Clinical Trials for Parkinson's Disease Drug Therapies: What Happened During Q3 2024?

Q3 2024 Trial Status Headlines (ref. dashboards pgs. 6-11)

What trials have . . .

Begun recruiting?

Recruiting began for eight trials including five of particular interest due to novel mechanisms of action:

- A Phase 2 trial of psilocybin (a naturally occurring psychedelic prodrug) being studied at UC San Francisco for depression in PD
- A Phase 1 trial of LBT-3627 (selective VPAC2 agonist from Longevity Biotech)
- A Phase 1 trial of LY3962681 (an intrathecally delivered siRNA targeting aSN mRNA from Eli Lilly)
- Two Phase 1 trials with dopamine neural progenitor cell therapies (CT1-DAP001 from Sumitomo Pharma and NouvNeu001 from iRegene Therapeutics)

An additional three trials began recruiting by invitation only – including another cell therapy study at Harvard (Brigham & Women's Hospital). Eight other trials were newly listed but not yet recruiting at quarter end including a 450-patient Phase 3 trial of solengepras (selective GPR6 inverse agonist from Cerevance), a Phase 2 trial with BIIB122 (LRRK2 inhibitor from Biogen & Denali) in patients with LRRK2-associated PD, and another cell therapy study (Anhui Provincial Hospital in China).

Completed enrollment?

Three trials completed enrollment:

- A Phase 2 trial of UCB0599 (inhibitor of aSN misfolding from UCB & Neuropore)
- A Phase 2 trial of BIA28-6156 (Gcase activator from Bial)
- A Phase 1/2 trial of UB-312 ("endobody" to aSN from Vaxxinity)

Reached clinical completion?

Eight trials were noted as now clinically complete including a Phase 3 trial of tavapadon (Dopamine D1/5 partial agonist from Cerevel) in patients with early disease and two notable Phase 2 trials:

- A trial of NLY-01 (pegylated exenatide from Neuraly)
- A trial of DIVE (intra-cerebroventicular dopamine infusion from Lille University Hospital in France and InBrain Pharma)

Also reaching clinical completion were large Phase 1 trials of BIIB094 (antisense oligomer to LRRK2 from Biogen) and RO7486967 (NRLP3 inhibitor from Roche).

Been delayed (or accelerated)?

Delays in completion date were disclosed for ten studies with most of the delays being at least seven months. For three the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov.

Three studies had an accelerated completion date disclosed during the quarter. Notable is a Phase 2 extension study for UCB0599 (inhibitor of aSN misfolding from UCB) which was initially projected to run through 2029 but was updated with an April 2027 projected completion date.

Q3 2024 Trial Results Headlines (ref. dashboard pgs. 12-21)

What trials . . .

Have had results disclosed for the first time?

Results for ten trials were disclosed for the first time in Q3 including four Phase 3 trials:

- A trial of tavapadon (dopamine D1/D5 partial agonist from Cerevel) in patients with early PD for which efficacy and safety results were said to support planned regulatory submissions according to a company press release
- A trial of buntanetap (aSN aggregation inhibitor from Annovis) which failed to achieve the primary efficacy endpoint although the company press release contends that results (especially on cognition) in patients with early disease were compelling
- A trial of buspirone (an approved medicine for anxiety) used with amantadine to treat dyskinesias in advanced disease. According to a conference abstract, the study failed to show a benefit – perhaps due to insufficient dose or use on top of amantadine
- A trial of solifenacin (an approved antimuscarinic bladder relaxant) vs. behavioral therapy for urinary symptoms of PD. Results posted on clinicaltrials.gov indicated the study was negative with solifenacin less effective than behavioral therapy

Also notable was interim data from two ongoing open-label Phase 1 studies of cell therapies:

- S. Biomedics reported in a press release that the first three patients who received their ESC-derived allogenic dopamine progenitor cells (TED-A9) had improved motor abilities one year after surgery
- Aspen Neuroscience reported in a conference presentation that there were no serious surgical complications in the first three patients who received their autologous iPSC-derived neural precursor cells (ANPD001) delivered via a novel posterior surgical approach

Finally, in a conference abstract investigators from Lille University Hospital in France reported clinical feasibility, safety, and initial evidence of efficacy with an intra-cerebroventricular dopamine infusion via an implanted pump (DIVE) in a Phase 1-2 study.

Have had additional detail on results disclosed?

