InnoMedica Business Case Neurology

Talineuren (TLN): Regenerative Therapy for Parkinson‘s Disease

Fall 2025

Executive Summary

- Parkinsons disease is a widespread progressive nervous system disorder. No existing drug can halt disease progression. There is a clear need for a new drug generation.

- Talineuren (TLN) is the world's first clinical nanoparticle to cross the blood-brain barrier, delivering neuroprotective GM1 to the CNS. Talineuren indicates potential to halt Parkinson's disease progression.

- Talineuren's potential to halt Pakinsons's disease progression, together with a favorable safety profile, have been indicated in a Phase I/IIa trial with treatments over up to three years. A Phase IIb trial with placebo control and biomarker analysis is planned for 2026.

- InnoMedica, a Swiss-based biotech with approx. 50 employees, develops Talineuren in Parkinson's disease, along with other indications and pipeline products based on its proprietary liposomal technology, based on strong IP rights and inhouse GMP production capabilities.

«If this actually provides disease modification, it will mean a change in paradigm; and will be widely prescribed»

Director of Neurological Disorders Outreach and Professor of Neurology In a prestigious Research & Medical center in the East Coast, US, July 2025 (source: IQVIA)

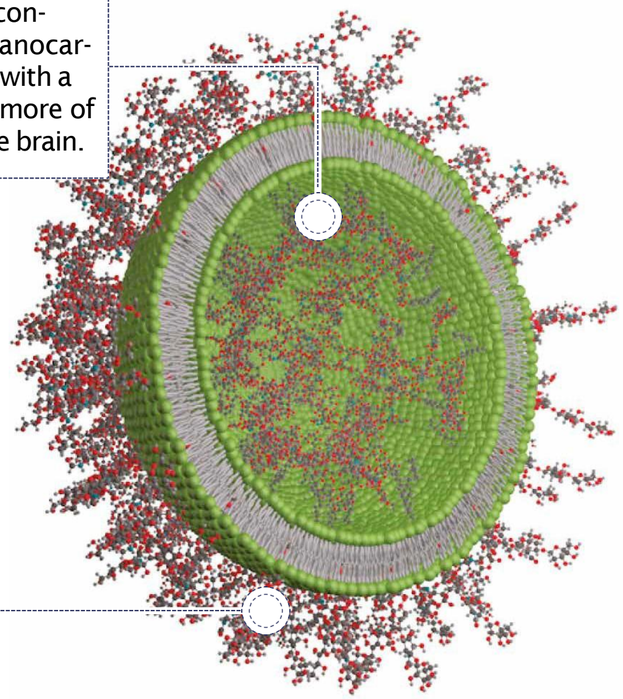
Talineuren at a Glance

Talineuren is a biological nanoparticle and consists of 100% endogenous molecular building blocks.

Nanostructure of Talineuren

Transport shell

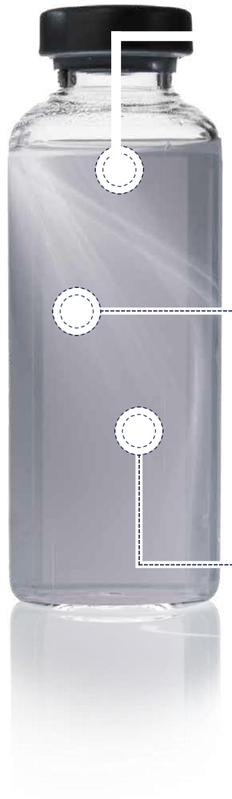
Being 30 nanometers in size and constructed from natural lipids, the nanocarrier endows the active ingredient with a «targeting mechanism,» allowing more of the active ingredients to reach the brain.



Active ingredient

The glycolipid GM1 ganglioside is an integral part of the lipid envelope of the nanocarrier and is released upon uptake by the cells.

Unique features of Talineuren



Penetrating the blood-brain barrier

Talineuren crosses the blood-brain barrier in a targeted manner and transports GM1 to the affected nerve cells.

High safety

Long-known endogenous active ingredient with good tolerability

Potential

Application in various neurodegenerative diseases (e.g. Alzheimer‘s disease)

Urgent Need for Regenerative Therapies for Parkinson’s Disease

Talineuren as a first-in-class treatment for Parkinson’s disease.

Background

- Parkinson’s disease, a progressive disease of the nervous system, is one of the most common neurological diseases, especially in old age. The causes of Parkinson’s are unknown.
- At least 9.4 million people are affected worldwide, and around 1.2 million in Europe.
- The incidence of Parkinson’s has doubled in the last 25 years.
- Parkinson’s causes high costs (around USD 52 billion per year in the USA).

Treatment and research

- Treatment of the symptoms is possible, but the disease progresses relentlessly.
- Standard treatment with dopamine (levodopa) alleviates symptoms but is limited in its effect as the disease progresses.
- Recent research successes enable earlier diagnosis of the disease and thus an earlier start of treatment.
- Research focuses on dopamine precursors and antagonists, cell therapies and other forms of therapy at the experimental stage.

