

Clinical Trials for Parkinson’s Disease Drug Therapies: What Happened During Q4 2024?

Q4 2024 Trial Status Headlines (ref. dashboards pgs. 5-9)

What trials have . . .

Begun recruiting?

Recruiting began for nine trials including four of particular interest:

- A Phase 3 trial of solengepras (a selective GPR6 inverse agonist from Cerevance) in patients with motor complications
- A Phase 2 trial of BIIB122 (LRRK2 inhibitor from Biogen & Denali) in patients with LRRK2-associated PD
- A small (n=24) Phase 2 trial of exidavnemab (Mab targeting aggregated aSN) from BioArcticAB
- A Phase 1 cell replacement therapy trial of autologous midbrain dopaminergic progenitor cells at Massachusetts General Hospital

Three other trials were newly listed but not yet recruiting at quarter end including a Phase 2 trial of NEU-411 (another LRRK2 inhibitor – this one from Neuron23), and a Phase 2 repurposing study of varenicline (partial nicotine receptor agonist approved for smoking cessation) looking at reducing falls in PD

Completed enrollment?

Six trials completed enrollment:

- A Phase 3 open-label extension trial of tavapadon (dopamine D1/5 partial agonist) available to patients who completed the various Phase 3 tavapadon trials
- A Phase 2 trial of solengepras (selective GPR6 inverse agonist from Cerevance) as monotherapy in early PD
- A small (n=30) Phase 2 trial of intranasal insulin sponsored by HealthPartners Institute
- The Phase 1 STEM-PD cell replacement therapy study (Lund University & University of Cambridge) using allogenic ventral midbrain dopaminergic progenitor cells
- A Phase 1 trial at the University of Arizona of allopregnanolone (positive allosteric modulator of GABA) as a potential regenerative treatment
- A Phase 1 trial at the University of Kentucky of autologous unconditioned peripheral nerve tissue delivered bilaterally to the substantia nigra at the time participants are undergoing DBS

Reached clinical completion?

Eight trials were noted as now clinically complete including a Phase 3 trial of flexible dosing of tavapadon (Dopamine D1/5 partial agonist from Cerevel) in patients with early disease and a large (n=496) Phase 2 trial of minzasolmin (inhibitor of aSN misfolding from UCB and Neuropore) also in patients with early disease

Also reaching clinical completion were early trials of two gene therapy candidates and one cell replacement therapy:

- Phase 1 trial of VY-AADC02 (AADC gene therapy, Neurocrine Biosciences & Voyager Therapeutics) in patients with motor fluctuations
- Phase 1-2 trial of AAV-GAD gene therapy (MeiraGTx)
- Phase 1 cell replacement therapy trial of bemdaneprocel (allogenic human ESC-derived neural precursor cells, Bayer/BlueRock Therapeutics)

Been delayed (or accelerated)?

Delays in completion date were disclosed for nine studies with most of the delays being at least six months. For five the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov. The longest delay (30 months) was for a Phase 2 extension study for minzasolmin (inhibitor of aSN misfolding from UCB and Neuropore) which over the last two quarters has swung from a projected 2029 completion date to 2027 and then back to 2029 suggesting changing plans by the sponsor rather than a true delay in study conduct.

Two studies had an accelerated completion date disclosed during the quarter but only of a few days.

Q4 2024 Trial Results Headlines (ref. dashboards pgs. 10-15)

What trials . . .

Have had results disclosed for the first time?

Results for eleven trials were disclosed for the first time in Q4 including two Phase 3 trials:

- Right at the end of the quarter, a press release from Cure Parkinson's UK announced that the long-awaited Phase 3 trial of exenatide (GLP-1 agonist) was negative with no benefit seen over placebo
- A final Phase 3 trial of of tavapadon (dopamine D1/D5 partial agonist from Cerevel) using flexible dosing in patients with early PD was positive and regulatory submissions are planned for 2025 according to a company press release

Results were also disclosed for three substantial Phase 2 trials:

- A second Phase 2 trial of prasinezumab (immunotherapy Mab to aSN from Roche & Prothena) which showed a numerical delay in motor progression and positive trends on multiple secondary and exploratory endpoints but failed to achieve the primary efficacy endpoint according to a company press release. Next steps for the program are to be determined.
- A trial of minzasolmin (inhibitor of aSN misfolding from UCB and Neuropore) which failed to show any evidence of clinical benefit relative to placebo according to a company press release
- A trial of ACI-7104 (aSN vaccine from AC Immune) in early PD for which a company press release reported interim data showing high aSN antibody levels (16-fold higher than placebo) after three immunizations

Among smaller trials for which results were disclosed during the quarter, encouraging results were reported in company press releases for AAV-GAD gene therapy from MeriaGTx and ESC-derived cell replacement therapy (TED-A9) from S. Biomedics Co. Ltd.,

Have had additional detail on results disclosed?

Additional results were disclosed for five trials for which at least top-line results had been previously reported. Notable were:

- A peer-reviewed manuscript on the positive Phase 2 trial with solengepras (selective GPR6 inverse agonist from Cerevance) showing reduced off-time in patients with motor fluctuations
- A peer-reviewed manuscript on an exploratory analysis of long-term open-label data from the first Phase 2 trial of prasinezumab (immunotherapy Mab to aSN from Roche & Prothena) compared to real world data from the PPMI suggesting that there may be a sustained slowing in motor progression

Are due to have results disclosed soon?

This analysis looks at trials completed at least six months ago (end of Q2 2024) but for which results were not disclosed by the end of Q4 2024. These trials are likely to have results disclosed soon. The twelve trials in this group are largely Phase 1 or small exploratory Phase 2 studies with no obvious notable trials – but there can always be surprises.

Methodology

- Trial data for Parkinson's disease Phase 1, 2, and 3 trials downloaded from clinicaltrials.gov on first and last days of quarter.
- "Status" parameter compared at beginning and end of quarter to identify trials that: Were registered, started or completed recruitment, or were completed or withdrawn during the quarter. "Primary completion date" parameter compared at beginning and end of quarter to determine trials with a change in expected primary completion date.
- Dashboards limited to Phase 1 to Phase 3 trials evaluating pharmaceuticals, including biologics, cell and gene therapies. The "Parkinson's Disease Drug Therapies in the Clinical Trial Pipeline" reports for 2020 through 2023 and The Hope List were references in identifying the "agent description" and "company/sponsor" fields.
- Note that not all trials are registered on clinicaltrials.gov. For example, if trials don't have any US sites, sponsors may choose to register them only in similar databases in the regions or countries involved in the trial. Furthermore, the accuracy of the data in clinicaltrials.gov is dependent on sponsors updating trial status and other information in a timely manner. As a result, for about 10% of the trials matching the specifications for this analysis the status is "unknown" or the completion date has passed and yet the status indicates the trial is still underway.
- Dashboards on Trial Results are based on alerts from PubMed.gov, review of conference abstract books, daily emails from Parkinson's News Today, the Science of Parkinson's Disease blog, pre-print servers, and the Parkinson's Research Interest Group on Facebook. It is challenging to capture all results disclosures, so if anything is missing, please let us know at PDTrialTracker@outlook.com.

