Clinical Trials for Parkinson's Disease Drug Therapies: What Happened During Q3 2023?

Q3 2023 Trial Status Headlines (ref. dashboards 1-3 on pages 5-11**)**
What trials have . . .

Begun recruiting?

Recruiting began for eight trials including several of particular interest:

- Phase 2 trial of ACI-704 a vaccine against aSN from AC Immune
- Phase 2 trial of fasudil a ROCK inhibitor being repurposed for PD (it is approved in Japan and China for cerebral vasospasm)
- Phase 1 trial of PDM608 a GM-CSF fusion protein from Calibir (a spin-off from Scripps Research)

Six other trials were newly listed but not yet recruiting at quarter end -- most notable are:

- A large Phase 2 trial (n=189) of UCB and Neuropore's inhibitor of aSN misfolding (UCB0599)
- A Phase 2 trial of Cerevance's selective GPR6 inverse agonist (CVN424)

Completed enrollment?

Six trials completed enrollment including three Phase 3 trials: A study of Cerevel's tavapadon (dopamine D1/5 partial agonist) in patients with motor fluctuations, a long-term safety study with the apomorphine sub-cutaneous pump from Supernus, and a study of solifenacin (antimuscarinic approved for overactive bladder) for urinary symptoms in PD.

Also completing enrollment was the very large (n=586) Phase 2 study with prasinezumab a monoclonal anti-body to aSN from Roche and Prothena. An earlier Phase 2 study with this agent has shown signs of slowing disease progression in patients with early PD.

Reached clinical completion?

Another five trials were noted as now clinically complete (although two of them completed before Q3 but sponsors were apparently delayed in updating clinicaltrials.gov). Two studies that did complete during Q3 were a small Phase 2 study of mesenchymal stem cell therapy at the University of Texas (Houston) and a Phase 1 study with UCB7853 an antibody versus aSN from UCB and Neuropore.

Been delayed (or accelerated)?

Delays in completion date were disclosed for 11 studies (for 7 the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov) with virtually all the delays being at least 8 months. Most notable were a large (n=400) study of the supplement nicotinamide riboside (20-month delay) and Inhibikase Therapeutic's Phase 2 trial of the c-Abl kinase inhibitor risvodetinib (9-month delay).

Completion projected within the next six-months?

Thirty-four trials are projected to complete by Q1 2024 with 20 to complete in Q4 2023. This group has many interesting studies of agents with novel mechanisms of action (relative to approved medicines for PD) including:

- Phase 3 trials of exenatide (GLP-1 agonist), and a second Phase 3 trial with tavapadon (D1/5 partial agonist)
- Phase 2-3 open-label safety trial of Addex Therapeutics dipraglurant (mGluR5 negative allosteric modulator)
- Phase 2 trials of CPL500036 (PDE 10A inhibitor), VY-AADC02 (AADC gene therapy), and K0706 (Bcr/Abl kinase inhibitor)
- Phase 1-2 trials of A9-DPC (embryonic stem cell-derived dopamine progenitor cell therapy), and AAV-GAD (GAD gene therapy)
- Phase 1 studies of HER-096 (peptidomimetic for CDNF), AAV2-GDNF (GDNF gene therapy), BIIB094 (antisense oligomer to LRRK2), and PDM608 (GM-CSF fusion protein)

Q3 2023 Trial Results Headlines (ref. dashboard 4 on pages 12-18)
What trials have . . .

Had results disclosed for the first time?

Results for nine trials were disclosed for the first time. Only three had a primary efficacy endpoint (e.g., for the others the primary endpoints were safety-related), but results were viewed as favorable for eight of the nine trials.

The most exciting results disclosure was for a Phase 2 trial of the GLP-1 agonist lixisenatide. The trial hit its primary efficacy endpoint (meaning that the results were statistically significant) and results showed beneficial effects on motor progression in patients with early PD supporting a disease-modifying effect said to warrant further investigation in Phase 3.

Other highlights included:

- A Phase 3 extension study with the foslevodopa/foscarbidopa sub-cutaneous pump from Abbvie (currently under FDA review) that showed good tolerability and sustained improvements in motor fluctuations and morning stiffness.
- A Phase 2 study with cannabidiol (CBD) at the University of Colorado that showed a small *detrimental* effect on cognition following short-term use.
- A Phase 2 trial with ambroxol (a Gcase enhancer currently approved in Europe as a cough medicine) in PD Dementia. The primary endpoint was safety (and the drug was well tolerated) and secondary efficacy endpoints showed favorable trends in patients with the GBA mutation.
- Three abstracts on intial results from a Phase 2 trial with mesenchymal stem cells at the University of Texas (Houston). Results were said to indicate good tolerability and support the continuation of the study to eventually quantify treatment efficacy.

