Clinical Trials for Parkinson's Disease Drug Therapies: What Happened During Q1 2024?

Q1 2024 Trial Status Headlines (ref. dashboards pgs. 4-8)

What trials have . . .

Begun recruiting?

Recruiting began for six trials including two of particular interest:

- A Phase 1-2 cell therapy trial in China of NouvNeu001 (human dopaminergic progenitor cells from iRegene Therapeutics)
- An Early Phase 1 trial of RGL-193 a dual AADC and GDNF gene therapy from Shanghai Regenelead Therapies Co., Ltd.

Four other trials were newly listed but not yet recruiting at quarter end including Phase 2 trials of AB-1005 (GDNF gene therapy from Bayer subsidiary AskBio) and vutiglabridin (which promotes mitophagy and is being developed by Glaceum, Inc.)

Completed enrollment?

Ten trials completed enrollment including a Phase 3 trial of tavapadon (Dopamine D1/5 partial agonist from Cerevel) in early PD and three notable Phase 2 trials:

- Two trials of JM-010 a repurposed combination of buspirone and zolmitriptan for levodopa-induced dyskinesia from Contera Pharma
- A large (N=168) trial of ondansetron (5-HT3 antagonist currently approved for prevention of nausea & vomiting) for hallucinations in PD

Also completing enrollment were Phase 1-2 trials of another cell therapy (TED-A9, ESC-derived dopamine progenitor cells from S. Biomedics Co., Ltd.) and another gene therapy (AAV-GAD from MeiraGTx).

Reached clinical completion?

Two Phase 2 trials were noted as now clinically complete including a trial of CST-103 and CST-107 (combination therapy to restore brain homeostasis from CuraSen Therapeutics) and a trial of SAGE-718 (NMDA receptor modulator from Sage Therapeutics) for cognitive impairment in PD.

Been delayed (or accelerated)?

Delays in completion date were disclosed for 17 studies (for 5 the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov) with most of the delays being at least 5 months. Most notable were Phase 2 studies of ondansetron a 5-HT3 antagonist for hallucinations being studied by University College London (8-month delay), and CPL5000036 a PDE 10A inhibitor from Celon Pharma (7-month delay).

Only one study had an accelerated completion date disclosed: A Phase 1 trial of R07486967 a NRLP3 inhibitor from Roche (1-month acceleration).

Q1 2024 Trial Results Headlines (ref. dashboards pgs. 9-15)

What trials . . .

Have had results disclosed for the first time?

Results for seven trials were disclosed for the first time in Q1. Results for five trials were viewed as supporting further development of the agents studied. Only one Phase 2 trial (bumetanide, B&A Therapeutics) had a primary efficacy endpoint, and the peer-reviewed manuscript reported this was negative with no evidence of efficacy in a modest population of 40 patients. For the other trials the primary endpoints were safety related.

The other notable initial results disclosures were:

- A Phase 1-2 trial of TED-A9 (ESC-derived dopamine progenitor cell therapy from S. Biomedics Co., Ltd.) for which a press release reported no safety issues up to 3-months post-transplant surgery in 12 patients.
- A large (N=100) Phase 1 trial of UCB0022 (positive allosteric modulator of D1 receptor from UCB Pharma) for which the safety profile in both healthy volunteers and PD patients reported in a conference abstract was said to support progression to Phase 2.
- A Phase 1 trial of ALX-001 (silent allosteric modulator of mGluR5 from Allyx Therapeutics) which in a conference abstract was reported to demonstrate good safety & tolerability and full receptor occupancy at trough blood levels.

Have had additional detail on results disclosed?

Additional results were disclosed for 19 trials for which at least top-line results had been previously reported. Notable were:

- A press release on a Phase 1 trial with AB-1005 (GDNF gene therapy from Bayer/AskBio) reporting favorable safety data 18 months post-surgery. A Phase 2 trial is planned to begin in the 1st half of 2024.