High demand for therapeutic innovations

- Development of therapies that modify the course of Parkinson’s disease, not just alleviate symptoms.
- Permanent improvement in tremor, gait, balance, posture, dexterity and communication skills.
- Ensuring early treatment before severe symptoms arise, as the burden on patients increases significantly as the disease progresses.

Talineuren opens up new perspectives for Parkinson’s treatment with its neuroprotective and regenerative effects.

Benefits of the Active Ingredient GM1 in Parkinson's Disease

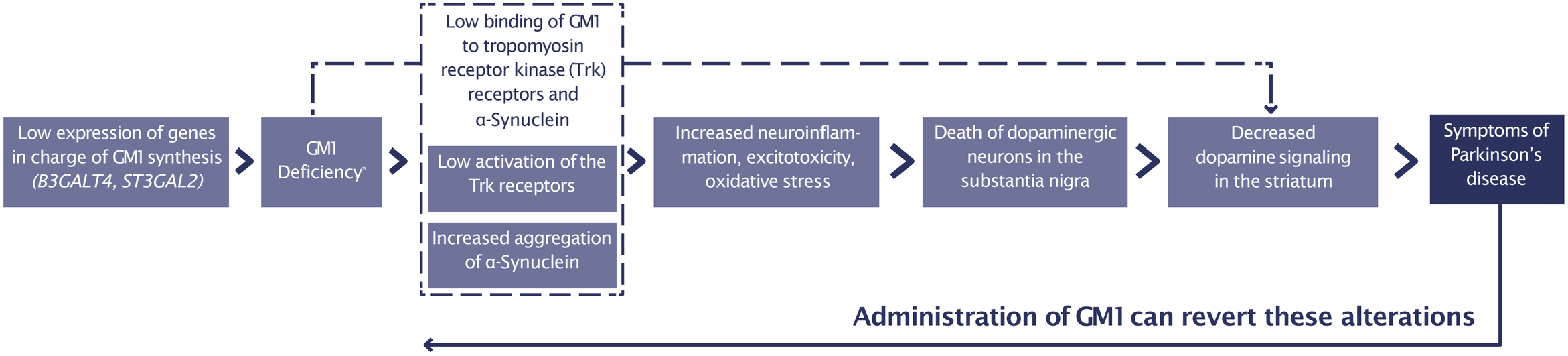
The endogenous substance stimulates various neuroprotective and regenerative processes.

GM1 ganglioside is a natural component of cell membranes and is mainly found in nerve cells. Parkinson's patients have been shown to have insufficient GM1 of their own. Low level of GM1 can lead to the death of nerve cells in the brain.

GM1 is multifunctional

- Strengthens and protects neurons
- Strengthens the body's own dopamine production
- Promotes neuronal growth and nerve cell interaction
- Binds protein aggregates such as α-synuclein

GM1 deficit in Parkinson's disease



*Studies by Robert Ledeen et al. (2022) and Mylene Huebecker et al. (2019) show that there is less GM1 in the central nervous system of Parkinson's patients than in healthy people.

How Does GM1 Reach the Brain with Talineuren?

Talineuren transports GM1 to the diseased nerve cells and enables their regeneration.

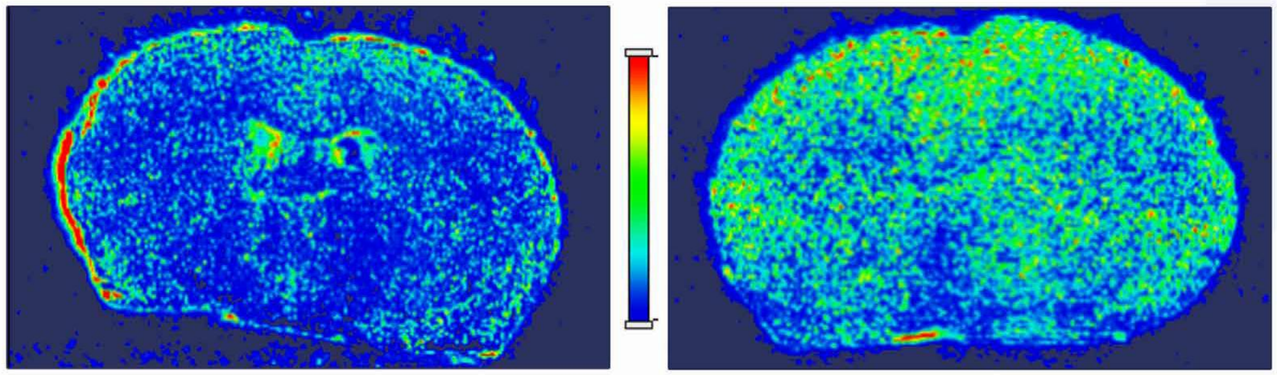
Talineuren is a revolutionary drug: For the first time, it is possible to specifically transport GM1 across the blood-brain barrier.