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 preprint on sub-group analyses from the Phase 2 study with prasinezumab (monoclonal anti-body to aSN) which showed that efficacy was greatest in early-stage patients with rapidly progressing disease.
- Multiple conference abstracts on additional positive results from Phase 2 and Phase 3 trials with the sub-cutaneous pump products from Abbvie, Mitubishi Tanabe / Neuroderm, and Supernus.
- A compelling conference abstract on the Phase 1 study with bemdaneprocel (human embryonic stem cell-derived neural precursor cells) reporting safety, sustained engraftment, and exploratory efficacy supporting further development (and a Phase 2 trial is expected to start in 2024)
- A conference abstract on Phase 2 results with amantadine showing 50% reduced dyskinesia and slower deterioration in freezing of gait, fatigue & quality of life.

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. Trials with "Primary completion date" within 6 months were also identified.
- 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, 2021, 2022, 2023 and The Hope List were references in identifying pharma vs. non-pharma trials within the Phase 1-3 trials, along with some information in the "agent description" and "company/sponsor" fields.
- Dashboards on Trial Results 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 2023

*Registered, Started or Finished Recruiting, Completed

posted on ClinicalTrials.gov between July 1, 2023, and September 30, 2023

dashboard 1

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT02339064	SPN-830 (apomorphine (SQ infusion)	Supernus/US Worldmeds	Apomorphine infusion	Phase 3	Infusion of Apomorphine: Long-term Safety Study	99	Unknown status	Active, not recruiting
NCT03149809	Solifenacin	Astellas Pharma	Antimuscarinic bladder relaxant	Phase 3	Behavioral or Solifenacin Therapy for Urinary Symptoms in Parkinson Disease	77	Recruiting	Active, not recruiting
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	500	Recruiting	Active, not recruiting
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	Recruiting	Active, not recruiting
NCT06021756	PT-001	Pharmather	Ketamine	Phase 1	Phase I Open-label Study of Low-dose Ketamine Infusion Treatment in Levodopa-Induced Dyskinesia in Parkinson's Disease	9	Not in CT.GOV	Active, not recruiting
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	Not in CT.GOV	Active, not recruiting
NCT02789020	Rasagiline	Generics available	Monoamine oxidase-B inhibitor	Phase 2	Image Parkinson's Disease Progression Study	96	Active, not recruiting	Completed
NCT04273932	Lithium	Buffalo University	Protein kinase C inhibitor (treatment for bipolar disorder)	Phase 1	Effects of Lithium Therapy on Blood-based Therapeutic Targets in Parkinson's Disease.	19	Active, not recruiting	Completed
NCT04506073	Mesenchymal stem cells	University of Texas, Houston	Mesenchymal stem cells	Phase 2	Phase IIa Randomized Placebo Controlled Trial: Mesenchymal Stem Cells as Disease-modifying Therapy	45	Active, not recruiting	Completed
NCT04651153	UCB7853	UCB and Neuropore	aSN antibody	Phase 1	A Safety and Pharmacokinetics Study of UCB7853 in Healthy Participants and Participants With PD	57	Active, not recruiting	Completed