Clinical Trials of Parkinson’s Disease Drug Therapies
Trial Change in Status* Dashboard: Q4 2024
*Registered, Started or Finished Recruiting, Completed
posted on ClinicalTrials.gov between October 1, 2024, and December 31, 2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phaspe	Trial Title	Enrollment	Prior Status	New Status
NCT04251585	Nasal insulin	HealthPartners Institute	Intra-nasal insulin	Phase 2	Intranasal Insulin in Parkinson's Disease	30	Recruiting	Active Not Recruiting
NCT04760769	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Open-label Trial in Parkinson's Disease (PD)	992	Enrolling By Invitation	Active Not Recruiting
NCT05377281	Autologous Unconditioned Peripheral Nerve Tissue	University of Kentucky	Peripheral nerve tissue	Phase 1	Feasibility and Safety of AutoloGous Unconditioned PEripheral Nerve Tissue Delivery to the Substantia Nigra (GUIDE)	10	Recruiting	Active Not Recruiting
NCT05635409	STEM-PD	Lund University & University of Cambridge	Ventral midbrain dopaminergic progenitor (stem) cells	Phase 1	A Trial to Determine the Safety and Tolerability of Transplanted Stem Cell Derived Dopamine Neurons to the Brains of Individuals With Parkinson's Disease	8	Recruiting	Active Not Recruiting
NCT06006247	Solengepras (CVN424)	Cerevance	Selective GPR6 Inverse Agonist	Phase 2	Early Parkinson's Disease Monotherapy With CVN424	62	Recruiting	Active Not Recruiting
NCT06263010	Allopregnanolone (brexanolone)	University of Arizona	Positive allosteric modulator of GABA	Phase 1	Allopregnanolone As a Regenerative Treatment for Parkinson's Disease	10	Recruiting	Active Not Recruiting
NCT03562494	VY-AADC02	Neurocrine Biosciences Voyager Therapeutics	AADC gene therapy	Phase 1	VY-AADC02 for Parkinson's Disease With Motor Fluctuations (RESTORE-1)	14	Active Not Recruiting	Completed
NCT03790670	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Assessments of Leukine During Treatment of Parkinson's Disease	7	Active Not Recruiting	Completed
NCT04223193	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Flexible-Dose Trial in Early Parkinson's Disease (PD)	304	Active Not Recruiting	Completed
NCT04658186	Minzasolmin (UCB0599)	UCB and Neuropore (NPT 200-11)	Inhibitor of aSN misfolding	Phase 2	A 18-month Study to Evaluate the Efficacy, Safety, Tolerability and Pharmacokinetics of Oral UCB0599 in Study Participants With Early-stage Parkinson's Disease	496	Active Not Recruiting	Completed