- Therapies with GM1 are finally possible —a molecule that is normally blocked by the blood-brain barrier.
- The full potential of GM1 can be unlocked. Previous studies show the highly regenerative effect of GM1.* Due to the lack of transport to the brain and the high side effects of standard injection, GM1 could not previously be used for the treatment of Parkinson‘s disease.
- The pharmaceutical industry has not pursued extensive research with GM1, as GM1 cannot be patented in its free form.

Talineuren delivers GM1 to the damaged nerve cells

- Crossing of the blood-brain barrier through GM1 nanoparticles, administered intravenously once a week.
- Talineuren‘s nanoparticles deliver large amounts of GM1 into the central nervous system, where it exerts its effect on the nerve cells.

Talineuren delivers GM1 into the brain



Mouse brain scan without Talineuren treatment

Mouse brain scan after Talineuren treatment

MALDI imaging mass spectrometry of brain cross-sections of untreated mice (left) and mice treated with orally administered Talineuren (right). The intensity scale shows the amount of GM1 detected in the brain. Significantly more GM1 is detectable after treatment with Talineuren.

*Study by J. S. Schneider et al. (2020) showed that the administration of GM1 improves symptoms in Parkinson‘s patients. However, the very high concentration of free GM1 (100 mg subcutaneously, twice daily) caused significant side effects such as blood clots and bruising at the injection site.

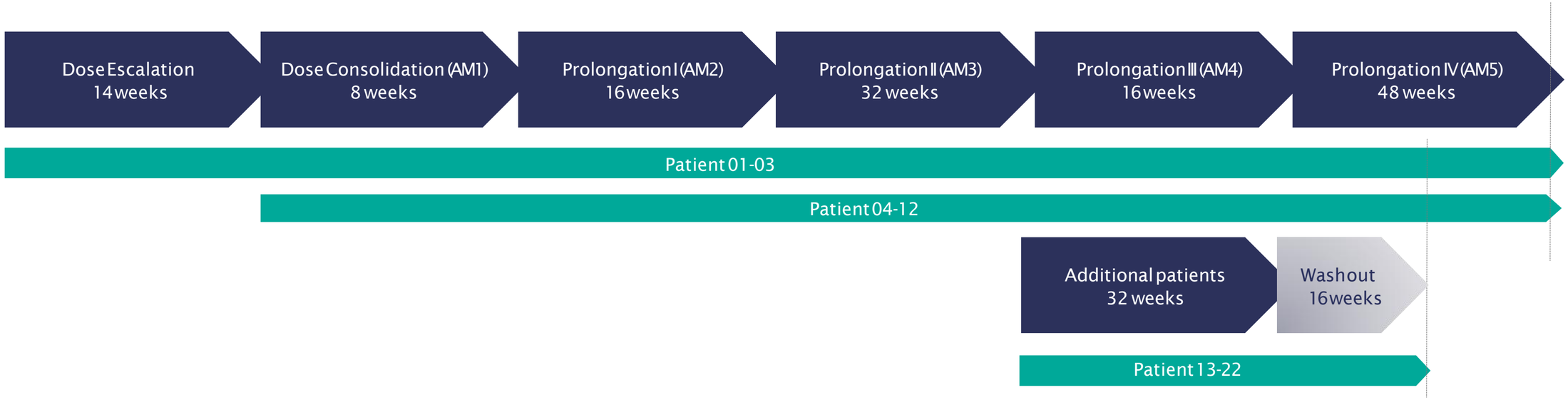
NEON Study – Safety Evaluation of Intravenous Talineuren

Phase I/IIa Trial

Safety Evaluation of Intravenous Talineuren in Parkinson's Disease-affected Patients. An open-label single arm interventional trial, add-on therapy

- Primary outcome: Safety (Occurrence of AE, SAE)
- Secondary outcome: Preliminary Efficacy (MDS-UPDRS, LEDD and other)

Promising results in dose consolidation phase and patient desire for continued treatment led to four trial prolongations. Additional patients were included to replicate initial results from first cohort and to further investigate safety in early administrations



NEON Study – Talineuren Halts Disease Progression

Stabilization of Parkinson's disease in ALL 11 patients over 24 to 30 months with good tolerability of the weekly infusion*