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT05435729	DSP 9632P	Sumitomo Pharma Co., Ltd	Transdermal levodopa	Phase 1	A Pharmacodynamics and Safety Study of DSP-9632P in Patients With Levodopa-Induced Dyskinesia in Parkinson's Disease	7	Recruiting	Completed
NCT05931484	FHL-301	Forest Hill Labs	Increases GDNF via PPARa pathway	Phase 2	Study to Evaluate the Safety, Tolerability, Efficacy, and PK of FHL-301 in Parkinson's Disease Patients.	32	Not in CT.GOV	Not yet recruiting
NCT05979415	AZ-009 (inhaled apomorphine)	Alexza Pharmaceuticals	Inhaled apomorphine	Phase 2	Study to Evaluate the Efficacy and Safety of Staccato Apomorphine (AZ-009) in Patients With Parkinson's Disease Experiencing OFF Episodes	50	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 in CT.GOV	Not yet recruiting
NCT06004180	Lu AF28996	Lundbeck	D1/D2 agonist	Phase 1	A Trial Investigating Lu AF28996 in Adult Japanese Participants With Parkinson's Disease (PD)	6	Not in CT.GOV	Not yet recruiting
NCT06006247	CVN424	Cerevance	Selective GPR6 Inverse Agonist	Phase 2	Early Parkinson's Disease Monotherapy With CVN424	60	Not in CT.GOV	Not yet recruiting
NCT06055985	UCB0599	UCB and Neuropore (NPT 200-11)	Inhibitor of aSN misfolding	Phase 2	A Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of UCB0022 in Study Participants With Advanced Parkinson's Disease	189	Not in CT.GOV	Not yet recruiting
NCT05084365	Sulphoraphane	Central South University (China)	Antioxidant, anti-inflammatory	Phase 2	A 6-month Study to Evaluate Sulforaphane Effects in PD Patients	100	Not yet recruiting	Recruiting
NCT05824728	AGB101	AgeneBio	Low dose levetiracetam (anti-epileptic)	Phase 2	Clinical Trial Evaluating the Efficacy and Safety of AGB101 for Treatment of Parkinson's Disease Related Psychosis	30	Not yet recruiting	Recruiting
NCT05931575	Fasudil	Technical University of Munich	ROCK inhibitor	Phase 2	Safety, Tolerability and Symptomatic Efficacy of the ROCK-Inhibitor Fasudil in Patients With Parkinson's Disease	75	Not in CT.GOV	Recruiting
NCT05950906	PDM608	Calibir (Scripps Research)	GM-CSF fusion protein	Phase 1	Study to Assess PDM608 in Healthy Adult Subjects	88	Not in CT.GOV	Recruiting
NCT05959044	Folic acid	Bangabandhu Sheikh Mujib Medical University	Vitamin B9	Phase 2	Effect of Folic Acid in Levodopa Treated Parkinson's Disease Patients	60	Not in CT.GOV	Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT05962957	Pentoxifylline	Tanta University	Supresses TLR4/NF-κB & activates Nrf2	Phase 2	Pentoxifylline and Parkinsonism	50	Not in CT.GOV	Recruiting
NCT05997043	Botulinum Toxin	Calgary University/Allergan	Botulinum toxin type A	Early Phase 1	Safety and Efficacy of Botulinum Toxin A for Treatment of Overactive Bladder in Parkinson's Disease	60	Not in CT.GOV	Recruiting
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	Not in CT.GOV	Recruiting
NCT05418673	BIIB122 (DNL151)	Biogen & Denali	LRRK2 inhibitor	Phase 3	A Study to Assess if BIIB122 Tablets Are Safe and Can Slow Worsening of Early-Stage Parkinson's Disease in Participants With Specific LRRK2 Genetic Variants Between the Ages of 30 and 80 Using the Movement Disorder Society-Unified Parkinson's Disease Rating Scale	6	Active, not recruiting	Terminated
NCT03594656	Lingzhi (Ganoderma)	Xuanwu Hospital, Beijing	Mushroom extract	Phase 3	Effects of Lingzhi on Disease Progression in Patients With Untreated Early Parkinson's Disease	288	Recruiting	Unknown status
NCT03684122	Mesenchymal stem cells	Jordan University	Mesenchymal stem cells	Phase 1| Phase 2	Use of Mesenchymal Stem Cells (MSCs) Differentiated Into Neural Stem Cells (NSCs) in People With Parkinson's (PD).	10	Active, not recruiting	Unknown status
NCT03858270	Memantine	Wayne State University	NMDA receptor modulator	Phase 3	Inhibition of alpha synuclein Cell-cell Transmission by NMDAR Blocker, Memantine	50	Recruiting	Unknown status
NCT04043338	XC130	Xoc Pharmaceutical	Dopamine agonist	Phase 1	Single Ascending Dose Study Investigating the Safety, Tolerability, and PK of XC130-A10H in Healthy Adult Subjects	56	Active, not recruiting	Unknown status
NCT04152655	Idebenone	Zhejiang University	Analogue of coenzyme Q10	Phase 2| Phase 3	A Study of Efficacy and Safety of Idebenone vs. Placebo in Prodromal Parkinson Disease	180	Recruiting	Unknown status
NCT05036473	WD-1603	Hong Kong WD Pharma Co	Extended release carbidopa/levodopa	Phase 2	A Study of the Efficacy and Safety of Carbidopa-Levodopa Extended-Release Tablets in Patients With Parkinson's Disease	40	Recruiting	Unknown status
NCT05056194	XW10172 (Valiloxybate)	XW Pharma	GABA B agonist	Phase 2	Valiloxybate (XW10172 MR) Efficacy and Safety Parkinson's Disease Study	70	Not yet recruiting	Unknown status

Clinical Trials of Parkinson's Disease Drug Therapies

Change in Completion Date Dashboard: Q3 2023

posted on ClinicalTrials.gov between July 1, 2023, and September 30, 2023

dashboard 2

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT04470037	DAAOI-P	China Medical University Hospital	D-amino acid oxidase inhibitor	Phase 2	Multidisciplinary Study of Novel NMDA Modulation for Neurodegenerative Disorder	60	1-Dec-2022	1-Dec-2024	731
NCT03568968	Nicotinamide riboside	Haukeland University Hospital	Nicotinamide riboside	Not Applicable	A Randomized Controlled Trial of Nicotinamide Riboside Supplementation in Early Parkinson's Disease	400	15-May-2023	31-Dec-2024	596
NCT04691661	Radotinib	Il Yang	c-Abl kinase inhibitor	Phase 2	Safety, Tolerability, Pharmacokinetics and Efficacy Study of Radotinib in PD	40	31-Dec-2022	30-Jun-2024	547
NCT05471609	Buccal levodopa/carbidopa	University of Minnesota	Levodopa/Carbidopa Sachets	Early Phase 1	Sustained Release Oral Formulation for Treatment of Parkinson's Disease	6	2-Aug-2023	2-Dec-2024	488
NCT05084365	Sulphoraphane	Central South University (China)	Antioxidant, anti-inflammatory	Phase 2	A 6-month Study to Evaluate Sulforaphane Effects in PD Patients	100	1-Oct-2022	15-Nov-2023	410
NCT02897063	Droxidopa	Loma Linda Univ/Lundbeck	L-threo-dihydroxyphenylserine	Phase 1	Effects of Midodrine and Droxidopa on Splanchnic Capacitance in Autonomic Failure	34	1-Mar-2023	1-Mar-2024	366
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)	25	1-Dec-2023	1-Dec-2024	366
NCT05424276	Risvodetinib (iKT-148009)	Inhibikase Therapeutics	c-Abl kinase inhibitor	Phase 2	Randomized, Double-Blind, Placebo-Controlled Trial of IkT-148009 in Untreated PD	120	30-Sep-2023	30-Jun-2024	274
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	7-Feb-2023	30-Sep-2023	235
NCT05709301	Donepezil	Oregon Health & Science University	Cholinesterase inhibitor	Phase 2	Randomized Trial of Donepezil for Treatment of Mild Cognitive Impairment in PD	120	1-May-2025	1-Nov-2025	184
NCT04251585	Nasal insulin	Multiple programs	Intra-nasal insulin	Phase 2	Intranasal Insulin in Parkinson's Disease	30	1-Jun-2023	1-Oct-2023	122