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

- A conference abstract on the Phase 1 trial with AB-1005 (GDNF gene therapy from Bayer/AskBio) reporting favorable safety data, clinical stability in the mild patient cohort and improvement in the moderate patient cohort 18 months after treatment

- Two conference abstracts on the Phase 1 cell therapy trial with bemdaneprocel (human ESC-derived neural precursor cells from Bayer/BlueRock Therapeutics) reporting favorable safety and tolerability along with trends toward clinical benefit (higher dose cohort) or stability (lower dose cohort) at 18-months post-surgery (and 6-months post discontinuation of immunosuppression).
- A conference abstract on a Phase 1 cell therapy trial in Korea with NouvNeu001 (human allogenic dopamine progenitor cells) reporting initial efficacy and safety supporting potential clinical utility.
- Multiple conference abstracts on various results from the Phase 3 clinical trials with ABBV-951 (sub-cutaneous foslevodopa/foscarbidopa pump from Abbvie) and ND0612 (sub-cutaneous levodopa/carbidopa pump from Mitsubishi Tanabe & Neuroderm) demonstrating utility on endpoints such as motor complications, QoL, sleep, etc. with up to two years of use.

Are due to have results disclosed soon?

This analysis looks at trials completed at least six months ago (end of Q1 2024) but for which results were not disclosed by the end of Q3 2024. These trials are likely to have results disclosed soon. The trials in this group include a Phase 3 academic trial (nortriptyline & escitalopram for depression in PD) and several interesting industry trials:

- A Phase 2 trial with CST-103 & CST-107 (together are said to restore brain homeostasis) from CuraSen Therapeutics for mild cognitive impairment or dementia.
- A Phase 1 trial with MT101-5 (herbal formula said to block aggregated aSN) from Mthera Pharma.
- A Phase 1 trial with UCB7853 (aSN antibody) from UCB and Neuropore.
- A Phase 1 trial with LU AF28996 (dopamine D1/D2 agonist) from Lundbeck

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: Q3 2024

*Registered, Started or Finished Recruiting, Completed

posted on ClinicalTrials.gov between July 1, 2024, and September 30, 2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior status	New Status
NCT05543252	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	Enrolling by invitation	Active Not Recruiting
NCT05634876	UB-312	Vaxxinity (was United Neuroscience)	"Endobody" to aSN	Phase 1|Phase 2	UB-312 in Patients With Synucleinopathies	8	Recruiting	Active Not Recruiting
NCT05819359	BIA28-6156/ LTI-291	Bial (acquired Lysosomal Therapeutics)	Gcase activator	Phase 2	Efficacy, Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of BIA 28-6156 in GBA-PD	237	Recruiting	Active Not Recruiting
NCT03976349	BIIB094	Biogen/Ionis	Antisense oligo to LRRK2	Phase 1	A Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of BIIB094 in Adults With Parkinson's Disease	82	Active not recruiting	Completed
NCT04154072	NLY-01 (pegylated exenatide)	Neuraly/ Johns Hopkins	GLP-1 agonist	Phase 2	A Clinical Study of NLY01 in Patient's With Early Parkinson's Disease	255	Active not recruiting	Completed
NCT04201093	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Fixed-Dose Trial in Early Parkinson's Disease (PD)	522	Active not recruiting	Completed
NCT04332276	DIVE	Lille University Hospital/ InBrain Pharma	Intra-cerebroventricular dopamine	Phase 1| Phase 2	Dopaminergic RestauratIon by IntraVEntriculaire Administration	12	Recruiting	Completed
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	Recruiting	Completed
NCT05924243	RO7486967	Roche	NRLP3 inhibitor	Phase 1	A Study to Investigate The Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of RO7486967 in Participants With Early Idiopathic Parkinson's Disease.	60	Recruiting	Completed