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phaspe	Trial Title	Enrollment	Prior Status	New Status
NCT04739423	CST-103 and CST-107	CuraSen Therapeutics	Restores brain homeostasis	Phase 2	A Study of Clenbuterol (CST-103) Co-administered With Nadolol (CST-107) in Subjects With Neurodegenerative Disorders	41	Active Not Recruiting	Completed
NCT04802733	Bemdaneprocel (BRT-DA01)	Bayer (was BlueRock Therapeutics)	Human ESC-derived neural precursor cells	Phase 1	PHASE 1 Safety and Tolerability Study of MSK-DA01 Cell Therapy for Advanced Parkinson's Disease	12	Unknown	Completed
NCT05603312	AAV-GAD	MeiraGTx	Gene therapy	Phase 1-Phase 2	A Double-blind Study to Evaluate the Safety of Glutamic Acid Decarboxylase Gene Transfer in Parkinson's Participants	14	Active Not Recruiting	Completed
NCT05677633	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Validation Following Sargramostim Treatment in Parkinson's Disease	11	Active Not Recruiting	Completed
NCT06679374	Varenicline	Pfizer	Partial nicotine receptor agonist	Phase 2	Reducing Falls with Varenicline in Hypocholinergic Parkinson Disease	102	Not In Ct.Gov	Not Yet Recruiting
NCT06680830	NEU-411	Neuron23	LRRK2 inhibitor	Phase 2	A PHASE 2 Study of NEU-411 in Companion Diagnostic-Positive Participants with Early Parkinson's Disease	150	Not In Ct.Gov	Not Yet Recruiting
NCT06732180	GT-02287	Gain Therapeutics	Allosteric regulator of GCase	Phase 1	Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of GT-02287 in Parkinson's Disease	20	Not In Ct.Gov	Not Yet Recruiting
NCT05995782	FB418	1ST Biotherapeutics, Inc.	c-Abl/LRRK2	Phase 1	A PHASE 1, SAD and MAD Study to Evaluate the Safety and Tolerability of FB418	64	Not Yet Recruiting	Recruiting
NCT06339034	Lithium	State University of New York at Buffalo	Protein kinase C inhibitor (treatment for bipolar disorder)	Phase 1-Phase 2	Repurposing Lithium for Parkinson's Disease: a RCT	20	Not Yet Recruiting	Recruiting
NCT06553027	Solengepras (CVN424)	Cerevance	Selective GPR6 Inverse Agonist	Phase 3	To Evaluate the Efficacy of CVN424 in Parkinson's Disease Participants With Motor Complications	330	Not Yet Recruiting	Recruiting
NCT06602193	BIIB122 (DNL151)	Biogen & Denali	LRRK2 inhibitor	Phase 2	Safety and Pharmacodynamic Effects of BIIB122 in Participants With LRRK2-Associated Parkinson's Disease (LRRK2-PD)	50	Not Yet Recruiting	Recruiting
NCT06629389	Kanbis (cannabidiol)	Laboratorio Elea Phoenix S.A.	Cannabidiol oral liquid	Phase 2	Clinical Trial with Cannabidiol (Kanbis) for Parkinson Disease Symptoms	88	Not In Ct.Gov	Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phaspe	Trial Title	Enrollment	Prior Status	New Status
NCT06659562	HER-096	Herantis	Peptidomimetic for cerebral dopamine neurotrophic factor	Phase 1	Clinical Study of HER-096 in Healthy Volunteer Subjects and Patients with Parkinson's Disease	40	Not In Ct.Gov	Recruiting
NCT06671938	Exidavnemab	BioArctic AB	Mab targeting aggregated aSN	Phase 2	Safety, Tolerability, and Pharmacokinetics of Exidavnemab in Patients with Parkinson's Disease	24	Not In Ct.Gov	Recruiting
NCT06687837	Autologous midbrain dopaminergic progenitor cells	Massachusetts General Hospital	Autologous midbrain dopaminergic progenitor cells	Phase 1	Treating Parkinson's Disease Through Transplantation of Autologous Stem Cell-Derived Dopaminergic Neurons	8	Not In Ct.Gov	Recruiting
NCT06722729	KDT-3594/AM006	Kissei/AffaMed	DA receptor agonist	Phase 2	A Late PHASE II Clinical Trial of KDT-3594 in Patients With Parkinson's Disease	150	Not In Ct.Gov	Recruiting
NCT05516875	JM-010 (Buspirone/ Zolmitriptan)	Contera Pharma/ Bukwang	Serotonin 1 receptor agonist combination (buspirone and zolmitriptan)	Phase 2	Open-Label Extension Study of ASTORIA	6	Not Yet Recruiting	Terminated
NCT02579473	SER-214 (Rotigotine polymer conjugate)	Serina Therapeutics	Continuous delivery of rotigotine	Phase 1	A Study of Weekly Subcutaneous Injections of SER-214 in Subjects With Parkinson's Disease (PD), to Determine the Safety, Tolerability and Pharmacokinetic (PK) Profile of SER-214	20	Active Not Recruiting	Unknown
NCT04293159	Synbiotic	Tanta University	Lactobacillus acidophilus and prebiotic fibers	NA	Effect of Probiotic on Constipation in Patients With Parkinson's Disease	30	Not In Ct.Gov	Unknown
NCT05435755	Human Amniotic Epithelial Stem Cells	Shanghai iCELL Biotechnology Co., Ltd	Human Amniotic Epithelial Stem Cells	Early Phase 1	Precise Transplantation of hA ESCs Into the Ventricle for Parkinson's Disease.	12	Not Yet Recruiting	Unknown
NCT05796167	Pimavanserin	Strasbourg University Hospital	Inverse agonist/antagonist of 5HT2a receptors	Early Phase 1	Pimavanserin for Sleep in Parkinson Disease	0	Recruiting	Withdrawn

Clinical Trials of Parkinson’s Disease Drug Therapies
Change in Completion Date Dashboard: Q4 2024
posted on ClinicalTrials.gov between October 1, 2024, and December 31, 2024