Clinical Trials of Parkinson's Disease Drug Therapies
with Primary Completion Date within 6 months of 30-September-2023
trial data: ClinicalTrials.gov

dashboard 3

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
NCT04251585	Nasal insulin	Multiple programs	Intra-nasal insulin	Phase 2	Intranasal Insulin in Parkinson's Disease	30	1-Oct-2023	1-Dec-2023
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	23-Oct-2023	23-Oct-2023
NCT03790670	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Assessments of Leukine During Treatment of Parkinson's Disease	7	30-Oct-2023	30-Dec-2024
NCT05297201	CPL500036	Celon Pharma	PDE 10A inhibitor	Phase 2	Efficacy, Safety and Pharmacokinetic Study of CPL500036 in Patients With Levodopa Induced Dyskinesia	108	1-Nov-2023	1-Dec-2023
NCT05915247	HER-096	Herantis	Peptidomimetic for cerebral dopamine neurotrophic factor	Phase 1	Single Ascending Doses of HER-096 in Healthy Subjects	60	1-Nov-2023	1-Nov-2023
NCT05084365	Sulphoraphane	Central South University (China)	Antioxidant, anti-inflammatory	Phase 2	A 6-month Study to Evaluate Sulforaphane Effects in PD Patients	100	15-Nov-2023	31-Dec-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
NCT02616120	SQJZ herbal mixtures	Dongzhimen Hospital, Beijing	Herbal mixture	Phase 2	Effect of SQJZ Herbal Mixtures on Non-motor Symptoms of Parkinson's Disease	240	1-Dec-2023	1-Dec-2023
NCT02914366	Ambroxol	Lawson Health Research Institute	Cough medicine, Gcase enhancer	Phase 2	Ambroxol as a Treatment for Parkinson's Disease Dementia	55	1-Dec-2023	1-Dec-2023
NCT03562494	VY-AADC02	Neurocrine Biosciences| Voyager Therapeutics	AADC gene therapy	Phase 2	VY-AADC02 for Parkinson's Disease With Motor Fluctuations (RESTORE-1)	85	1-Dec-2023	1-Dec-2023
NCT03575195	Rifaximin	Taipei Medical University	Antibiotic	Phase 1| Phase 2	Microbiota Intervention to Change the Response of Parkinson's Disease	86	1-Dec-2023	1-Dec-2023