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior status	New Status
NCT05950906	PDM608	Calibir (Scripps Research)	GM-CSF fusion protein	Phase 1	Study to Assess PDM608 in Healthy Adult Subjects	64	Recruiting	Completed
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	Not in CT.gov	Completed
NCT06422208	Autologous midbrain dopamine neurons	Brigham & Women's Hospital / Harvard University	Autologous iPSC-derived neural precursor cells	Phase 1	Autologous iPSC-Derived Dopamine Neuron Transplantation for Parkinson's Disease	6	Not yet recruiting	Enrolling By Invitation
NCT06537050	JX2105	Zhejiang Jingxin Pharmaceutical Co., Ltd.	Not disclosed	Phase 1	A Randomized, Double-blind, Placebo-controlled Phase 1 Study to Evaluate the Safety, Tolerability and Pharmacokinetics of JX2105 in Healthy Chinese Subjects	52	Not in CT.gov	Enrolling By Invitation
NCT06592014	Lithium	State University of New York at Buffalo	Protein kinase C inhibitor (treatment for bipolar disorder)	Phase 1| Phase 2	Lithium for Parkinson's: an Extension Trial	35	Not in CT.gov	Enrolling By Invitation
NCT06498687	CYR-064	Cyrano Therapeutics	Intranasal theophylline	Phase 1	Theophylline Nasal Spray for PD-Related Hyposmia and Anosmia	15	Not in CT.gov	Not Yet Recruiting
NCT06553027	Solengepras (CVN424)	Cerevance	Selective GPR6 Inverse Agonist	Phase 3	Phase 3 Study of CVN424	330	Not in CT.gov	Not Yet Recruiting
NCT06583291	iDAP	Anhui Provincial Hospital (China)	Allogeneic Dopaminergic Neural Precursor Cell	Early Phase 1	iDAP Injection in the Treatment of Parkinson's Disease	12	Not in CT.gov	Not Yet Recruiting
NCT06596876	HRG2010	Jiangsu HengRui Medicine Co., Ltd.	Carbidopa/levodopa FDC	Phase 3	A Study to Evaluate the Efficacy and Safety of HRG2010 in Parkinson's Disease With Motor Fluctuations	450	Not in CT.gov	Not Yet 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 in CT.gov	Not Yet Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior status	New Status
NCT06604065	AMS2434	University of Arkansas	Essential amino acids that target improving muscle health & brain neurotransmitter balance	Phase 1	Essential Amino Acids and Parkinsons Disease	15	Not in CT.gov	Not Yet Recruiting
NCT06607900	HUC-MSC-sEV-001	Xuanwu Hospital, Beijing	Human umbilical cord mesenchymal stem cell-derived small extracellular vesicles nasal drops	Phase 1	HUC-MSC-sEV-001 Nasal Drops for Neurodegenerative Diseases	100	Not in CT.gov	Not Yet Recruiting
NCT06612593	Cilostazol	Ain Shams University	Selective inhibitor of phosphodiesterase-3	Phase 2	Cilostazol in Parkinson’s Disease	50	Not in CT.gov	Not Yet Recruiting
NCT06455293	Psilocybin	UC San Francisco	naturally occurring psychedelic prodrug	Phase 2	Psilocybin Therapy for Depression in Parkinson's Disease	60	Not yet recruiting	Recruiting
NCT06466525	LBT-3627	Longevity Biotech	Selective VPAC2 agonist	Phase 1	A Two-Part Single and Multiple Ascending Dose Trial of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of LBT-3627 in Healthy Participants and in Participants With Parkinson's Disease.	64	Not yet recruiting	Recruiting
NCT06482268	CT1-DAP001	Sumitomo Pharma	Allogenic iPSC-derived dopamine neural progenitor cells	Phase 1	Transplantation of Human iPS Cell-derived Dopaminergic Progenitors (CT1-DAP001) for Parkinson's Disease (Phase I/II)	7	Not in CT.gov	Recruiting
NCT06530290	Mirtazapine	Generics available	Noradrenergic and specific serotonergic antidepressant	Phase 2	Evaluating the Effect of Mirtazapine on Anxiety in Parkinson's Disease Patients	64	Not in CT.gov	Recruiting
NCT06556173	VTX3232	Ventyx Biosciences	NLRP3 Inhibitor	Phase 2	Phase 2a Study of VTX3232 in Parkinson's Disease	10	Not in CT.gov	Recruiting
NCT06565195	LY3962681	Eli Lilly	Intrathecally Delivered siRNA Targeting α-synuclein mRNA	Phase 1	A Clinical Trial of LY3962681 in Healthy Volunteers and in Patients With Parkinson's Disease	108	Not in CT.gov	Recruiting
NCT06596005	TJ0133	Hangzhou Tianji Jishi Biotechnology Co., Ltd.	Mitophagy inducer	Phase 2	Efficacy and Safety of TJ0113 Capsule in Patients With Parkinson's Disease	150	Not in CT.gov	Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior status	New Status
NCT06608355	NouvNeu001	iRegene Therapeutics Co., Ltd.	Human Dopaminergic Progenitor Cells	Phase 1	The Safety, Tolerability and Preliminary Efficacy of NouvNeu001 for Early-onset Parkinson's Disease	6	Not in CT.gov	Recruiting
NCT03655236	Vodobatinib (K0706)	Sun Pharma/SPARC	Bcr/Abl kinase inhibitor	Phase 2	PROSEEK: A Phase 2 Study In Early Parkinson's Disease Patients Evaluating The Safety And Efficacy Of Abl Tyrosine Kinase Inhibition Using K0706	513	Active not recruiting	Terminated
NCT05492019	Doxycycline	Bangabandhu Sheikh Mujib Medical University	Tetracycline class antibiotic	Phase 2	Effect of Doxycycline in Levodopa Treated Parkinson's Disease Patients	60	Recruiting	Unknown
NCT05493462	Human Fibroblast Growth Factor 1 (FGF-1)	Zhittya Genesis Medicine, Inc.	Intranasal FGF-1	Phase 1	Intranasal Human FGF-1 for Subjects With Parkinson's Disease	4	Not yet recruiting	Unknown
NCT04935762	CST-103 and CST-107	CuraSen Therapeutics	Restores brain homeostasis	Phase 2	A Study of CST-103 Co-administered With CST-107 in Subjects With Parkinson's Disease Having Freezing of Gait (CLIN-012)	0	Not yet recruiting	Withdrawn