Clinical Trials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT05543252	Minzasolmin (UCB0599)	UCB and Neuropore (NPT 200-11)	Inhibitor of aSN misfolding	Phase 2	An Extension Study to Evaluate the Long-Term Efficacy, Safety and Tolerability of Minzasolmin (UCB0599) in Study Participants With Parkinson's Disease	428	19-Apr-2027	8-Oct-2029	903
NCT02897063	Droxidopa	Loma Linda University/ Lundbeck	L-threo-dihydroxyphenylserine	Phase 1	Effects of Midodrine and Droxidopa on Splanchnic Capacitance in Autonomic Failure	34	1-Sep-2024	1-Sep-2025	365
NCT04944017	Ketamine (IV)	VA Office of Research and Development	Ketamine	Phase 2	Ketamine for the Treatment of Depression in Parkinson's Disease	56	1-Aug-2024	1-Aug-2025	365
NCT06263010	Allopregnanolone (brexanolone)	University of Arizona	Positive allosteric modulator of GABA	Phase 1	Allopregnanolone As a Regenerative Treatment for Parkinson's Disease	10	1-Sep-2024	1-May-2025	242
NCT06175767	MT101-5	Mthera Pharma	Herbal formula that blocks aggregated aSN neurotoxicity	Phase 2	A Study to Evaluate the Safety, Tolerability and Efficacy of MT101-5 in Subjects with Early Parkinson's Disease	120	1-Dec-2024	1-Jul-2025	212
NCT06356662	Tenofovir disoproxil	The Fourth Affiliated Hospital of Zhejiang University School of Medicine	Triple antiviral combination product	Phase 1	Tenofovir Disoproxil Fumarate in the Treatment of Parkinson's Disease	60	31-Aug-2024	31-Dec-2024	122
NCT06498687	CYR-064	Cyrano Therapeutics	Intranasal theophylline	Phase 1	Theophylline Nasal Spray for PD-Related Hyposmia and Anosmia	15	1-Jan-2026	1-May-2026	120
NCT06055985	UCB0022	UCB Pharma	Positive allosteric modulator of the dopamine 1 receptor (D1 PAM)	Phase 2	A Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of UCB0022 in Study Participants With Advanced Parkinson's Disease	189	9-Dec-2024	27-Mar-2025	108
NCT05995782	FB418	1ST Biotherapeutics, Inc.	c-Abl/LRRK2	Phase 1	A PHASE 1, SAD and MAD Study to Evaluate the Safety and Tolerability of FB418	64	1-Sep-2024	1-Dec-2024	91

Clinical Trials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT04251585	Nasal insulin	HealthPartners Institute	Intra-nasal insulin	Phase 2	Intranasal Insulin in Parkinson's Disease	30	1-Sep-2024	27-Aug-2024	-5
NCT04777331	Prasinezumab (RO7046015/PRX002)	Roche/Prothena	Immunotherapy (Mab to aSN)	Phase 2	A Study to Evaluate the Efficacy and Safety of Intravenous Prasinezumab in Participants With Early Parkinson's Disease	586	20-Sep-2024	11-Sep-2024	-9

Results Dashboard: Q4 2024

Clinical Trials of Parkinson's Disease Drug Therapies with Results Newly Disclosed Between 1-October-2024 and 31-December-2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Type of Disclosure	Primary Efficacy Endpoint	Secondary Efficacy Endpoints	Safety	Conclusions	Reference
NCT03128450	ANGE-S003	Second Affiliated Hospital of Soochow University	Fetal neural stem cells for nasal delivery	Phase 2-Phase 3	A Study To Evaluate the Safety and Efficacy of Human Neural Stem Cells for Parkinson's Disease Patient	12	Peer-reviewed Manuscript	NA	Favorable	No safety concerns	Feasible, generally safe & well tolerated; Larger study warranted.	https://pubmed.ncbi.nlm.nih.gov/38724232/
NCT04223193	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Flexible-Dose Trial in Early Parkinson's Disease (PD)	304	Press Release / Corporate Communications	Positive	Favorable	Consistent with other trials; Most AEs mild to moderate	Positive topline results from pivotal PHASE 3 trial evaluating use as a flexible-dose monotherapy in early PD; NDA to be filed in 2025	https://news.abbvie.com/2024-12-09-AbbVie-Announces-Positive-Topline-Results-for-the-PHASE-3-TEMPO-2-Trial-Evaluating-Tavapadon-as-a-Monotherapy-for-Parkinsons-Disease
NCT04232969	Exenatide	University College, London	GLP-1 agonist	Phase 3	Exenatide Once Weekly Over 2 Years as a Potential Disease Modifying Treatment for Parkinson's Disease	194	Press Release / Corporate Communications	Negative	Negative	Not reported	Study did not meet its primary endpoint	https://cureparkinsons.org.uk/exenatide/exenatide-pd3-results/
NCT04658186	Minzasolmin (UCB0599)	UCB and Neuropore (NPT 200-11)	Inhibitor of aSN misfolding	Phase 2	A 18-month Study to Evaluate the Efficacy, Safety, Tolerability and Pharmacokinetics of Oral UCB0599 in Study Participants With Early-stage Parkinson's Disease	496	Press Release / Corporate Communications	Negative	Negative	No new safety issues	No evidence of clinical benefit in both primary & secondary endpoints. Biomarker data, in which there was a preliminary signal, still being analyzed	https://www.ucb.com/newsroom/press-releases/article/findings-from-minzasolmin-proof-of-concept-orchestra-study-shape-next-steps-in-ucb-parkinson-s-research-program