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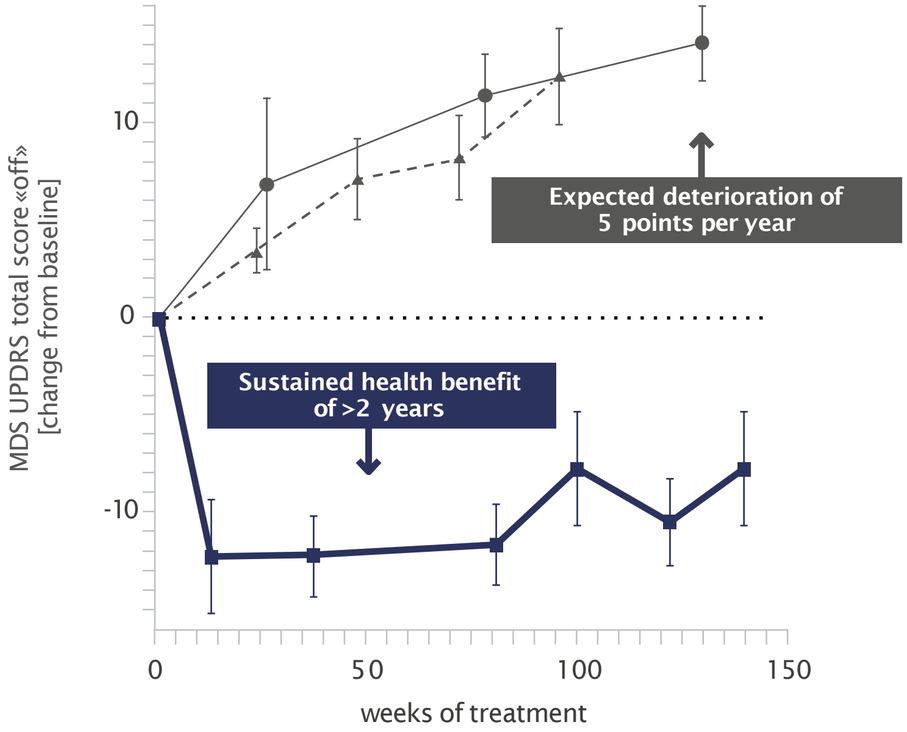
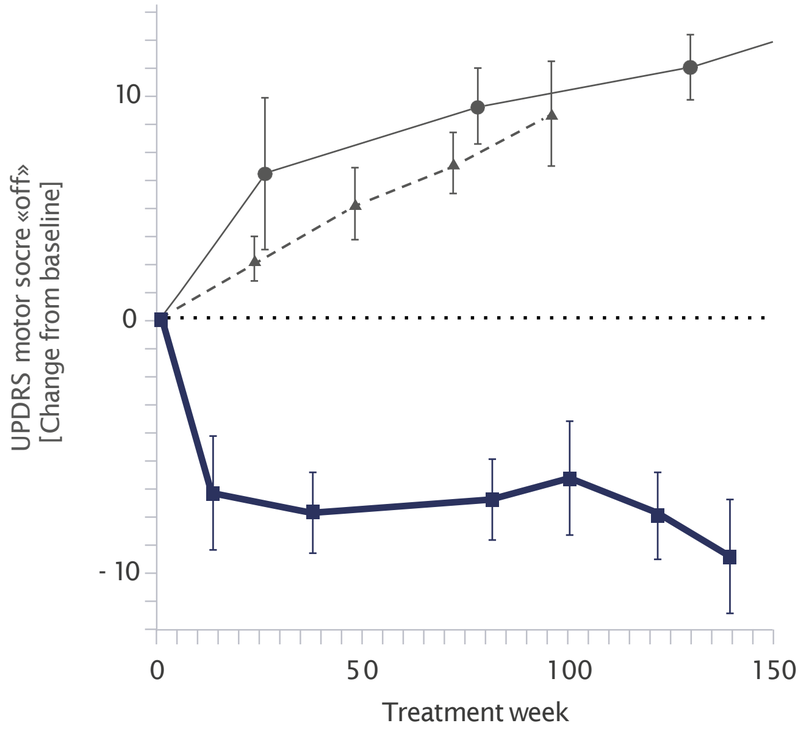
UPDRS total score, change from baseline



UPDRS motor score, change from baseline



early-stage Parkinson's patients in the Parkinson's Progression Markers Initiative (Simuni et al. 2018)
control patients (Schneider et al. 2013)
Talineuren

* The Unified Parkinson's Disease Rating Scale (UPDRS) measures disease progression in Parkinson's. On average, the score increases by about 5 points per year.
88 treatments administered over a total period of up to 30 months due to treatment-free intervals.
First part of the study published (PLOS Medicine), further publications inpreparation.

NEON Study – How Can Talineuren Be Safely Dosed?

What does the safety extension of the NEON study show?