- A conference abstract on a Phase 1 trial with bemdaneprocel (human ESC-derived neural precursor cells from Bayer/BlueRock Therapeutics) reporting sustained engraphtment and increased F-DOPA imaging signal 18-months post-surgery. Clinical endpoints continued to improve from 12 to 18-months post-surgery with notably large effects in the higher dose cohort (although this is a small uncontrolled study)
- A peer-reviewed manuscript on a Phase 3 trial with ND0612 (a sub-cutaneous pump formulation of levodopa/carbidopa from Mitsubishi/Neuroderm) providing more detail on the previously reported data on increased on time without troublesome dyskinesia and reduced off time compared to oral LD/CD therapy.
- A conference abstract comparing open-label results with prasinezumab (monoclonal antibody from Roche/Prothena) from a Phase 2 trial to a real-world cohort with early PD from the PPMI. Results indicated progression might be slowed with prasinezumab but this needs to be confirmed in further trials.

Are due to have results disclosed soon?

For the second time, a new analysis looks at trials that completed at least six months ago (end of Q3 2023) but for which results were not disclosed by the end of Q1 2024. These trials are likely to have results disclosed soon. The seven trials in this group include two Phase 3 academic trials with available agents (nortriptyline & escitalopram for depression in PD and buspirone for dyskinesia) and five industry trials:

- A Phase 3 repurposing trial with solifenacin (antimuscarinic approved for overactive bladder from Astellas Pharma) for urinary symptoms in PD.
- A Phase 2 trial with TAK-071 (M1 positive allosteric modulator) from Takeda.
- 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 HER-096 (peptidomimetic for CDNF) from Herantis.

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, 2021, 2022 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 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: Q1 2024

*Registered, Started or Finished Recruiting, Completed

posted on ClinicalTrials.gov between January 1, 2024, and March 31, 2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
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	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	81	Recruiting	Active, not recruiting
NCT04167813	Ondansetron	University College London	Treatment for hallucinations	Phase 2	Trial of Ondansetron as a Parkinson's HAllucinations Treatment	168	Recruiting	Active, not recruiting
NCT04201093	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Fixed-Dose Trial in Early Parkinson's Disease (PD)	522	Recruiting	Active, not recruiting
NCT04377945	JM-010 (Buspirone/ Zolmitriptan)	Contera Pharma/Bukwang	Serotonin 1 receptor agonist combination (buspirone and zolmitriptan)	Phase 2	Study in Parkinson's Disease Patients With Dyskinesia With Combinations of JM-010 and Its Individual Components	148	Recruiting	Active, not recruiting
NCT04459052	N-acetyl cysteine	Thomas Jefferson University	Glutathione precursor	Phase 2	FDOPA PET and Nutritional Support in Parkinson's Disease	50	Recruiting	Active, not recruiting
NCT04497168	Citalopram	Michigan University	SSRI	Phase 2	Citalopram as a Posterior Cortical Protective Therapy in Parkinson Disease	58	Recruiting	Active, not recruiting
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	Recruiting	Active, not recruiting
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	Recruiting	Active, not recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT06212089	TR-012001	SNLD, Ltd.	Nasal levodopa	Phase 2	Phase II Clinical Study of TR-012001 in Japanese Patients With Parkinson's Disease	12	Not in CT.GOV	Active, not recruiting
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	Recruiting	Completed
NCT05318937	SAGE-718	Sage Therapeutics	NMDA receptor modulator	Phase 2	A Study to Evaluate the Effects of SAGE-718 in Participants With Parkinson's Disease Cognitive Impairment	86	Recruiting	Completed
NCT06189170	KP405	Kariay Pharmaceutticals	Dual incretin agonist	Early Phase 1	Phase I Study to Evaluate KP405 in Healthy and Parkinson's Disease Patients	88	Not in CT.GOV	Not yet recruiting
NCT06231563	Ketamine (IV)	VA Office of Research and Development	Ketamine	Phase 2	Ketamine for Veterans With Parkinson's Disease	80	Not in CT.GOV	Not yet recruiting
NCT06285643	AB-1005 (AAV2-GDNF)	Bayer / Ask Bio (was Brain Neurotherapy Bio)	GDNF gene therapy	Phase 2	A Study of AAV2-GDNF in Adults With Moderate Parkinson's Disease (REGENERATE-PD)	87	Not in CT.GOV	Not yet recruiting
NCT06329141	Vutiglabridin (HSG4112)	Glaceum, Inc.	Promotes mitophagy	Phase 2	A Study to Assess the Efficacy and Safety of Vutiglabridin in Early Parkinson's Disease Patients	90	Not in CT.GOV	Not yet recruiting
NCT05796167	Pimavanserin	Strasbourg University Hospital	Inverse agonist/antagonist of 5HT2a receptors	Early Phase 1	Pimavanserin for Sleep in Parkinson Disease	10	Not yet recruiting	Recruiting
NCT06167681	NouvNeu001	iRegene Therapeutics Co., Ltd.	Human Dopaminergic Progenitor Cells	Phase 1| Phase 2	The Safety, Tolerability and Efficacy of NouvNeu001 for Parkinson's Disease	40	Not yet recruiting	Recruiting
NCT06193421	Ambroxol	Lawson Health Research Institute	Cough medicine, Gcase enhancer	Phase 1| Phase 2	High-Dose Ambroxol in GBA1-Related Parkinson	40	Not in CT.GOV	Recruiting
NCT06195124	RGL-193	Shanghai Regenelead Therapies Co., Ltd.	AADC & GDNF gene therapy via AAV	Early Phase 1	A Study on the Safety and Tolerability of RGL-193 in Patients With Advanced Parkinson's Disease	8	Not in CT.GOV	Recruiting
NCT06263010	Allopregnanolone (brexanolone)	University of Arizona	Positive allosteric modulator of GABA	Phase 1	Allopregnanolone as a Regenerative Treatment for Parkinson's Disease	10	Not in CT.GOV	Recruiting
NCT06309147	ALX-001 (BMS-984923)	Allyx Therapeutics	Silent allosteric modulator of mGluR5	Phase 1	A Study to Assess the Safety of BMS-984923 Compared to Placebo, in People With Parkinson's	18	Not in CT.GOV	Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
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	8	Not yet recruiting	Terminated
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	Not yet recruiting	Unknown status
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	Recruiting	Unknown status
NCT03938922	ENT-01 (Kenterin)	Enterin	Displaces aSN aggregates	Phase 1	A Study to Evaluate ENT-01 for the Treatment of Parkinson's Disease Dementia	0	Suspended	Withdrawn

