from the time of administration of trial medication up until Day 29 were reported in 25/30 participants
- No TEAEs led to withdrawal or treatment discontinuation
- No relevant changes in vital signs and ECG were observed
- Reports reflect a range of complications seen in GBS patients treated with SOC

Summary

Imlifidase produced a rapid fall in endogenous serum IgG levels

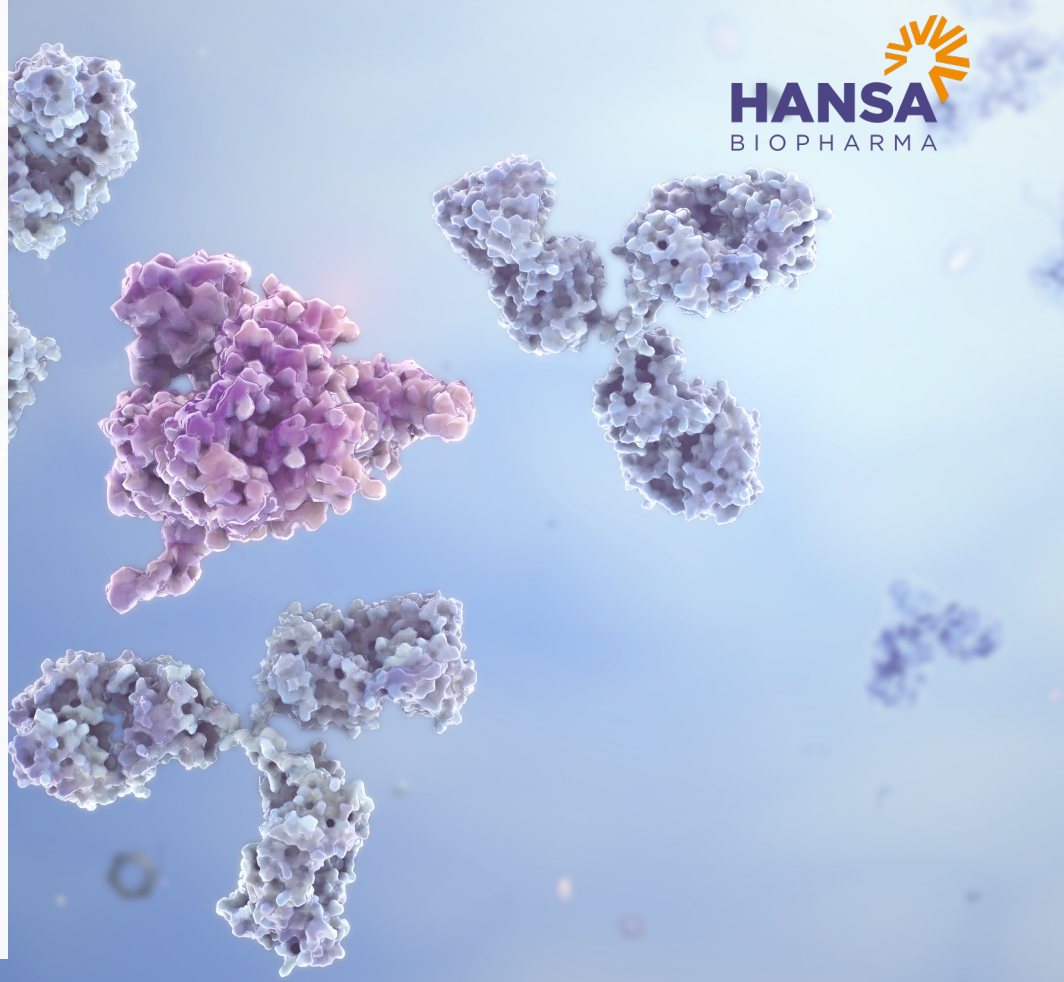
There was an associated rapid improvement in strength and disability

The infusion was well tolerated and appears safe in combination with IVIg SOC

15-HMedIdeS-09 indirect analysis to IGOS real-world comparator group treated with IVIg