Background

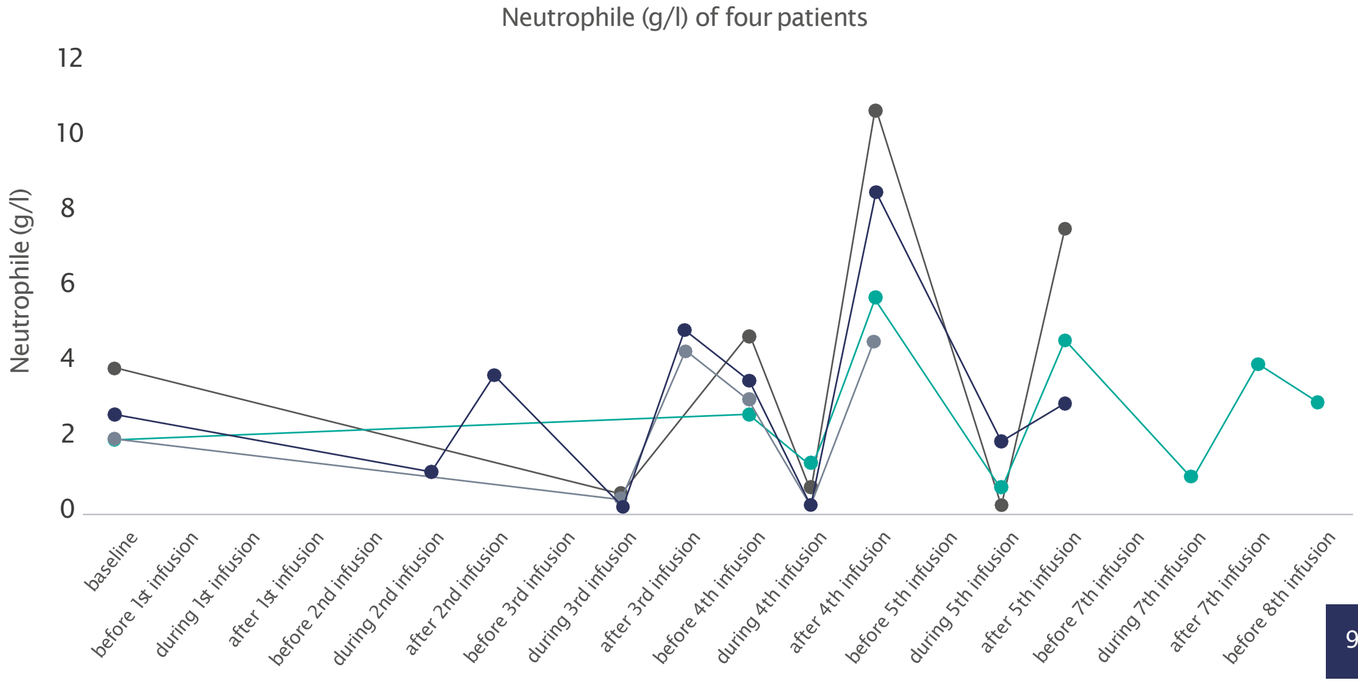
An infusion reaction in the NEON study was observed in 60% of patients 01–12 (7 out of 12) during the 2nd, 3rd, or 4th treatment. Reactions included neck pain, headache, and a rash at the injection site.

Key findings

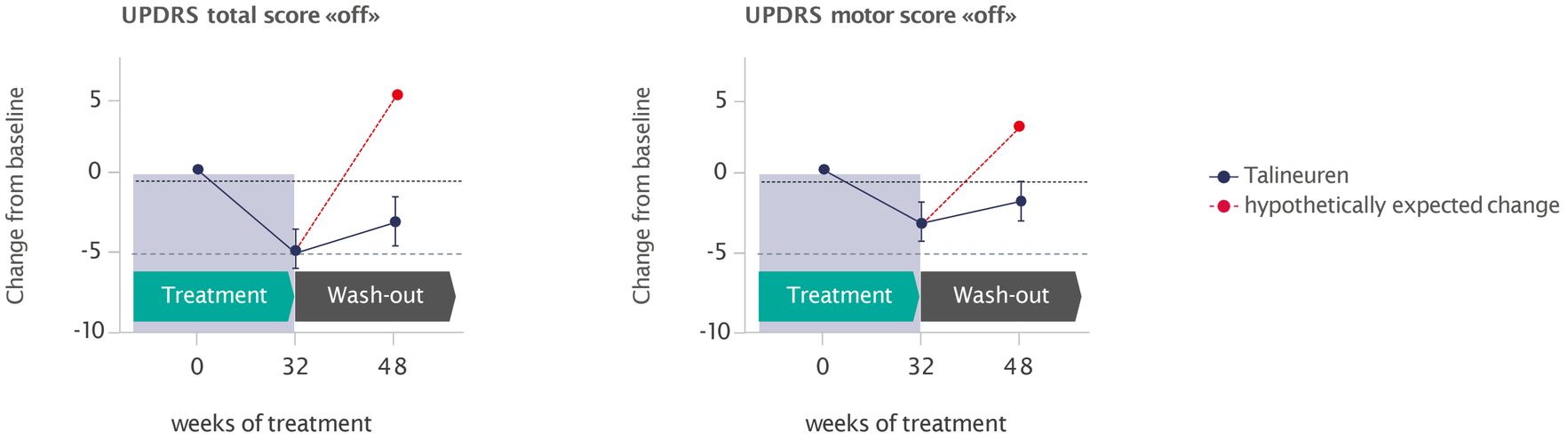
- Controlled infusion speed resulted in only 1 patient experiencing mild infusion reactions.
- Transient pseudo-neutropenia was observed in some patients, with values fully restored within 1–2 hours after infusion start. These occurred only in the early phase of the study (adaptation effect).

Study design

10 patients were included in the safety extension in order to investigate the mechanism of this reaction, to test the administration regimen, and to prevent infusion reactions.