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Type of Disclosure	Primary Efficacy Endpoint	Secondary Efficacy Endpoints	Safety	Conclusions	Reference
NCT04777331	Prasinezumab (RO7046015/ PRX002)	Roche/ Prothena	Immuno-therapy (Mab to aSN)	Phase 2	A Study to Evaluate the Efficacy and Safety of Intravenous Prasinezumab in Participants With Early Parkinson's Disease	586	Press Release / Corporate Communications	Negative	Favorable	Well tolerated; No new safety issues	Numerical delay in motor progression & positive trends on multiple secondary & exploratory endpoints; Next steps TBD	https://www.roche.com/media/releases/med-cor-2024-12-19
NCT05603312	AAV-GAD	MeiraGTx	Gene therapy	Phase 1-Phase 2	A Double-blind Study to Evaluate the Safety of Glutamic Acid Decarboxylase Gene Transfer in Parkinson's Participants	14	Press Release / Corporate Communications	NA	Favorable	Safe and well tolerated	Extent of motor score improvements with high dose treatment combined with significant QoL improvement very encouraging	https://www.globenewswire.com/en/news-release/2024/10/15/2963048/0/en/MeiraGTx-Announces-Positive-Data-from-Randomized-Sham-controlled-Clinical-Bridging-Study-of-AAV-GAD-for-the-Treatment-of-Parkinson-s-Disease.html
NCT05887466	TED-A9 (A9-DPC)	S.Biomedics Co., Ltd. Yonsei University	ESC-derived Dopamine Progenitor Cell Therapy	Phase 1-Phase 2	Study to Evaluate the Safety and Efficacy of ESC-derived Dopamine Progenitor Cell Therapy in PD Patients	12	Press Release / Corporate Communications	NA	Favorable	No issues related to transplanted cells. One patient experienced mild hemorrhaging in area unrelated to transplant	Results demonstrate a cell therapy that promotes behavioral recovery and also confirms mechanism through neuroimaging	https://www.morningstar.com/news/business-wire/20241126606645/sbiomedics-investigational-cell-therapy-for-parkinsons-disease-with-ted-a9-shows-positive-data-at-12-months-in-PHASE-12a-clinical-trial
NCT05962957	Pentoxifylline & Celecoxib	Tanta University	PTX: Supresses TLR4/NF-κB & activates Nrf2; Celecoxib: NSAID	Phase 2	Role of Pentoxifylline and Celecoxib in Parkinsonism	80	Peer-reviewed Manuscript	Positive	Not reported in abstract	Not reported in abstract	Could be a promising adjuvant therapy	https://link.springer.com/article/10.1007/s10787-024-01567-z