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
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	81	1-Dec-2023	1-Dec-2023
NCT04147949	AV-101 (L-4-chlorokyurenine or 4-Cl-KYN)	VistaGen Therapeutics	NMDAR GlyB modulator	Phase 2	AV-101 (L-4-chlorokynurenine) in Parkinson's Disease Subjects With Levodopa-Induced Dyskinesia	20	1-Dec-2023	1-Apr-2024
NCT04167540	AAV2-GDNF	Ask Bio (was Brain Neurotherapy Bio)	GDNF gene therapy	Phase 1	GDNF Gene Therapy for Parkinson's Disease	11	1-Dec-2023	1-Jun-2027
NCT05116813	Dipraglurant	Addex Therapeutics	mGluR5 negative allosteric modulator	Phase 2| Phase 3	Open-label Safety Study of Dipraglurant (ADX48621) in Patients With Parkinson's Disease Receiving Levodopa-based Therapy	140	1-Dec-2023	1-Dec-2023
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	2-Dec-2023	2-Dec-2023
NCT03683225	CTC-413	Chase Therapeutics	Extended-release pramipexole	Phase 2	A Study to Evaluate in Patients With Parkinsonian Type Disorders	24	30-Dec-2023	30-Dec-2023
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	31-Dec-2023	31-Dec-2023
NCT02864004	Apomorphine (pump)	Supernus/ US Worldmeds	Apomorphine infusion	Phase 3	Apomorphine Pump in Early Stage of Parkinson's Disease (EARLY-PUMP)	192	31-Dec-2023	30-Jun-2025
NCT04167813	Ondansetron	University College London	Treatment for hallucinations	Phase 2	Trial of Ondansetron as a Parkinson's Hallucinations Treatment	306	1-Jan-2024	14-Jan-2025
NCT04978597	Opicapone	Neurocrine	Catechol-O-methyltransferase (COMT) inhibitor	Phase 3	Early ParkinSon wIth L-DOPA/DDCI and OpicapoNe (EPSILON Study)	410	1-Jan-2024	1-Jan-2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
NCT05887466	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	1-Jan-2024	1-Jan-2026
NCT05603715	Pyridostigmine	University of Vermont	Cholinesterase inhibitor	Phase 2	Pyridostigmine for the Treatment of Constipation in Parkinson Disease	16	1-Feb-2024	1-Dec-2024
NCT05677633	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Validation Following Sargramostim Treatment in Parkinson's Disease	10	1-Feb-2024	1-May-2024
NCT05979415	AZ-009 (inhaled apomorphine)	Alexza Pharmaceuticals	Inhaled apomorphine	Phase 2	Study to Evaluate the Efficacy and Safety of Staccato Apomorphine (AZ-009) in Patients With Parkinson's Disease Experiencing OFF Episodes	50	1-Feb-2024	1-Mar-2024
NCT04232969	Exenatide	Florida University	GLP-1 agonist	Phase 3	Exenatide Once Weekly Over 2 Years as a Potential Disease Modifying Treatment for Parkinson's Disease	194	24-Feb-2024	30-Jun-2024
NCT02897063	Droxidopa	Loma Linda University/Lundbeck	L-threo-dihydroxyphenylserine	Phase 1	Effects of Midodrine and Droxidopa on Splanchnic Capacitance in Autonomic Failure	34	1-Mar-2024	1-Aug-2024
NCT03655236	K0706/SCC - 138	Sun Pharma/SPARC	Bcr/Abl kinase inhibitor	Phase 2	PROSEEK: A Phase 2 Study In Early PD Patients Evaluating The Safety And Efficacy Of Abl Tyrosine Kinase Inhibition Using K0706	504	1-Mar-2024	1-Mar-2024
NCT04542499	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Flexible-Dose, Adjunctive Therapy Trial in Adults With PD With Motor Fluctuations	500	1-Mar-2024	1-Apr-2024
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	1-Mar-2024	1-Mar-2024
NCT05781711	Metformin	Tanta University	Biguanide antidiabetic (increases insulin sensitivity)	Phase 2	Clinical Study to Evaluate the Possible Efficacy of Metformin in Patients With Parkinson's Disease	60	20-Mar-2024	20-Mar-2025
NCT05950906	PDM608	Calibir (Scripps Research)	GM-CSF fusion protein	Phase 1	Study to Assess PDM608 in Healthy Adult Subjects	88	26-Mar-2024	30-Apr-2024

Results Dashboard: Q3 2023

Clinical Trials of Parkinson's Disease Drug Therapies with *Results Newly Disclosed* Between 1-July-2023 and 30-September-2023

dashboard 4

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
NCT05121831	DGX-001	Viage Therapeutics	Vagus nerve stimulator	Phase 1	A First in Human Study to Assess the Safety, Tolerability, and Pharmacokinetics of DGX-001	68	Press Release / Corporate Communications	NA	NA	Well tolerated	Potential signals of clinical activity, including potential to improve cognitive & executive functions, as measured through qEEG changes	https://www.prnewswire.com/news-releases/viage-therapeutics-announces-data-from-a-phase-1-study-with-dgx-001-a-first-in-class-oral-neurotherapeutic-targeting-cognitive-impairment-in-patients-with-alzheimers-disease-and-parkinsons-disease-301885909.html
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	Peer-reviewed Manuscript	NA	Negative	Adverse cognitive events reported at least twice as often as placebo	CBD/THC has a small detrimental effect on cognition following short-term use	https://movementdisorders.onlinelibrary.wiley.com/doi/10.1002/mds.29447#mds29447-bib-0013
NCT03552068	Clonidine	Lyon (Hospices Civil)	Adrenergic receptor agonist	Phase 2	Study of Clonidine Efficacy for the Treatment of Impulse Control Disorders in Parkinson's Disease:	38	Peer-reviewed Manuscript	Negative	Favorable	Well tolerated	Study not large enough to demonstrate superiority compared to placebo in reducing ICDs	https://link.springer.com/article/10.1007/s00415-023-11814-y#Tab3
NCT03439943	Lixisenatide	Sanofi/ CPT-LCT/ Van Andel	GLP-1 agonist	Phase 2	Study to Evaluate the Effect of Lixisenatide in Patient With Parkinson's Disease	156	Conference Abstract or Presentation	Positive	Mix of neutral & favorable	Nausea	Beneficial effects on motor progression in patients with early PD, supporting disease-modifying effect that warrants further investigation	https://www.mdsabstracts.org/abstract/multicenter-randomized-placebo-controlled-double-blind-parallel-group-proof-of-concept-study-of-lixisenatide-in-patients-with-early-parkinsons-disease-pd-the-lixipark-trial-nct0343994/