Clinical Trials of Parkinson's Disease Drug Therapies

Change in Completion Date Dashboard: Q3 2024

posted on ClinicalTrials.gov between July 1, 2024, and September 30, 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)
NCT04643327	Levetiracetam	Queensland University	Anti-epileptic	Phase 2	Uncovering a Novel Therapeutic Target to Reduce Dementia Risk in Parkinson's Disease	28	1-Jun-2023	1-Jan-2025	580
NCT04691661	Radotinib	Il Yang	c-Abl kinase inhibitor	Phase 2	Safety, Tolerability, Pharmacokinetics and Efficacy Study of Radotinib in Parkinson's Disease	40	30-Jun-2024	31-Dec-2025	549
NCT04226248	Rivastigmine	Bristol University	Cholinesterase inhibitor	Phase 3	CHIEF-PD (CHolinesterase Inhibitor to prEvent Falls in Parkinson's Disease)	600	26-Apr-2023	2-May-2024	372
NCT03683225	CTC-413	Chase Therapeutics	Extended-release pramipexole	Phase 2	A Study to Evaluate in Patients With Parkinsonian Type Disorders	24	30-Dec-2024	30-Dec-2025	365
NCT05804383	ALX-001 (BMS-984923)	Allyx Therapeutics	Silent allosteric modulator of mGluR5	Phase 1	A Multiple Ascending Dose Study in Healthy Volunteers and Patients With Alzheimer's Disease	50	15-Jul-2024	15-Jul-2025	365
NCT05766813	ITI-214 (lenrispodun)	Intra-cellular Therapies	PDE-1 inhibitor	Phase 2	Lenrispodun as Adjunctive Therapy in the Treatment of Patients With Motor Fluctuations Due to Parkinson's Disease	132	1-Feb-2025	1-Sep-2025	212
NCT06422208	Autologous midbrain dopamine neurons	Brigham & Women's Hospital / Harvard University	Autologous iPSC-derived neural precursor cells	Phase 1	Autologous iPSC-Derived Dopamine Neuron Transplantation for Parkinson's Disease	6	1-Aug-2026	1-Dec-2026	122
NCT04251585	Nasal insulin	Multiple development programs	Intra-nasal insulin	Phase 2	Intranasal Insulin in Parkinson's Disease	30	1-Jun-2024	1-Sep-2024	92
NCT05424276	Risvodetinib (iKT-148009)	Inhibikase Therapeutics	c-Abl kinase inhibitor	Phase 2	A Randomized, Double-Blind, Placebo-Controlled Trial of IkT-148009 in Untreated Parkinson's Disease	120	30-Jun-2024	30-Sep-2024	92
NCT04658186	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	7-Oct-2024	11-Oct-2024	4

Clinical Trials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT03790670	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Assessments of Leukine During Treatment of Parkinson's Disease	7	30-Oct-2024	1-Oct-2024	-29
NCT04167540	AB-1005 (AAV2-GDNF)	Bayer / Ask Bio (was Brain Neurotherapy Bio)	GDNF gene therapy	Phase 1	GDNF Gene Therapy for Parkinson's Disease	11	1-Dec-2023	17-Oct-2023	-45
NCT05543252	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	10-Dec-2029	19-Apr-2027	-966