Elisabeth Sonesson

Global Franchise Lead Autoimmunity



Contextualization objectives

Support Hansa Biopharma in evidence-based decision making for imlifidase in the treatment of Guillain-Barré Syndrome (GBS), using data from a single-arm trial (15-HMedIdeS-09) and applying the appropriate methodologies for comparative effectiveness

The output of this work addresses the following aim:

To perform unanchored matching adjusted indirect comparisons (MAIC) to compare outcomes of GBS patients treated with imlifidase + intravenous immunoglobulin (IVIg) vs patients treated with only IVIg using data derived from the International Guillain-Barré Syndrome Outcome Study (IGOS)

Abbreviations: GBS, Guillain-Barré Syndrome; IGOS, International Guillain-Barré Syndrome Outcome Study; MAIC, Matching Adjusted Treatment Comparison;

15-HMedIdeS-09 patient data and IGOS real-world comparator data are similar

		15-HMedIdeS-09 imlifidase + IVIg N=27	IGOS IVIg N=754
Media Age		60	60
Female Gender n (%)		13 (48)	319 (42)
Baseline GBS DS n (%)	3	6 (22)	218 (29)
	4	20 (74)	478 (63)
	5	1 (4)	58 (8)
Baseline MRC sum score	N	27	747
	Median	42	45
	Mean (SD)	39 (14)	41 (15)
Mean days from onset of weakness to start of treatment (SD)		4.5 (1.8)	5.6 (3.1)
Cranial Involvement at baseline		12 (44)	329 (44)
Presence of diarrhea (<4 wks prior to screening)		15 (56)	211/752 (28)

- ✓ Propensity score weighting using all available IGOS patients treated with IVIg and with GBS DS ≥3.
- ✓ Imlifidase + IVIg treatment arm patients were weighted to match external control prognostic variables.
- ✓ Weighted prognostic variables included:
  - Time from weakness onset to treatment initiation
  - Age
  - GBS DS
  - Cranial nerve involvement
  - MRC sum score
  - preceding diarrhea

Contextualization method

Matching Adjusted Indirect Comparison (unanchored)
following guidance from NICE DSU TSD 18[1,2]

27
Severe GBS patients imlifidase

Individual patient level data

vs.

754
Severe GBS patients IVIg IGOS

IGOS aggregate patient population data for severe GBS patients treated with IVIg

Reweighting

	Original unadjusted population	After matching-adjusted weighting
15-HMedIdeS-09 (Imlifidase+IVIg) Patients		
IGOS (IVIg) Patients		

Endpoints analyzed

- Median time to one point improvement in GBS disability (GBS DS)
- Median time to return to independently walking (GBS DS ≤ 2)
- Proportion of patients independently walking at 1, 2 and 4 weeks following initiation of imlifidase treatment