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
NCT02914366	Ambroxol	Lawson Health Research Institute	Cough medicine, Gcase enhancer	Phase 2	Ambroxol as a Treatment for Parkinson's Disease Dementia	55	Conference Abstract or Presentation	NA	Favorable	Well tolerated	Preliminary analysis suggests patients receiving high dose demonstrated improvements in Neuropsychiatric Inventory & GBA carriers demonstrated improvement on ADAS Cog	https://www.mdsabstracts.org/abstract/a-phase-2-randomized-double-blind-placebo-controlled-trial-of-ambroxol-as-a-disease-modifying-treatment-for-parkinsons-disease-dementia/
NCT04685265	Anle 138b	Modag/Cure Parkinson's Trust	Inhibits aSN oligomerisa-tion	Phase 1	A Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of anle138b in Parkinson's Disease	70	Conference Abstract or Presentation	NA	Not reported	No SAEs or terminations due to AEs	Safe & well tolerated; Exposures above the minimally effective plasma levels seen in animal models; Efficacy trials planned	https://www.mdsabstracts.org/abstract/anle138b-p1-02-a-randomised-double-blinded-placebo-controlled-phase-1b-study-to-investigate-safety-tolerability-pharmacokinetics-and-pharmacodynamics-of-the-oligomer-modulator-anle138b-in-parkins/
NCT03552068	Clonidine	Lyon (Hospices Civil)	Adrenergic receptor agonist	Phase 2	Study of Clonidine Efficacy for the Treatment of Impulse Control Disorders in Parkinson's Disease:	38	Conference Abstract or Presentation	Neutral	Favorable	Orthostatic hypotension	Well tolerated but study not powerful enough to demonstrate significant superiority despite greater reduction of total QUIP score	https://www.mdsabstracts.org/abstract/efficacy-and-safety-of-clonidine-for-the-treatment-of-impulse-control-disorder-in-parkinsons-disease-a-multicentre-parallel-randomised-double-blind-phase-2b-clinical-trial/
NCT04379050	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/Carbi dopa prodrug	Phase 3	Extension Study To Evaluate Safety And Tolerability Of 24-Hour Daily Exposure Of Continuous Subcutaneous Infusion of ABBV-951 In Adult Participants With Parkinson's Disease	130	Conference Abstract or Presentation	NA	Favorable	Non-serious & mild or moderate	Generally safe & well tolerated; effected sustained improvements in motor fluctuations & morning akinesia	https://www.mdsabstracts.org/abstract/open-label-extension-study-of-long-term-safety-and-tolerability-of-foslevodopa-foscarbidopa-for-treatment-of-advanced-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
NCT04506073	Mesenchymal stem cells	University of Texas, Houston	Mesenchy-mal stem cells	Phase 2	Phase IIa Randomized Placebo Controlled Trial: Mesenchymal Stem Cells as a Disease-modifying Therapy for iPD	45	Conference Abstract or Presentation	NA	Not reported	Not reported	Non-statistically significant increase in normalized NM signal in the left SNpc, contrary to current understanding of NM loss with disease progression	https://www.mdsabstracts.org/abstract/preliminary-report-on-neuromelanin-sensitive-mri-signal-change-after-allogeneic-bone-marrow-derived-mesenchymal-stem-cells-therapy-phase-iia-double-blind-randomized-controlled-trial/
NCT04506073	Mesenchymal stem cells	University of Texas, Houston	Mesenchy-mal stem cells	Phase 2	Phase IIa Randomized Placebo Controlled Trial: Mesenchymal Stem Cells as a Disease-modifying Therapy for iPD	45	Conference Abstract or Presentation	NA	Mixed	Not reported	Results warrant completing 88-week study & final unblinded analysis to quantify treatment efficacy	https://www.mdsabstracts.org/abstract/preliminary-report-on-the-efficacy-of-allogeneic-bone-marrow-derived-mesenchymal-stem-cells-as-a-disease-modifying-therapy-for-idiopathic-parkinsons-disease-phase-iia-double-blind-randomized-contr/
NCT04506073	Mesenchymal stem cells	University of Texas, Houston	Mesenchy-mal stem cells	Phase 2	Phase IIa Randomized Placebo Controlled Trial: Mesenchymal Stem Cells as a Disease-modifying Therapy for iPD	45	Conference Abstract or Presentation	NA	Not reported	Mild-moderate & transient	Infusions appear safe & well tolerated in subjects with mild to moderate PD	https://www.mdsabstracts.org/abstract/preliminary-report-on-the-safety-and-tolerability-of-allogeneic-bone-marrow-derived-mesenchymal-stem-cells-as-a-disease-modifying-therapy-for-parkinsons-disease-phase-iia-double-blind-rando/
NCT04687878	Nasal insulin	Multiple development programs	Intra-nasal insulin	Phase 2	The Effect of Intranasal Insulin on Motor and Non-motor Symptoms in Parkinson's Disease Patients	40	Conference Abstract or Presentation	Negative	Favorable	No AEs including hypo-glycemia	Promising treatment to attenuate memory and cognitive dysfunctions	https://www.mdsabstracts.org/abstract/the-effect-of-intranasal-insulin-administration-on-motor-and-non-motor-symptoms-in-parkinsons-disease-patients-a-randomized-double-blinded-placebo-controlled-clinical-trial/