Clinical Trials of Parkinson's Disease Drug Therapies

Change in Completion Date Dashboard: Q1 2024

posted on ClinicalTrials.gov between January 1, 2024, and March 31, 2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
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-2025	731
NCT03775096	Carvedilol	Cedars Sinai	Adrenergic blocker	Phase 2	Adrenergic Blockers for Cardiac Changes in Early Parkinson's Disease (Protocol 53136)	15	1-May-2023	1-Aug-2024	458
NCT02879136	Methylphenidate/ Atomoxetine	Cleveland Clinic	Norepinephrine-dopamine reuptake inhibitor/norepinephrine transport inhibitor	Early Phase 1	TAME-PD - Physical Therapy, Atomoxetine and, Methylphenidate, to Enhance Gait and Balance in Parkinson's Disease	42	1-Dec-2024	1-Dec-2025	365
NCT04459052	N-acetyl cysteine	Thomas Jefferson University	Glutathione precursor	Phase 2	FDOPA PET and Nutritional Support in Parkinson's Disease	50	1-May-2024	1-May-2025	365
NCT04976127	Talineuren	Innomedica	GM1 in liposomes	Phase 1	Safety Evaluation of Intravenous Talineuren (TLN) in Parkinson's Disease-affected Patients	22	1-Aug-2024	1-Aug-2025	365
NCT04167813	Ondansetron	University College London	Treatment for hallucinations	Phase 2	Trial of Ondansetron as a Parkinson's HAllucinations Treatment	168	1-Jan-2024	30-Aug-2024	242
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-Jun-2024	213
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	30-Sep-2023	30-Apr-2024	213
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-Sep-2024	184
NCT04497168	Citalopram	Michigan University	SSRI	Phase 2	Citalopram as a Posterior Cortical Protective Therapy in Parkinson Disease	58	1-Sep-2025	1-Mar-2026	181