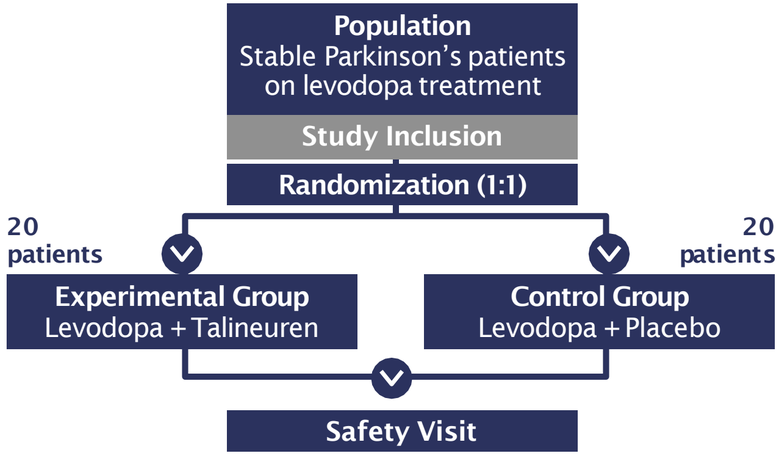
NEON Study – Safety Extension / Efficacy Data



- If Talineuren only suppressed the symptoms of Parkinson's while the disease continued to progress in the background, an average UPDRS score increase of **4 to 5 points** above baseline would be expected after 48 weeks (hypothetical red line).
- However, the UPDRS score measured after 48 weeks remains significantly below baseline. This is further evidence of Talineuren's disease-slowing effect.
- The UPDRS score measured 16weeks after therapy discontinuation is about 1.5 to 2 points higher than at 32 weeks. This indicates that therapy with Talineuren should be continued, as Parkinson's disease progresses at the expected rate without treatment.
- In the NEON study, treatments have now been completed. A follow-up observation phase of 12months is underway to analyze whether disease progression accelerates again.

Upcoming: LIBRA Study – Trial Design

The placebo-controlled assessment of Talineuren's efficacy in accordance with regulatory standards.



LIBRA trial: Phase IIb

- Phase II trial approved by Swissmedic and Swissethics with conditions. Treatment of Parkinson's patients in summer 2026
- Fully randomized, placebo-controlled study (20+20 patients), treatment duration 4 months (expected total duration 1.5 years).
- Cost estimate CHF 3 million (approx. CHF 1.5 million for study management, CHF 1.5 million for Talineuren on a CoGS basis). Study fully set up, including databases, monitoring, etc.
- Study start postponed (awaiting Swissmedic approval) and requires adjustments of the Talineuren formulation.
- Applications for PRIME/Breakthrough Therapy Designation based on interim results, once NEON results are confirmed.

LIBRA Study – Biomarkers

Further evidence on Talineuren's mode of action.

	Family of biomarkers in the context of PD	Biomarker	Sample	Changes in this biomarker have been clinically associated with:
1	α-synuclein species	total α-synuclein	plasma	cognitive decline (Lin, Yang et al. 2017)
2	Inflammatory mediators	Selected cytokines (TNF- α, IL1-β, IL-2, IL-6, IL-10, IFN-γ)	serum	motor progression and lower cognitive status (Williams-Gray, Wijeyekoon et al. 2016, Rathnayake, Chang and Udagama 2019)
		C-reactive protein (CRP)	serum	reduced life prognosis (Sawada, Oeda et al. 2015)
		Neutrophil-to-lymphocyte ratio	whole blood	indicative of overall inflammatory status (Munoz-Delgado, Macias-Garcia et al. 2021)
3	Mitochondrial dysfunction, iron homeostasis and oxidative stress	Ferritin	serum	low antioxidants alter ROS/RNS production and dysregulate iron homeostasis, contribute to alterations observed in the pathophysiology of PD (neurodegeneration) (Medeiros, Schumacher-Schuh et al. 2016)
		Iron	serum	
		Transferrin	serum	
		NOx	serum	
		Thiobarbituric acid reactive substances (TBARS)	serum	
		Advanced oxidation protein products (AOPP)	plasma	
4	Axonal damage	Neurofilament (NfL)	serum	motor impairment and cognitive decline (Ye, Locascio et al. 2021) (Niemann, Lezius et al. 2021) (Ygland Rodstrom, Mattsson-Carlgren et al. 2022)
5	Neurotrophins	Brain-derived neuronal factor (BDNF)	serum	cognitive impairment, depression, and restless legs syndrome (Azman and Zakaria 2022)

How Large Is the Market Potential of Talineuren?

Talineuren holds the realistic potential to achieve a breakthrough in the treatment of Parkinson's disease and other neurological disorders. This view is supported by the encouraging clinical data to date as well as by positive feedback from leading neurologists, pharmaceutical companies, and international Parkinson's foundations.

Phase IIa results demonstrated an exceptional efficacy profile combined with excellent tolerability —a combination that has not been observed before. To scientifically and regulatorily substantiate these findings, confirmation is now being pursued in a standardized, placebo-controlled study.