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-2023 and 30-September-2023

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
NCT02906020	Venglustat (GZ/ SAR402671)	Sanofi	GCS inhibitor	Phase 2	A Global Study to Assess the Drug Dynamics, Efficacy, and Safety of Venglustat (GZ/SAR402671) in Parkinson's Disease Patients Carrying a Glucocerebrosidase (GBA) Gene Mutation	273	Peer-reviewed Manuscript	Negative	Negative	Constipation & nausea	Satisfactory safety profile but no beneficial treatment effect compared with placebo	https://pubmed.ncbi.nlm.nih.gov/37479372/
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	Preprint	Negative	Negative	Not reported	Efficacy was greater in individuals with early-stage PD with a more rapidly progressing phenotype	https://www.researchsquare.com/article/rs-3128098/v1
NCT03295786	CDNF (Cerebral Dopamine Neurotrophic Factor)	Herantis	Cerebral dopamine neurotro-phic factor	Phase 1-Phase 2	Clinical Study to Test the Safety of CDNF by Brain Infusion in Patients With Parkinson's Disease	17	Peer-reviewed Manuscript	NA	Favorable in select patients	Adverse events related to infusion procedure	Safe & well tolerated; possible signs of biological response observed in individual patients	https://movementdisorders.onlinelibrary.wiley.com/doi/10.1002/mds.29426
NCT04435431	IRL 790 (mesdopetam)	Integrative research laboratories/ Ipsen	Dopamine D3 receptor antagonist	Phase 2	A Clinical Study of Mesdopetam in Patients With Parkinson's Disease Experiencing Levodopa Induced Dyskinesia	156	Conference Abstract or Presentation	Negative	Favorable	Similar to placebo	Significant antidyskinetic effects obtained without impairing motor function & further strengthened by apparent reduction in OFF-time	https://www.mdsabstracts.org/abstract/results-from-irl790c005-a-randomized-double-blind-placebo-controlled-phase-iib-study-evaluating-the-efficacy-of-mesdopetam-on-daily-on-time-without-troublesome-dyskinesia-in-patients-with-parkinso/
NCT02726386	ND0612	Mitsubishi Tanabe/ Neuroderm	Sub-cutaneous L-DOPA	Phase 2	A Long Term Safety Study of ND0612 Administered as a Continuous SC Infusion in Advanced Parkinson's Disease	214	Conference Abstract or Presentation	NA	Favorable	Infusion site reactions	Three-year data from open-label extension study support long-term safety, tolerability & efficacy	https://www.mdsabstracts.org/abstract/continuous-subcutaneous-levodopa-carbidopa-infusion-with-nd0612-for-parkinsons-disease-three-year-data-from-the-open-label-beyond-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
NCT04006210	ND0612	Mitsubishi Tanabe/ Neuroderm	Sub-cutaneous L-DOPA	Phase 3	Efficacy, Safety and Tolerability Study of ND0612 vs. Oral IR-LD/CD in Subjects With PD Experiencing Motor Fluctuations	381	Conference Abstract or Presentation	Positive	Favorable	Infusion site reactions	Clinically meaningful improvement in motor fluctuations & functional endpoints vs oral IR-LD/CD and generally well tolerated	https://www.mdsabstracts.org/abstract/continuous-subcutaneous-levodopa-carbidopa-infusion-with-nd0612-for-patients-with-parkinsons-disease-and-motor-fluctuations-results-from-the-phase-3-randomized-active-controlled-boundless-s/
NCT02726386	ND0612	Mitsubishi Tanabe/ Neuroderm	Sub-cutaneous L-DOPA	Phase 2	A Long Term Safety Study of ND0612 Administered as a Continuous SC Infusion in Advanced Parkinson's Disease	214	Conference Abstract or Presentation	NA	Favorable	Not reported	Provides preliminary support for 12-month efficacy in reducing OFF time	https://www.mdsabstracts.org/abstract/reductions-in-off-time-with-nd0612-for-patients-with-parkinsons-disease-experiencing-motor-fluctuations-responder-analysis-from-an-open-label-phase-2-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	Favorable	Favorable	Safety profile, evidence of sustained engraftment & positive exploratory clinical outcomes supports further investigation	https://www.mdsabstracts.org/abstract/dopaminergic-neuronal-cell-therapy-for-parkinsons-disease-results-from-a-phase-1-study-of-bemdaneprocel/
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 Participants With Parkinson's Disease (PD)	244	Conference Abstract or Presentation	NA	Favorable	Infusion site reactions	Favorable benefit/risk profile; may provide an efficacious, individualized, non-surgical treatment option for advanced PD	https://www.mdsabstracts.org/abstract/continuous-subcutaneous-foslevodopa-foscarbidopa-final-results-from-a-phase-3-open-label-study/
NCT01538329	Amantadine	Generics available	Nicotinic antagonist, dopamine agonist, and noncompetitive NMDA antagonist	Phase 2	Amantadine and L-DOPA-induced Dyskinesia in Early Parkinson's Disease	210	Conference Abstract or Presentation	NA	Mix of neutral & favorable	In line with previous use	50% lower dyskinesia after 18 months. Freezing of gait, fatigue &QoL outcomes deteriorated significantly less & L-DOPA daily dose increased less	https://www.mdsabstracts.org/abstract/decreased-occurrence-of-dyskinesia-when-combining-amantadine-to-l-dopa-in-early-parkinson-disease-pd-the-premandysk-trial/