Results Dashboard: Q3 2024

Clinical Trials of Parkinson's Disease Drug Therapies with *Results Newly Disclosed* Between 1-July-2024 and 30-September-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
NCT05357989	Buntanetap (ANVS-401, posiphen)	Annovis (was QR Pharma)	aSN (+tau +APP) aggregation inhibitor	Phase 3	A Double-blind Study to Investigate Efficacy and Safety of Buntanetap Compared With Placebo in Participants With Early PD	523	Press Release / Corporate Communications	Negative	Favorable on cognition	Consistent with AD studies	Safe & effective in improving motor & non-motor activities & improving cognitive functions in early PD	https://seekingalpha.com/article/4702593
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	MRI & CT scans after one year revealed no AEs	First 3 patients at low dose had significant improvement in motor abilities at one year	https://www.businesswire.com/news/home/20240709317387/en/S.BIOMEDICS-Dopamine-Cell-Therapy-for-Parkinson
NCT04332276	DIVE	Lille University Hospital/ InBrain Pharma	Intra-cerebroven-tricular dopamine	Phase - Phase 2	Dopaminergic RestauratIon by IntraVEntriculaire Administration	12	Conference Abstract or Presentation	NA	Favorable	No serious AEs	Demonstrated clinical feasibility, safety & initial evidence of efficacy motivating further development	https://www.mdsabstracts.org/abstract/pharmacological-neuromodulation-with-intracerebroventricular-administration-of-anaerobic-dopamine-for-parkinsons-disease/
NCT04201093	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Fixed-Dose Trial in Early Parkinson's Disease (PD)	522	Press Release / Corporate Communications	Positive	Positive	Majority of AEs were mild to moderate	Results support planned regulatory submissions	https://news.abbvie.com/2024-09-26-AbbVie-Announces-Positive-Topline-Results-from-Phase -3-TEMPO-1-Trial-Evaluating-Tavapadon-as-a-Monotherapy-for-Parkinsons-Disease
NCT06344026	ANPD001	Aspen Neuroscience	Autologous iPSC-derived neural precursor cells	Phase 1	Phase 1/2a Study of ANPD001 in Parkinson Disease	9	Conference Abstract or Presentation	NA	NA	No hemorrhages or serious surgical complica-tions in first three patients	Initial dose of 5M DANPC can be safely administered to post-commissural putamen using iMRI-guided posterior approach	https://www.mdscongress.org/IC24-lbas

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
NCT03968133	Ecologic BARRIER 849 (Probiotic)	British Columbia University	Probiotic	Phase 2	Treating Anxiety in Parkinson's Disease With a Multi-Strain Probiotic	61	Conference Abstract or Presentation	Negative	Positive	Not reported	No differences in anxiety or gut microbiota observed but appeared to improve cognition.	https://www.mdsabstracts.org/abstract/a-randomized-double-blind-placebo-controlled-trial-of-a-multi-strain-probiotic-for-anxiety-in-parkinsons-disease/
NCT04944017	Ketamine (IV)	VA Office of Research and Development	Ketamine	Phase 2	Ketamine for the Treatment of Depression in Parkinson's Disease	56	Conference Abstract or Presentation	Still blinded	Still blinded	Not reported	Initial blinded results indicate robust reductions in depression severity with evidence of sustained effects at 1 month	https://www.mdsabstracts.org/abstract/distinct-pattern-of-synaptic-loss-in-parkinsons-disease-depression-and-initial-findings-from-the-yale-ketamine-pd-ket-pd-trial/
NCT02617017	Buspirone	Oregon Health & Science University	Serotonin 1A agonist + amantidine	Phase 3	Buspirone Treatment of Iatrogenic Dyskinesias in Advanced Parkinson' Disease	99	Conference Abstract or Presentation	Negative	No difference from placebo	No worsening of symptoms or sleepiness	Failed to improve LID. Maybe due to insufficient dose or use with amantadine	https://www.mdsabstracts.org/abstract/multicentric-randomized-control-trial-of-buspirone-in-levodopa-induced-dyskinesias/
NCT05635461	Solengepras (CVN424)	Cerevance	Selective GPR6 Inverse Agonist	Phase 1	Relative Bioavailability and Food Effect Study of CVN424	32	CT.GOV	NA	NA	Well tolerated	Suspension absorption higher than tablet; Absorption higher with food	https://clinicaltrials.gov/study/NCT05635461?term=NCT05635461&rank=1&tab=results#study-record-dates
NCT03149809	Solifenacin	Astellas Pharma	Antimuscar-inic bladder relaxant	Phase 3	Behavioral or Solifenacin Therapy for Urinary Symptoms in Parkinson Disease	77	CT.GOV	Negative	Negative	Falls & edema	No statistics provided but appeared less effective than behavioral therapy	https://clinicaltrials.gov/study/NCT03149809?term=NCT03149809&rank=1&tab=results#study-record-dates