The economic potential of Talineuren can currently only be estimated within a range. Conservative market analyses forecast peak sales in the single-digit billion range, while more optimistic scenarios project **annual peak sales of over CHF 40 billion in the U.S. alone.** What is decisive is that the market for neurodegenerative diseases is growing strongly, with a high unmet medical need for **disease-modifying therapies.** Should Talineuren become the first drug to demonstrate a proven disease-modifying effect in Parkinson's disease, it could not only usher in a new era of treatment but also drive broad market adoption and corresponding revenue potential.

IQVIA

Moderate development risk	Sales from 2031 onwards	Following supply chain scale up, annually	Peak sales (conservative estimate IQVIA)	8 years of market exclusivity through patent protection
	CHF > 200 millions	> CHF 1 billion	> CHF 5 billion	Total cumulative > CHF 30 billion

Which Patents Protect the Market Potential of Talineuren?

InnoMedica's global patents on formulation, applications, and indications form the basis for commercial access to major markets in neurology.

Crossing the blood-brain barrier with Talineuren: Core neurology patent

Blood brain barrier crossing liposomes against neurodegenerative diseases: Liposomes comprising sphingomyelin (2017)

Inventor: Dr. Stéfan Halbherr (InnoMedica)

Europe: EP 3 501 495 A1, International WIPO(PCT): WO 2019 122220 A1, Canada: CA3086279A1, China: CN111787905A, Japan: JP7374500B2, USA: US11607385B2

Granted main claim:
«Liposomes for the treatment of neurodegenerative diseases and spinal cord injuries, comprising: sphingomyelin in a lipid bilayer which are configured to cross a blood-brain barrier, wherein the liposome is essentially free of ganglioside.»

Talineuren and Parkinson

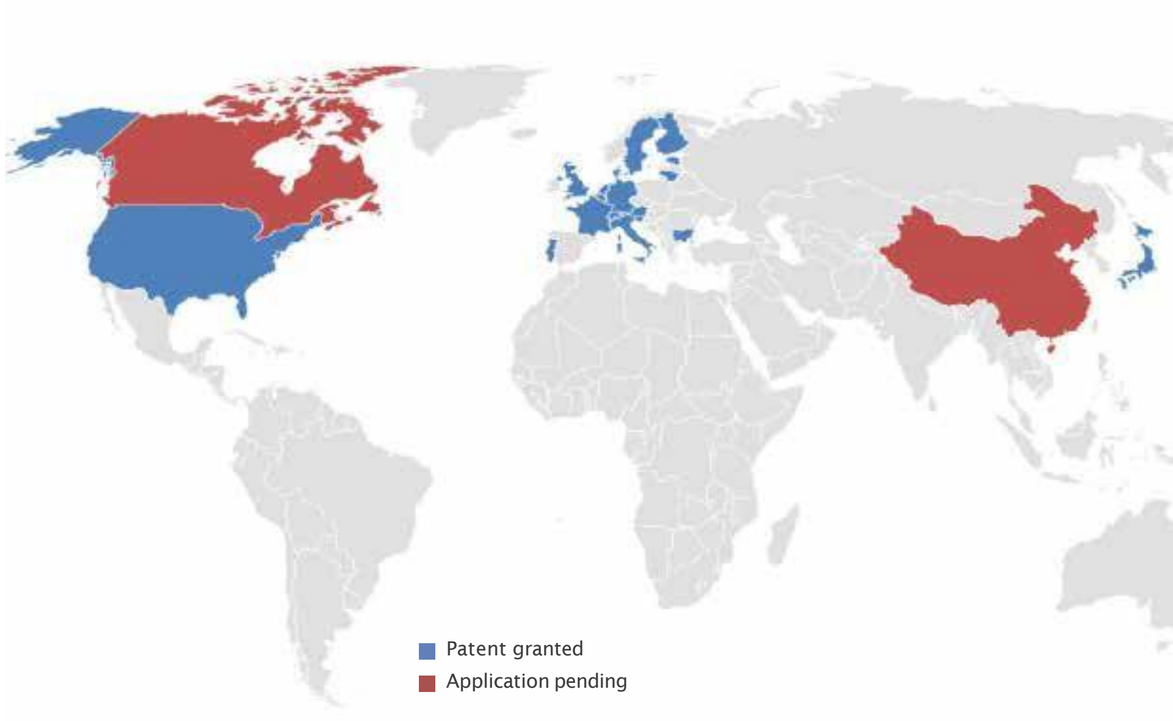
Patent application in February 2023 for Talineuren in Parkinson's disease, covering the treatment regimen and clinical data from the NEON study. The patent application was published in July 2023.

Talineuren: Liposomal composition for use in a method of treating Parkinson's disease (2023)

Inventors: Dr. Stéfan Halbherr and Dr. Camille Peitsch (InnoMedica)

Publication: July 2023

Filed main claim:
«Method for treating Parkinson's disease in a patient in need thereof, comprising administering to said patient a liposomal composition comprising sphingomyelin in a lipid bilayer and a therapeutically effective amount of GM1.»