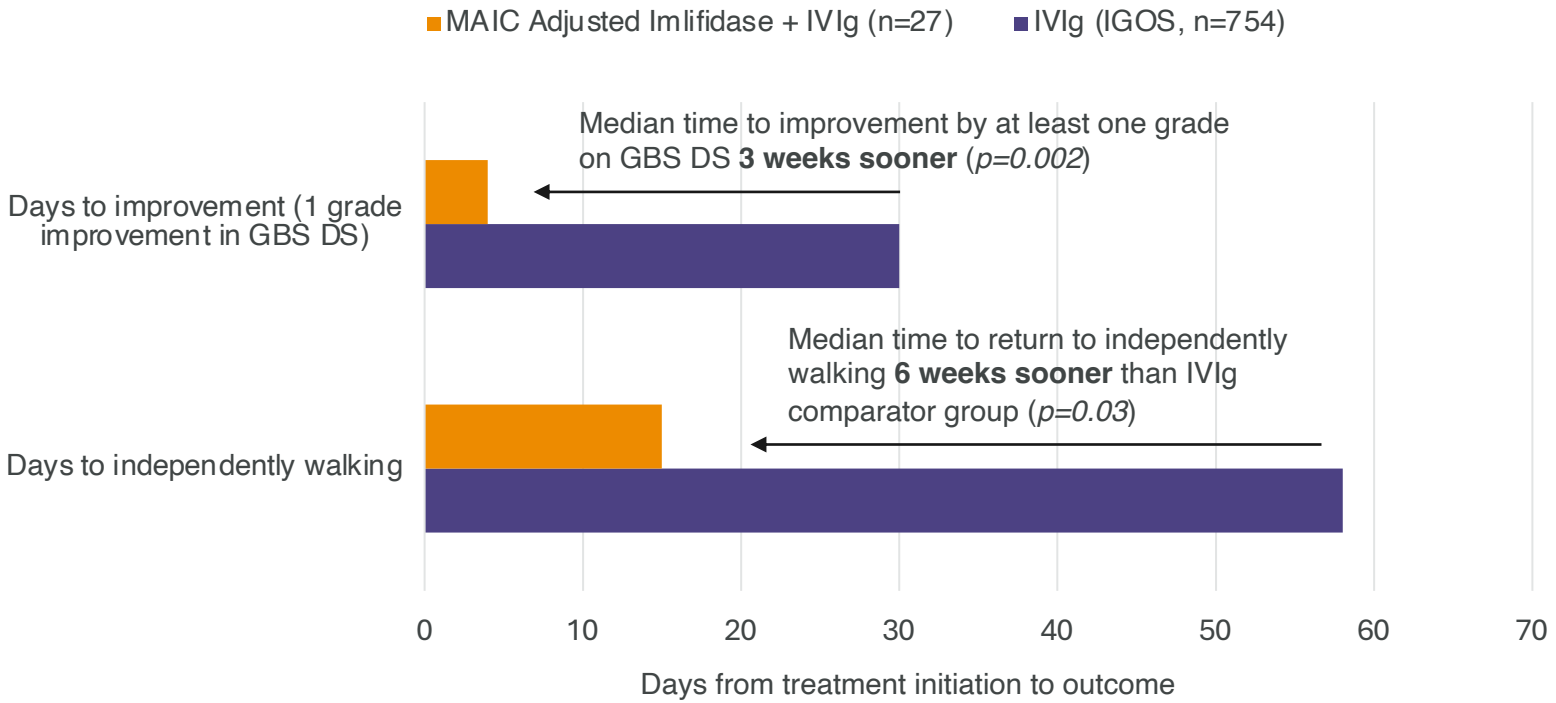
Sensitivity analyses were performed to assess the robustness of the results to changes in covariate selection

Abbreviations: GBS, Guillain-Barré Syndrome; IVIg, intravenous immunoglobulin; PE, plasma exchange; IGOS, International GBS Outcome Study

1. Phillippo DM, et al. NICE DSU Technical Support Document 18. 2016. 2. Phillippo DM, et al. Med Decis Making. 2018;38(2):200-211.

Indirect treatment comparison

Imlifidase + IVIg demonstrates rapid and sustained benefit over IVIg of severe GBS patients