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-July-2024 and 30-September-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
NCT04167540	AB-1005 (AAV2-GDNF)	Bayer / Ask Bio (was Brain Neurotherapy Bio)	GDNF gene therapy	Phase 1	GDNF Gene Therapy for Parkinson's Disease	11	Conference Abstract or Presentation	NA	Favorable	Well tolerated	Stability and/or improvement in clinical rating scales at 18 months after treatment	https://www.mdsabstracts.org/abstract/preliminary-efficacy-of-bilateral-intraputaminal-delivery-of-gdnf-gene-therapy-aav2-gdnf-ab-1005-in-parkinsons-disease-18-month-follow-up-from-a-Phase -1b-study/
NCT04802733	Bemdane-procel (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	Conference Abstract or Presentation	NA	Not reported	Not reported	Trends toward benefit in motor symptoms & stability in non-motor symptoms which persisted for 6 mnths post discontinuation of immunosuppression (18 mnths overall)	https://www.mdsabstracts.org/abstract/motor-and-non-motor-outcomes-of-bemdaneprocel-in-people-with-parkinsons-disease-results-up-to-24-months-from-a-Phase -1-study/
NCT04802733	Bemdane-procel (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	Conference Abstract or Presentation	NA	Not reported	A seizure one day after surgery considered possibly related to surgery. No deaths, discontinua-tions, or graft-induced dyskinesias	Generally safe & well tolerated 18 months post transplantation	https://www.mdsabstracts.org/abstract/safety-and-tolerability-of-bemdaneprocel-in-people-with-parkinsons-disease-results-up-to-24-months-from-a-Phase -1-study/

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
NCT03582137	Cannabidiol (CBD)	Colorado University, Denver	Cannabidiol	Phase 2	A Study of Tolerability and Efficacy of Cannabidiol on Motor Symptoms in Parkinson's Disease	74	CT.GOV	Negative	Negative	Dizziness, relaxation, fatigue, etc.	No benefit seen; Higher AE rate than with placebo	https://clinicaltrials.gov/study/NCT03582137?term=NCT03582137&rank=1&tab=results#adverse-events
NCT03781167	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/ Carbidopa prodrug	Phase 3	A Study to Evaluate the Safety and Tolerability of ABBV-951 in Subjects With Parkinson's Disease (PD)	244	Conference Abstract or Presentation	NA	Favorable	Mild to moderate non-serious AEs	Sustained improvement in motor fluctuations & QoL through 124 weeks	https://www.mdsabstracts.org/abstract/long-term-safety-and-efficacy-for-motor-fluctuations-and-quality-of-life-with-foslevodopa-foscarbidopa-in-patients-with-advanced-parkinsons-disease-interim-results-from-an-ongoing-open-label/
NCT04380142	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/ Carbidopa prodrug	Phase 3	Study Comparing Continuous Subcutaneous Infusion Of ABBV-951 With Oral Carbidopa/Levodopa Tablets For Treatment Of Motor Fluctuations In Adult Participants With Advanced Parkinson's Disease	174	Conference Abstract or Presentation	Positive	Favorable	Well tolerated & generally safe	Significantly more sleep responders & sleep responders demonstrated significant QoL improvements	https://www.mdsabstracts.org/abstract/correlation-between-sleep-and-quality-of-life-in-people-with-parkinsons-disease-treated-with-continuous-subcutaneous-infusion-of-foslevodopa-foscarbidopa/

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
NCT04380142	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/ Carbidopa prodrug	Phase 3	Study Comparing Continuous Subcutaneous Infusion Of ABBV-951 With Oral Carbidopa/Levodopa Tablets For Treatment Of Motor Fluctuations In Adult Participants With Advanced Parkinson's Disease	174	Conference Abstract or Presentation	Positive	Favorable	No difference in infusion reactions	No differences in efficacy & safety among PwP with and without care partner	https://www.mdsabstracts.org/abstract/efficacy-and-safety-of-foslevodopa-foscarbidopa-in-people-with-parkinsons-disease-with-and-without-care-partner-support/
NCT04380142	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/ Carbidopa prodrug	Phase 3	Study Comparing Continuous Subcutaneous Infusion Of ABBV-951 With Oral Carbidopa/Levodopa Tablets For Treatment Of Motor Fluctuations In Adult Participants With Advanced Parkinson's Disease	174	Conference Abstract or Presentation	Positive	Favorable	Infusion site reactions & infections	Most infections were non-serious, mild to moderate, did not result in discontinuation & resolved with or without antibiotics	https://www.mdsabstracts.org/abstract/evaluation-of-infusion-site-adverse-events-with-foslevodopa-foscarbidopa-in-a-12-week-randomized-study/
NCT04380142	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/ Carbidopa prodrug	Phase 3	Study Comparing Continuous Subcutaneous Infusion Of ABBV-951 With Oral Carbidopa/Levodopa Tablets For Treatment Of Motor Fluctuations In Adult Participants With Advanced Parkinson's Disease	174	Conference Abstract or Presentation	Positive	Favorable	Not reported	Improves predictability of motor states, which may help patients plan their day around periods of “On” time	https://www.mdsabstracts.org/abstract/predictability-of-motor-states-with-foslevodopa-foscarbidopa-in-patients-with-advanced-parkinsons-disease/
NCT03670953	IPX203	Amneal (was Impax Pharma)	L-DOPA/ carbidopa extended release	Phase 3	A Study to Evaluate the Safety and Efficacy of IPX203 in Parkinson's Disease Participants With Motor Fluctuations	630	Conference Abstract or Presentation	Positive	Favorable	Not reported	Significant increase in patients waking up “On” during study period	https://www.mdsabstracts.org/abstract/impact-of-ipx203-on-parkinsons-patients-motor-states-upon-awakening-analysis-of-patient-diary-data/