InnoMedica's Neurology Patents

Liposomes comprising sphingomyelin

Country	Application number	Application date	Granted number	Date of granting	End of protection
EU*	18825700.0	20.12.2018	3 727 328	07.02.2024	20.12.2038
UK	18825700.0	20.12.2018	3 727 328	07.02.2024	20.12.2038
Japan	2020-554586	20.12.2018	7374500	27.10.2023	20.12.2038
Switzerland	18825700.0	20.12.2018	3 727 328	07.02.2024	20.12.2038
USA	16/956,239	20.12.2018	11'607'385	21.03.2023	13.01.2039
Canada	3'086'279	20.12.2018			(2038)
China	201880089924.X	20.12.2018			(2038)

* Unitary Patent countries: Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Austria, Portugal, Sweden, Slovenia.

Liposomal composition for use in a method of treating Parkinson's disease

Country	Application number	Application date	Granted number	Date of granting	End of protection
worldwide	PCT/EP2024/05107 1	17.01.2024			(2044)

Accelerated procedure ongoing in the EU (Unitary Patent), United Kingdom, and Switzerland.

Where Is Talineuren Produced?

In the NanoFactory – InnoMedica's proprietary manufacturing platform for growth and quality

- **Own GMP production in Marly (Switzerland)**
  «independent, flexible, scalable»
- **Proprietary lipid nanoparticle technology**
  «The process is the product»
- **Full control over quality, costs, and timelines**
- **Ready for clinical and commercial quantities**
  «exponentially scalable»
- **Strategic advantage for approval and partnerships**

How Is InnoMedica Holding AG Organized?

Supported by a broad shareholder base with a strong shareholder pool: CHF 87 million raised to date.

Corporate Structure

InnoMedica Holding AG
Headquarters: Zug
Shares: 15,998,808 at CHF 0.10 per share
Issues research mandate to InnoMedica Schweiz AG

Management:
Dr. Stéfan Halbherr, CEO
Dr. Martin Stähle, CFO
Andrea Zurkirchen

InnoMedica Schweiz AG
Headquarters: Bern
Share capital: CHF 100,000
Owned 100% by Holding

Dr. Stéfan Halbherr
Pascal Halbherr
Andrea Zurkirchen
Dr. Martin Stähle

InnoMedica Deutschland GmbH
Headquarters: Freiburg im Breisgau
Share capital: EUR 100,000
Owned 100% by Holding

Dr. Stéfan Halbherr

YDDS
Headquarters: Ibaraki
Share capital: YEN 10million
Owned 100% by Holding

Dr. Noboru Yamazaki

Executive Board of InnoMedica Holding AG

CEO

Co-founder
Stéfan Halbherr
Dr. rer. nat.,
Universität Bern

Head Investor Relation, Legal, Stab

Co-founder
Andrea Zurkirchen
lic. phil.,
Universität Zürich

CFO

With InnoMedica for 7 years
Martin Stähle
Dr. oec.,
Universität Hohenheim

Well-coordinated team
- Clear division of roles and strong mutual trust
- Leadership continuity through long-standing experience within InnoMedica

The Board of Directors of InnoMedica

Martin Scholl

CEO ZKB

2007–2022

Startup-investor Verve Ventures

Prof. Dr. Patrick Hunziker

President of the International Society for Nanomedicine

Deputy Head of Intensive Care Medicine, University Hospital Basel

Christian Mauriand

Global Head Corporate Development Roivant

Sale of assets worth over USD 11 billion (incl. acquisition of Telavant by Roche)

Prof. Dr. Urs Wälchli (President)

Professor of Corporate Finance (Simon Business School, London Business School, Université de Neuchâtel, Rochester-Bern Executive Programs)

Entrepreneur, advisor, board member

Dr. Leila Nobs

Scientific Director at TRB Chemedica International SA, Genf

Pharmacist

Pascal Brenneisen

CEO Novartis Switzerland 2011–2015, 15'000 15'000 employees, USD 800m revenue

Serial entrepreneur in pharma and medtech industry

Dr. Denis Bron (Vice president)

Chief Physician, Swiss Air Force

Neurological research (Harvard Medical School, Boston)

InnoMedica offers a Highly Attractive Pipeline Portfolio

Program	Product	Indication	Phase
Neurology	**TLN-1** GM1 Ganglioside	Parkinson's Disease	Clinical Phase II
	TLN-1 GM1 Ganglioside	ALS	Preclinics
Oncology	**TLD-1** Doxorubicin	Soft Tissue Sarcoma STS	Clinical Phase III
	L-Vincristine Vincristine	Leukemia	Preclinics
	TLTaxel Docetaxel	Under investigation	Preclinics
	TL-AD Doxorubidin and Alendronate	Combined chemotherapy and immune therapy	Preclinics
Diagnostics	**Talitrace**	Diagnostic tumor marker for precise surgical removal	Preclinics
	TLD-S Zr89	Screening with radiotracer for PET-imaging	Preclinics

Contact

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