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT04377945	JM-010 (Buspirone/Zolmitriptan)	Contera Pharma/ Bukwang	Serotonin 1 receptor agonist combination (buspirone and zolmitriptan)	Phase 2	Study in Parkinson's Disease Patients With Dyskinesia With Combinations of JM-010 and Its Individual Components	148	17-Jul-2024	3-Jan-2025	170
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-Aug-2024	153
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-Apr-2024	122
NCT05471609	Buccal levodopa/carbidopa	University of Minnesota	Levodopa/Carbidopa Sachets for Buccal delivery	Early Phase 1	Sustained Release Oral Formulation for Treatment of Parkinson's Disease	6	2-Dec-2024	16-Mar-2025	104
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	31-Dec-2025	31-Mar-2026	90
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	1-Jan-2024	7-Feb-2024	37
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	1-Sep-2019	9-Sep-2019	8
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	72	3-Mar-2025	30-Jan-2025	-32

Results Dashboard: Q1 2024

Clinical Trials of Parkinson's Disease Drug Therapies with *Results Newly Disclosed* Between 1-January-2024 and 31-March-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
NCT03773796	Nabilone	Innsbruck University	THC analogue	Phase 3	Nabilone for Non-motor Symptoms in Parkinson's Disease	22	Peer-reviewed Manuscript	NA	Favorable	Concentration difficulties	OLE shows continuous long-term safety & efficacy in patients responding early to nabilone without intolerable side effects	https://www.nature.com/articles/s41531-024-00665-7
NCT03899324	Bumetanide	B&A Therapeutics	Diuretic	Phase 2	Evaluation of the Efficacy and Safety of Bumetanide in Parkinson's Disease	40	Peer-reviewed Manuscript	Negative	Negative	Urinary problems & fatigue	No evidence of efficacy in improving motor symptoms	https://movementdisorders.onlinelibrary.wiley.com/doi/full/10.1002/mds.29726?campaign=wolearlyview
NCT04483479	ENT-01 (Kenterin)	Enterin	Displaces aSN aggregates	Phase 2	Orally Administered ENT-01 for Parkinson's Disease-Related Constipation Follow-on Safety "Roll-over" Study (Rollover)	27	CT.GOV	NA	NA	Nausea, diarrhea & dizziness	Poor recruitment/retention due to pandemic. Data not analyzed due to early termination	https://classic.clinicaltrials.gov/ct2/show/results/NCT04483479?term=NCT04483479&draw=2&rank=1
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	NA	No safety issues up to 3 mnths post transplant	TED-A9 could represent a fundamental treatment that surpasses current therapies	https://www.businesswire.com/news/home/20240229508525/en/S.BIOMEDICS-completes-brain-transplant-of-hESC-derived-dopaminergic-progenitors-TED-A9-for-Phase-12a-study-in-patients-with-Parkinson
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	Press Release / Corporate Communications	NA	NA	No issues	At least as good PK as Inbrija, showing quicker absorption during first minutes	https://www.prnewswire.com/news-releases/pureims-gears-up-for-abbreviated-registration-of-levodopa-cyclops-dpi-against-off-episodes-in-parkinsons-disease-with-the-successful-completion-of-a-comparative-pharmacokinetic-study-302038313.html

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
NCT04867642	UCB0022	UCB Pharma	Positive allosteric modulator of the dopamine 1 receptor (D1 PAM)	Phase 1	A Study to Test the Safety, Tolerability, and Blood Levels of UCB0022 in Healthy Participants and Participants With Parkinson's Disease	100	Conference Abstract or Presentation	NA	Not reported	Treatment emergent AEs rarely reported	Acceptable safety & tolerability profile; Supports progression to Phase 2	https://cslide.ctimeetingtech.com/adpd24/attendee/confcal/session/calendar/2024-03-06
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	Conference Abstract or Presentation	NA	NA	Well tolerated without serious AEs	Safe & well-tolerated. Plasma exposures achieve full receptor occupancy at trough	https://cslide.ctimeetingtech.com/adpd24/attendee/confcal/presentation/list?q=alx