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
NCT02438215	IRX4204	Io Therapeutics	Selective RXR agonist	Phase 1	Study of IRX4204 for Treatment of Early Parkinson's Disease	15	Conference Abstract or Presentation	NA	Favorable	Safe and well tolerated	Demonstrated brain penetrance & improvement of motor functions in 13/15 patients in open label Phase I/II trial	https://iotherapeutics.com/wpcontent/uploads/2024/07/IORX4204forNormalBrainAgingPDandADFASEBRetinoidsConference_2024.pdf
NCT02439203	JM-010 (Buspirone/ Zolmitriptan)	Contera Pharma Bukwang	Serotonin 1 receptor agonist combination (buspirone & zolmitrip-tan)	Phase 2	Efficacy and Safety of JM-010 in PD With Levodopa-Induced Dyskinesia	30	Conference Abstract or Presentation	Positive	Favorable	No serious AEs	Significantly reduced LID severity without worsening Parkinsonian motor function.	https://www.mdsabstracts.org/abstract/buspirone-zolmitriptan-combination-exerts-synergistic-reduction-in-dyskinesia-without-worsening-parkinson-disease-motor-symptomatology/
NCT06037590	Levodopa Cyclops	PureIMS, B.V.	Inhaled levodopa	Phase 1	A Pilot Comparative Bioavailability Study of Levodopa Administered Via Levodopa Cyclops Relative to INBRIJA	26	Conference Abstract or Presentation	NA	NA	Diarrhea (1 event)	Absorption from both DPIs comparable fulfilling bioequivalence criteria, albeit with improved usability	https://www.mdsabstracts.org/abstract/a-comparative-bioavailability-study-between-a-marketed-capsule-based-levodopa-dry-powder-inhaler-and-a-new-pre-filled-levodopa-dry-powder-inhaler/
NCT04273932	Lithium	State University of New York at Buffalo	Protein kinase C inhibitor (treatment for bipolar disorder)	Phase 1	Effects of Lithium Therapy on Blood-based Therapeutic Targets in Parkinson's Disease.	19	Conference Abstract or Presentation	NA	Favorable	Two of 16 patients discontinued	Associated with median reductions in serum NfL. Larger controlled trials necessary	https://www.mdsabstracts.org/abstract/lithium-therapy-associated-with-reductions-in-serum-neurofilament-light-chain-nfl-in-parkinsons-disease/
NCT04006210	ND0612	Mitsubishi Tanabe/ Neuroderm	Sub-cutaneous L-DOPA	Phase 3	Efficacy, Safety and Tolerability Study of ND0612 vs. Oral Immediate Release Levodopa/Carbidopa (IR-LD/CD) in Subjects With Parkinson's Disease Experiencing Motor Fluctuations	381	Conference Abstract or Presentation	Positive	Favorable	Generally well tolerated	Efficacy on motor fluctations QoL and most movement symptoms sustained for 12 months	https://www.mt-pharma-america.com/media/news/press-releases/2024/09/30/mitsubishi-tanabe-pharma-america-presents-open-label-extension-outcomes-and-additional-data-from-Phase -3-boundless-trial-of-investigational-nd0612-in-parkinsons-disease