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Type of Disclosure	Primary Efficacy Endpoint	Secondary Efficacy Endpoints	Safety	Conclusions	Reference
NCT06015841	ACI-7104	AC Immune (acquired Affiris)	aSN vaccine	Phase 2	A Study to Evaluate the Effects of ACI-7104.056 Vaccination in Patients With Early Stages of Parkinson's Disease	150	Press Release / Corporate Communications	NA	NA	Transient injection site reactions (49%) and headaches (18%)	Interim Part 1 results show high aSN antibody levels on average 16-fold higher than placebo after 3 immunizations	https://ir.acimmune.com/news-releases/news-release-details/ac-immune-reports-positive-interim-results-PHASE - 2-trial-aci
NCT06088784	ATH-399A (HL192)	HanAll BioPharma Co., Ltd. NurrOn Pharmaceut- icals, Inc.	Nurr1 activator	Phase 1	A Study Assessing the Safety of Oral ATH-399A in Healthy Adult Participants	76	Press Release / Corporate Communications	NA	NA	Well tolerated with no major safety issues	Demonstrated safety and tolerability in healthy volunteers, including older adults	https://www.prnewswire.com/news-releases/hanall-biopharma-daewoong-pharmaceutical-and-nurron-pharmaceuticals-announce-successful-completion-of-a-first-in-human-study-for-potential-disease-modifying-therapy-for-parkinsons-disease-302315158.html
NCT06539260	Vitamin D3	Suzhou Municipal Hospital of Anhui Province	Vitamin D3	Early Phase 1	Clinical Relationship Between Vitamin D- mediated Th17 and Treg Cells and Parkinson's Disease	30	Preprint	NA	Favorable	Not reported	Believe it is necessary for patients with low vitamin D to supplement to normal levels	https://www.researchsquare.com/article/rs-5145248/v1

Note that clinical trial results are often disclosed for the first time via company press releases and/or investor presentations. For public companies this is often driven by requirements for timely disclosure of material events deemed likely to inform investment decisions. These corporate disclosures typically include only the key top-line results. More detailed trial results may be disclosed via posters or presentations at scientific conferences. Eventually comprehensive trial results are generally published in medical journals sometimes as a “pre-print” (that has not yet been reviewed by experts not involved in the trial) and ultimately as a final peer-reviewed manuscript. Trial results can also be posted by sponsors in the ClinicalTrials.gov database.

Clinical Trials of Parkinson's Disease Drug Therapies with Additional Results Disclosed Between 1-October-2024 and 31-December-2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Type of Disclosure	Primary Efficacy Endpoint	Secondary Efficacy Endpoints	Safety	Conclusions	Reference
NCT04191577	Solengepras (CVN424)	Cerevance	Selective GPR6 Inverse Agonist	Phase 2	Study of CVN424 in Parkinson's Disease Patients With Motor Fluctuations	136	Peer-reviewed Manuscript	NA	Favorable	Headache, nausea, and vomiting	Safe & well-tolerated. Clinically meaningful reduction in OFF-time. Supports further development.	https://www.sciencedirect.com/science/article/pii/S2589537024004619
NCT03100149	Prasinezumab (RO7046015/PRX002)	Roche/ Prothena	Immuno-therapy (Mab to aSN)	Phase 2	A Study to Evaluate the Efficacy of Prasinezumab (RO7046015/PRX002) in Participants With Early Parkinson's Disease	316	Peer-reviewed Manuscript	Negative	Favorable vs. real-world data (PPMI) in open-label extension	Not reported	Exploratory analysis, which requires confirmation, suggests effect of prasinezumab in slowing motor progression may be sustained long-term	https://www.nature.com/articles/s41591-024-03270-6
NCT02728843	Deferiprone	ApoPharma (SKY)	Iron chelator	Phase 2	Study of Parkinson's Early Stage With Deferiprone	140	Peer-reviewed Manuscript	Negative	Negative	Nausea, vomiting, headache, abdominal pain	When combined with LD does not provide significant motor function benefit	https://journals.sagepub.com/doi/10.1177/1877718X241300295
NCT04293159	Synbiotic	Tanta University	Lacto-bacillus acidophilus and prebiotic fibers	NA	Effect of Probiotic on Constipation in Patients With Parkinson's Disease	30	Peer-reviewed Manuscript	NA	Favorable	Not reported	Demonstrates potential efficacy in ameliorating non-motor features	https://www.nature.com/articles/s41598-024-74400-w
NCT05699161	Adipose-derived Stromal Vascular Fraction Cells	National Autonomous University of Nicaragua	Autologous adipose tissue-derived stromal vascular fraction (SVF) cells	Phase 1-Phase 2	Adipose-derived Stromal Vascular Fraction Cells to Treat Parkinson	10	Peer-reviewed Manuscript	NA	Favorable	Postop pain, bruising & cutaneous sensitivity	Safe with evidence of clinical improvement at 12 & 24 months; Should be further evaluated in a placebo-controlled trial	https://www.prd-journal.com/article/S1353-8020(24)01226-4/fulltext