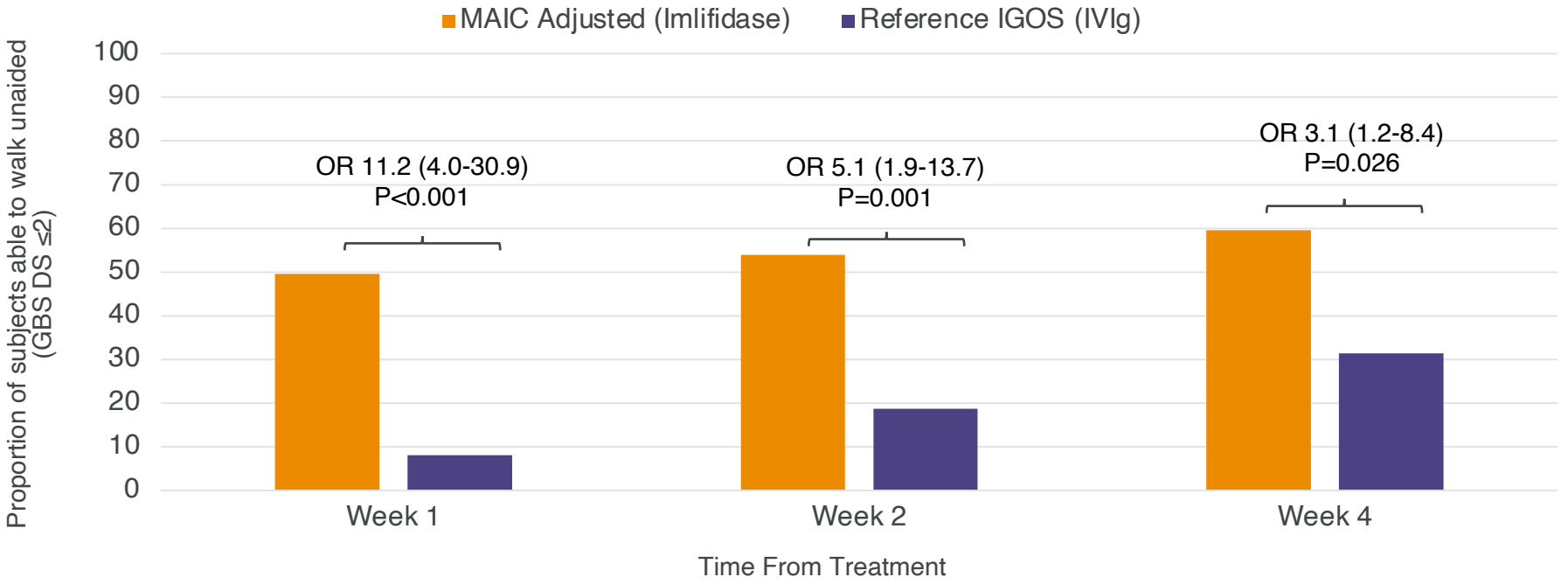


Abbreviations: IVIg, intravenous immunoglobulin; MAIC, matching-adjusted indirect comparison; IGOS, International GBS Outcome Study

MAIC Adjusted for days from weakness onset to treatment initiation, and baseline values for: age, GBS DS, cranial nerve involvement, MRC sum score, preceding diarrhea

Indirect treatment comparison

Imlifidase + IVIg demonstrates rapid and sustained benefit over IVIg of severe GBS patient able to return to unaided walking over the first 4 weeks after treatment



Abbreviations: IVIg, intravenous immunoglobulin; MAIC, matching-adjusted indirect comparison; IGOS, International GBS Outcome Study

MAIC Adjusted for days from weakness onset to treatment initiation, and baseline values for: age, GBS DS, cranial nerve involvement, MRC sum score, preceding diarrhea

Ushering a breakthrough in the treatment of GBS

There remains significant unmet medical need in GBS

- Treatment options for GBS patients have not changed in the last 30 years
- There is no FDA-approved therapy in U.S.
- IVIg is the only approved therapy in the EU

Imlifidase in combination with standard of care IVIg delivers rapid and sustained benefit to patients with severe GBS

- Median time to return to independently walking 6 weeks sooner compared to IGOS-IVIg group
- Median time to improvement by at least one grade on GBS DS 3 weeks sooner compared to IGOS-IVIg group

Q&A

Dr. David R. Cornblath

MD, Professor Emeritus, Neurology, Johns Hopkins University

Hitto Kaufmann

Chief R&D Officer, Hansa Biopharma

Dr. Simon Rinaldi

MRCP(Neuro), PhD, University of Oxford

Elisabeth Sonesson

VP, Global Franchise Lead Autoimmunity, Hansa Biopharma

HANSA BIOPHARMA

Virtual event

Autoimmune Deep Dive

Guillain-Barré Syndrome

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