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-January-2024 and 31-March-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	Press Release / Corporate Communications	NA	Not reported	Surgical delivery well tolerated; No SAEs thru 18 mnths	Favorable safety data at 18 mnths. Phase 2 to begin in 1st half 2024	https://www.bayer.com/media/en-us/askbio-phase-ib-trial-of-ab-1005-gene-therapy-in-patients-with-parkinsons-disease-meets-primary-endpoint/
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	GI AEs higher than placebo	Safe & well-tolerated; dosing sufficient to generate biological responses. May improve some cognitive outcomes	https://cslide.ctimeetingtech.com/adpd24/attendee/confcal/show/session/118
NCT04802733	Bemdanepro-cel (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	No major safety issues thru 18 mnths	18-month data: Evidence of sustained engraftment & increased F-DOPA signal; Clinical endpoints continued to improve from 12 to 18 mnths	https://www.bluerocktx.com/bluerock-therapeutics-phase-i-clinical-trial-for-parkinsons-disease-continues-to-show-positive-trends-at-18-months/
NCT03318523	BIIB054 (Cinpanemab)	Biogen	Immuno-therapy (Mab to aSN)	Phase 2	Evaluating the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of BIIB054 in Participants With Parkinson's Disease	357	Peer-reviewed Manuscript	Negative	Negative	Headache, nasopharynx-gitis & falls	Biomarker results indicated enrollment of intended population, but no significant correlation with disease progression or clear evidence of a treatment effect on biomarkers	https://pubmed.ncbi.nlm.nih.gov/38315945/
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	Negative	Negative	Dizziness, relaxation, fatigue, etc.	No benefit, a suggestion of worsened cognition & sleep and many mild adverse events	https://movementdisorders.onlinelibrary.wiley.com/doi/full/10.1002/mds.29768?campaign=wolearlyview

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
NCT02799381	Duodopa	Abbvie	Intestinal LD/CD	Phase 3	A Study Comparing Efficacy of Levodopa-Carbidopa Intestinal Gel/Carbidopa-Levodopa Enteral Suspension and Optimized Medical Treatment on Dyskinesia in Subjects With Advanced Parkinson's Disease (DYSCOVER)	63	Peer-reviewed Manuscript	Positive	Favorable	Not reported	Correlations observed between dyskinesia, pain & HRQoL at baseline. Improvements in dyskinesia & pain associated with improvements in HRQoL	https://link.springer.com/article/10.1007/s40120-024-00583-z
NCT04831281	Fosgonimeton (ATH-1017)	Athira Pharma	Enhances Hepatocyte Growth Factor activity	Phase 2	ATH-1017 Treatment in Subjects With Parkinson's Disease Dementia or Dementia With Lewy Bodies (SHAPE Trial)	28	Conference Abstract or Presentation	Negative	Favorable	Injection site reactions	Effects in 40 mg group underscore confidence in the Phase 2/3 LIFT-AD trial in mild to moderate Alzheimer's disease	https://www.athira.com/wp-content/uploads/2024/03/ADPD-2024_SHAPE_L1b-1-uai-1032x1376.jpg
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	244	Peer-reviewed Manuscript	NA	Favorable	Not reported	Improved sleep was associated with improved QoL and "Off" time	https://movementdisorders.onlinelibrary.wiley.com/doi/full/10.1002/mdc3.14018?campaign=wolearlyview
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	155	CT.GOV	Negative	Favorable	Reduced mobility	Favorable trends on several endpoints but statistics not provided	https://classic.clinicaltrials.gov/ct2/show/results/NCT04435431?term=NCT04435431&draw=2&rank=1
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	Peer-reviewed Manuscript	Positive	Favorable	No serious AEs	Significantly reduced dyskinesia severity without worsening motor function	https://movementdisorders.onlinelibrary.wiley.com/doi/epdf/10.1002/mds.29713