Clinical Trials of Parkinson's Disease Drug Therapies Completed Before 1-July-2024 But Without Results Disclosed by 31-December-2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
NCT03652870	Nortriptyline/ Escitalopram	University College London	Antidepressants	Phase 3	Antidepressants Trial in Parkinson's Disease	52	23-Jan-2023	30-Apr-2023
NCT05532358	Anle 138b	Modag/ Cure Parkinson's Trust	Inhibits aSN oligomerisation	Phase 1	A Drug-Drug Interaction Study to Assess the CYP1A2 and CYP3A4 Interaction Potential of TEV-56286 (anle138b)	54	28-Jan-2023	10-Feb-2023
NCT05844787	MT101-5	Mthera Pharma	Herbal formula that blocks aggregated aSN neurotoxicity	Phase 1	A Study to Evaluate the Safety, Tolerability and Pharmacokinetics Profile of MT101-5 in Healthy Volunteers	48	23-Feb-2023	23-Feb-2023
NCT04651153	UCB7853	UCB and Neuropore	aSN antibody	Phase 1	A Safety and Pharmacokinetics Study of UCB7853 in Healthy Study Participants and Study Participants With Parkinson's Disease (PD)	62	20-Jul-2023	20-Jul-2023
NCT06004180	Lu AF28996	Lundbeck	D1/D2 agonist	Phase 1	A Trial Investigating Lu AF28996 in Adult Japanese Participants With Parkinson's Disease (PD)	6	21-Nov-2023	21-Nov-2023
NCT05104463	CST-103 and CST-107	CuraSen Therapeutics	Restores brain homeostasis	Phase 2	A Study of CST-2032 and CST-107 in Subjects With Mild Cognitive Impairment or Mild Dementia Due to Parkinson's or Alzheimer's Disease	64	1-Dec-2023	1-Feb-2024
NCT06614153	HRG2010	Jiangsu HengRui Medicine Co., Ltd.	Carbidopa/levodopa FDC	Phase 2	Pharmacokinetics, Pharmacodynamics, Efficacy and Safety of HRG2010 in Parkinson's Disease Patients With Motor Fluctuations	61	31-Jan-2024	4-Mar-2024
NCT03956979	JM-010 (Buspirone/ Zolmitriptan)	Contera Pharma/ Bukwang	Serotonin 1 receptor agonist combination (buspirone and zolmitriptan)	Phase 2	A Study in Parkinson's Disease in Patients With Moderate to Severe Dyskinesia	89	7-Mar-2024	21-Mar-2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
NCT05950906	PDM608	Calibir (Scripps Research)	GM-CSF fusion protein	Phase 1	Study to Assess PDM608 in Healthy Adult Subjects	64	17-Mar-2024	19-Apr-2024
NCT05677633	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Validation Following Sargramostim Treatment in Parkinson's Disease	11	12-Apr-2024	1-Nov-2024
NCT05523570	HNC364	Guangzhou Henovcom Bioscience Co. Ltd.	Long-acting (monthly) injectable MAO-B inhibitor	Phase 1	A Study to Evaluate the Safety, Tolerability, PK and PD of HNC364 Injectable Suspension	34	15-Apr-2024	15-Apr-2024
NCT06212089	TR-012001	SNLD, Ltd.	Nasal levodopa	Phase 2	Phase 2 Clinical Study of TR-012001 in Japanese Patients With Parkinson's Disease	12	26-Apr-2024	30-May-2024

Note that this analysis includes only trials with primary completion after 1-January-2023 as this analyst did not systematically track trial result disclosures until Q4 2022. It is challenging to capture all results disclosures, so if results from any of these trials have been disclosed, please let us know at PDTrialTracker@outlook.com.