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 reactions, dyskinesia & nausea	Improvement in OFF time & Good-ON time observed at first titration visit & continued throughout 1-year maintenance phase; titration was well-tolerated	https://www.mdsabstracts.org/abstract/early-onset-of-efficacy-during-titration-in-us-phase-3-open-label-infuson-trial-of-apomorphine-subcutaneous-infusion-for-parkinsons-disease-motor-fluctuations/
NCT03781167	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/Carbi dopa prodrug	Phase 3	A Study to Evaluate the Safety and Tolerability of ABBV-951 in Participants With Parkinson's Disease (PD)	244	Conference Abstract or Presentation	NA	Not reported	Infusion site reactions	Most adverse events & discontinuations occurred within the first 10 weeks which included dose optimization period	https://www.mdsabstracts.org/abstract/safety-of-foslevodopa-foscarbidopa-during-optimization-and-maintenance-treatment-post-hoc-analysis-of-a-phase-3-single-arm-trial/
NCT03781167	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/Carbi dopa prodrug	Phase 3	A Study to Evaluate the Safety and Tolerability of ABBV-951 in Participants With Parkinson's Disease (PD)	244	Conference Abstract or Presentation	NA	Favorable	Not reported	More likely to wake up in good ON & experience fewer motor fluctuations within 1 wk, with improvements up to 52 wk.; permits greater predictability of motor responses	https://www.mdsabstracts.org/abstract/stability-and-predictability-of-motor-symptom-control-in-patients-with-advanced-parkinsons-disease-apd-receiving-continuous-subcutaneous-foslevodopa-foscarbidopa-ldp-cdp/
NCT06021756	PT-001	Pharmather	Ketamine	Phase 1	Phase I Open-label Study of Low-dose Ketamine Infusion Treatment in Levodopa-Induced Dyskinesia in Parkinson's Disease	9	Conference Abstract or Presentation	Positive	Favorable	Dissociation & hypertension	Results provide further support for the repurposing of subanesthetic ketamine for individuals with LID	https://www.mdsabstracts.org/abstract/subanesthetic-infusion-of-ketamine-produces-long-term-reduction-in-levodopa-induced-dyskinesia-and-depression-in-individuals-with-parkinsons-disease/
NCT04056689	DNL-151	Denali Therapeutics	LRRK2 inhibitor	Phase 1	Study to Evaluate DNL151 in Subjects With Parkinson's Disease	36	Conference Abstract or Presentation	NA	NA	No serious AEs	Potently inhibited peripheral and central LRRK2 activity at doses that were generally well tolerated	https://www.mdsabstracts.org/abstract/lrrk2-inhibition-by-biib122-dnl151-demonstrates-robust-target-and-lysosomal-engagement-pharmacokinetics-pharmacodynamics-and-safety-in-phase-1-and-phase-1b-studies-in-healthy-and-parkinsons/

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
NCT05148884	NLX-112 (befiradol)	Neurolixis	Selective serotonin 5-HT1A full agonist	Phase 2	Study to Assess the Safety, Tolerability and Preliminary Efficacy of NLX-112 Versus Placebo in L-dopa-induced Dyskinesia	27	Conference Abstract or Presentation	NA	Favorable	Good safety; no serious AEs	Safe, well tolerated and significantly reduced LID	https://www.mdsabstracts.org/abstract/nlx-112-has-favorable-safety-and-tolerability-and-displays-efficacy-against-levodopa-induced-dyskinesia-lid-in-parkinsons-disease-pd/
NCT02789020	Rasagiline	Generics available	Monoamine oxidase-B inhibitor	Phase 2	Image Parkinson's Disease Progression Study	96	CT.GOV	Negative	Negative	Comparable to placebo	No evidence that 1 mg/day rasagiline has a disease-modifying effect	https://classic.clinicaltrials.gov/ct2/show/results/NCT02789020?term=NCT02789020&draw=2&rank=1
NCT03815916	CNM-Au8 (Gold Nanocrystals)	Clene Nanoscience	Gold nano-particles	Phase 2	31P-MRS Imaging to Assess the Effects of CNM-Au8 on Impaired Neuronal Redox State in Parkinson's Disease	13	Preprint	NA	Mix of neutral & favorable	sinusitis, nasopharynx-gitis & paresthesia	Demonstrate brain target engagement as direct modulator of brain energy metabolism & support further investigation	https://www.researchsquare.com/article/rs-3168496/v1