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
NCT04006210	ND0612	Mitsubishi Tanabe/ Neuroderm	Sub-cutaneous L-DOPA	Phase 3	Efficacy, Safety and Tolerability Study of ND0612 vs. Oral Immediate Release Levodopa/Carbidopa (IR-LD/CD) in Subjects With Parkinson's Disease Experiencing Motor Fluctuations	381	Conference Abstract or Presentation	Positive	Favorable	Not reported	Results support clinical benefit across different symptom domains of MDS-UPDRS II and III	https://www.mdsabstracts.org/abstract/efficacy-of-continuous-subcutaneous-levodopa-carbidopa-infusion-nd0612-on-motor-signs-of-pd-and-experiences-of-daily-living/
NCT04006210	ND0612	Mitsubishi Tanabe/ Neuroderm	Sub-cutaneous L-DOPA	Phase 3	Efficacy, Safety and Tolerability Study of ND0612 vs. Oral Immediate Release Levodopa/Carbidopa (IR-LD/CD) in Subjects With Parkinson's Disease Experiencing Motor Fluctuations	381	Conference Abstract or Presentation	Positive	Favorable	Not reported	More stable motor control; fewer daily transitions between motor states & more time in ON state without dyskinesia	https://www.mdsabstracts.org/abstract/impact-of-24-hour-subcutaneous-levodopa-carbidopa-infusion-nd0612-on-motor-state-transitions-throughout-the-day/
NCT04006210	ND0612	Mitsubishi Tanabe/ Neuroderm	Sub-cutaneous L-DOPA	Phase 3	Efficacy, Safety and Tolerability Study of ND0612 vs. Oral Immediate Release Levodopa/Carbidopa (IR-LD/CD) in Subjects With Parkinson's Disease Experiencing Motor Fluctuations	381	Conference Abstract or Presentation	Positive	Favorable	Not reported	Improved quality-of-life as measured by PDQ-39 compared to IR-LD/CD	https://www.mdsabstracts.org/abstract/quality-of-life-with-24-hour-subcutaneous-levodopa-carbidopa-infusion-nd0612-pdq-39-results-from-a-Phase-3-randomized-active-controlled-study/
NCT06167681	NouvNeu001	iRegene Therapeutics Co., Ltd.	Human Dopamin-ergic Progenitor Cells	Phase - Phase 2	The Safety, Tolerability and Efficacy of NouvNeu001 for Parkinson's Disease	40	Conference Abstract or Presentation	NA	Favorable	Good safety	Initial first-in-human results indicate potential to be a safe & effective therapy	https://www.mdsabstracts.org/abstract/nouvneu001-a-Phase-1-stage-chemically-induced-human-dopaminergic-progenitor-cell-therapy-for-the-treatment-of-mid-to-late-stage-parkinsons-disease/
NCT04191577	Solengepras (CVN424)	Cerevance	Selective GPR6 Inverse Agonist	Phase 2	Study of CVN424 in Parkinson's Disease Patients With Motor Fluctuations	136	CT.GOV	NA	Favorable	Headache, nausea, and vomiting	Well tolerated; Reduction in OFF time but no statistics provided	https://clinicaltrials.gov/study/NCT04191577?term=NCT04191577&rank=1&tab=results#study-record-dates

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
NCT02339064	SPN-830 (apomorphine (SQ infusion)	Supernus/ US Worldmeds	Apomor-phine infusion	Phase 3	Infusion of Apomorphine: Long-term Safety Study	99	Conference Abstract or Presentation	NA	Favorable	Infusion site reactions	Data support long-term safety, tolerability & efficacy	https://www.mdsabstracts.org/abstract/continuous-subcutaneous-apomorphine-infusion-for-parkinson-disease-motor-fluctuations-long-term-data-from-the-ongoing-infuson-extension-study/
NCT02339064	SPN-830 (apomorphine (SQ infusion)	Supernus/ US Worldmeds	Apomor-phine infusion	Phase 3	Infusion of Apomorphine: Long-term Safety Study	99	Conference Abstract or Presentation	NA	Favorable	Not reported	Reduced daily number of OFF periods & more than doubled amount of uninterrupted Good ON time	https://www.mdsabstracts.org/abstract/improvement-in-uninterrupted-good-on-time-and-reduction-in-off-periods-with-csai-treatment/
NCT04334317	TAK-071	Takeda	M1 positive allosteric modulator	Phase 2	A Study of TAK-071 in People With Parkinson Disease	64	Conference Abstract or Presentation	Negative	Positive	Mild GI events	Generally safe & well-tolerated, did not improve gait parameters, but improved cognition	https://www.mdsabstracts.org/abstract/a-Phase -2-randomized-clinical-trial-of-tak-071-an-acetylcholine-m1-receptor-positive-allosteric-modulator-in-parkinson-disease-with-cognitive-impairment/
NCT04542499	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Flexible-Dose, Adjunctive Therapy Trial in Adults With Parkinson's Disease With Motor Fluctuations	507	Conference Abstract or Presentation	Positive	Positive	Acceptable safety profile; Majority of AEs mild to moderate	Demonstrated efficacy & safety when used adjunctive to levodopa for treatment of motor fluctuations	https://www.mdscongress.org/IC24-lbas

Clinical Trials of Parkinson's Disease Drug Therapies Completed Before 1-April-2024 But Without Results Disclosed by 30-September-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

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 actually been disclosed, please let us know at PDTrialTracker@outlook.com.