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
NCT02953665	Liraglutide	Novo Nordisk/ CPT-LCT/ Van Andel/ Cedars-Sinai	GLP-1 agonist	Phase 2	Safety and Efficacy of Liraglutide in Parkinson's Disease	63	CT.GOV	Mixed	Mixed	Injection site reactions; GI symptoms & lost appetite	Some favorable efficacy data but no statistics reported; High rates of nausea and lost appetite	https://classic.clinicaltrials.gov/ct2/show/results/NCT02953665?term=NCT02953665&draw=2&rank=1
NCT03611569	Lu AF82422	Lundbeck	aSN antibody	Phase 1	Lu AF82422 in Healthy Non-Japanese and Japanese Subjects and in Patients With Parkinson's Disease	74	Peer-reviewed Manuscript	NA	NA	Mainly study related	Safety & PK support further development; May provide CSF concentrations sufficient to target aggregated α-syn	https://movementdisorders.onlinelibrary.wiley.com/doi/full/10.1002/mds.29784?campaign=wolearlyview
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	Peer-reviewed Manuscript	Positive	Favorable	Infusion site reactions	Increased on time without troublesome dyskinesia & reduced off time, with a favorable benefit–risk profile.	https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(24)00052-8/abstract
NCT05083260	NE3107	Biovie	Reduces neuroinfla-mation and insulin resistance	Phase 1-Phase 2	NE3107 Activity and Safety in Patients With Parkinson's Disease Using Levodopa	46	Conference Abstract or Presentation	NA	Favorable	Not reported	May hold promise in ameliorating specific non-motor symptoms, particularly sleep/fatigue, urge to move legs & daytime drooling, in levodopa-treated patients	https://cslide.ctimeetingtech.com/adpd24/attendee/person/7700
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	Conference Abstract or Presentation	Negative	Favorable in open label extension vs. real world cohort (PPMI)	Not reported	Disease worsening less severe compared to the real world cohort; Might be effective in slowing progression, but results require confirmation in further trials	https://cslide.ctimeetingtech.com/adpd24/attendee/confcal/session/calendar/2024-03-06

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
NCT04350177	Risvodetinib (iKT-148009)	Inhibikase Therapeutics	c-Abl kinase inhibitor	Phase 1	A Study to Assess Single and Multiple Doses of IkT-148009 in Healthy Elderly Participants and Parkinson's Patients	101	Peer-reviewed Manuscript	NA	No acute effect	Favorable safety profile; no clinically meaningful AEs	Well tolerated; favorable safety & pharmacology profile over 7-day dosing	https://content.iospress.com/articles/journal-of-parkinsons-disease/jpd230319
NCT03881371	Safinamide	Zambon SpA	MAO-B inhibitor	Phase 3	A Study to Evaluate the Efficacy and Safety of Safinamide, as add-on Therapy, in Idiopathic Chinese Parkinson's Disease (PD) Patients With Motor Fluctuations Treated With Stable Doses of Levodopa	307	CT.GOV	Positive	Favorable	Dyskinesia	Significant improvements in multiple efficacy endpoints	https://classic.clinicaltrials.gov/ct2/show/results/NCT03881371?term=NCT03881371&draw=2&rank=1
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 nodules , dyskinesia, nausea, infusion site erythema & somnolence	Initiation & titration well tolerated; 86% continued with long-term use	https://pascongress.omnibooksonline.com/#p=54
NCT04075318	UB-312	Vaxxinity (was United Neuroscience)	"Endobody" to aSN	Phase 1	Study of UB-312 in Healthy Participants and Parkinson's Disease Patients	70	Conference Abstract or Presentation	NA	Not reported	Not reported	Target engagement achieved in CSF of several patients. Dosing optimization & trial in larger population will be conducted to confirm results	https://cslide.ctimeetingtech.com/adpd24/attendee/confcal/session/calendar/2024-03-06

Clinical Trials of Parkinson's Disease Drug Therapies Completed Before 1-October-2023 But Without Results Disclosed by 31-March-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
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
NCT04334317	TAK-071	Takeda	M1 positive allosteric modulator	Phase 2	A Study of TAK-071 in People With Parkinson Disease	64	27-Feb-2023	27-Feb-2023
NCT02617017	Buspirone	Oregon Health & Science University	Serotonin 1A agonist + amantidine	Phase 3	Buspirone Treatment of Iatrogenic Dyskinesias in Advanced Parkinson' Disease	99	23-Mar-2023	23-Mar-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)	57	20-Jul-2023	20-Jul-2023
NCT03149809	Solifenacin	Astellas Pharma	Antimuscarinic bladder relaxant	Phase 3	Behavioral or Solifenacin Therapy for Urinary Symptoms in Parkinson Disease	77	8-Sep-2023	8-Sep-2023
NCT05915247	HER-096	Herantis	Peptidomimetic for cerebral dopamine neurotrophic factor	Phase 1	Single Ascending Doses of HER-096 in Healthy Subjects	60	29-Sep-2023	29-Sep-2023

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.