Clinical Trials for Parkinson's Disease Drug Therapies: What Happened During Q2 2024?

Q2 2024 Trial Status Headlines (ref. dashboards pages 5-9)

What trials have . . .

Begun recruiting?

Recruiting began for four trials including two of particular interest:

- A Phase 2 trial of AB-1005 (GDNF gene therapy from Bayer subsidiary AskBio)
- A Phase 1 trial of ANDP001 (autologous iPSC-derived neural precursor cells from Aspen Neuroscience) which is enrolling only by invitation

Eight other trials were newly listed but not yet recruiting at quarter end including another Phase 1 trial of autologous iPSC-derived neural precursor cells (this one from Brigham & Women's Hospital at Harvard), a Phase 1-2 trial of VGN-R09b (AAV based AADC gene therapy) in Shanghai, and a Phase 2 study at UC San Francisco with psilocybin (a naturally occurring psychedelic) for depression in PD.

Completed enrollment?

Three large trials completed enrollment:

- A Phase 3 trial of tavapadon (Dopamine D1/5 partial agonist from Cerevel) in 296 patients with early PD
- A Phase 2 trial of KM819 (FAF 1 inhibitor from Kainos Medicine) with 314 subjects including both healthy volunteers and PD patients
- A Phase 2 trial of risvodetinib (c-Abl kinase inhibitor from Inhibikase Therapeutics) in 120 patients with previously untreated PD

Reached clinical completion?

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

- A trial of intra-nasal insulin for motor and non-motor symptoms
- A trial of fosgonimeton, which enhances hepatocyte growth factor activity and is being studied for PD dementia (and Lewy Body Dementia) by Athira Pharma

Also reaching clinical completion was a large (N=76) Phase 1 trial of ATH-399A (a Nurr1 activator from HanAll BioPharma and NurrOn Pharmaceuticals).

Been delayed (or accelerated)?

Delays in completion date were disclosed for eleven studies with most of the delays being at least five months. For three the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov. Another three of the delays involved studies with long-term follow up such that the delays in completion date may reflect a decision to extend follow up longer than originally planned.

Substantial delays were disclosed for two notable Phase 2 studies. Jazz Pharmaceuticals posted an eight-month delay in their study of suvecaltamide (a selective modulator of T-type calcium channels) for severe resistant tremor, and UCB and Neuropore posted a six-month delay in their study of UCB0599 (an inhibitor of aSN misfolding) being studied in early-stage PD.

No studies had an accelerated completion date disclosed during the quarter.

Q2 2024 Trial Results Headlines (ref. dashboards pages 10-16)

What trials . . .

Have had results disclosed for the first time?

Results for twelve trials were disclosed for the first time in Q2. Results for six trials were clearly negative with at least four (SAGE-718 for cognitive impairment, ondansetron for hallucinations, deferiprone for early-stage PD, and TAK-071) programs being terminated at least in part based on the trial results.

Two Phase 3 trials had positive statistically significant results for the primary efficacy endpoint:

- A trial of tavapadon (dopamine D1/D5 partial agonist from Cerevel) demonstrated off-time improvement among patients with motor fluctuations with favorable safety and tolerability
- A trial of opicapone (COMT inhibitor from Neurocrine) demonstrated significantly improved motor function when added to levodopa in patients with early PD.

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

- The STEM-PD investigators (ventral midbrain stem cell derived dopaminergic progenitor cells) reported that their low-dose group was completed, and the high-dose group is ongoing. Imaging was reported to show signs of cell survival at 6 to 12 months post-transplant.
- iRegene Therapeutics reported that NouvNeu001 (human dopaminergic progenitor cells) demonstrated improvements in motor scores and good safety

Have had additional detail on results disclosed?

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

- A peer-reviewed paper in the *New England Journal of Medicine* on the Phase 2 study with lixisenatide (GLP-1 agonist from Sanofi) provided full details on the positive trial which showed significantly reduced disease progression at 12-months versus placebo but with relatively high rates of GI adverse events.
- 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 possible clinical benefit in the moderate patient cohort. In addition, a case report on the autopsy of a patient from the trial (4-years post infusion, death unrelated to PD) showed increased GDNF gene expression and other effects suggesting regenerative potential.
- Two papers and a conference abstract with further analyses of the Phase 2 trial with prasinezumab (Mab to aSN from Roche & Prothena) suggested greater efficacy in patients with more rapidly progressing disease, and potentially slower disease progression compared to a real-world cohort.
- Two conference abstracts on The 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).

Are due to have results disclosed soon?

This analysis looks at trials completed at least six months ago (end of Q4 2023) but for which results were not disclosed by the end of Q2 2024. These trials are likely to have results disclosed soon. The eight trials in this group include two Phase 3 academic trials with available agents (nortriptyline & escitalopram for depression in PD and buspirone for dyskinesia) and six 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 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 HER-096 (peptidomimetic for CDNF) from Herantis.
- 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, 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: Q2 2024

*Registered, Started or Finished Recruiting, Completed

posted on ClinicalTrials.gov between April 1, 2024, and June 30, 2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT04223193	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Flexible-Dose Trial in Early Parkinson's Disease (PD)	296	Recruiting	Active Not Recruiting
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	Recruiting	Active Not Recruiting
NCT05670782	KM819	Kainos Medicine	FAF 1 inhibitor	Phase 2	A Study to Evaluate Safety and Efficacy of KM-819 in Healthy Adults and Participants With Parkinson's Disease	314	Recruiting	Active Not Recruiting
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	Active Not Recruiting	Completed
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	Active Not Recruiting	Completed
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	28	Unknown	Completed
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	Active Not Recruiting	Completed
NCT04932434	Psilocybin	UC San Francisco	Naturally occurring psychedelic prodrug	Phase 2	Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease	12	Active Not Recruiting	Completed
NCT06088784	ATH-399A (HL192)	HanAll BioPharma Co., Ltd.|NurrOn Pharmaceuticals, Inc.	Nurr1 activator	Phase 1	A Study Assessing the Safety of Oral ATH-399A in Healthy Adult Participants	76	Recruiting	Completed
NCT06212089	TR-012001	SNLD, Ltd.	Nasal levodopa	Phase 2	Phase II Clinical Study of TR-012001 in Japanese Patients With Parkinson's Disease	12	Active Not Recruiting	Completed

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT06344026	ANPD001	Aspen Neuroscience	Autologous iPSC-derived neural precursor cells	Phase 1	Phase 1/2a Study of ANPD001 in Parkinson Disease	9	Not In Ct.Gov	Enrolling By Invitation
NCT06339034	Lithium	Buffalo University	Protein kinase C inhibitor (treatment for bipolar disorder)	Phase 1| Phase 2	Repurposing Lithium for Parkinson's Disease: A RCT	20	Not In Ct.Gov	Not Yet Recruiting
NCT06388551	LY03017	Luye Pharma	Not disclosed	Phase 1	A Phase 1, SAD Study to Evaluate the Safety and Tolerability of LY03017	60	Not In Ct.Gov	Not Yet Recruiting
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 In Ct.Gov	Not Yet Recruiting
NCT06431971	Talineuren	Innomedica	GM1 in liposomes	Phase 2	Estimates of the Short-term Efficacy of Talineuren (TLN) and Placebo in Patients With Parkinson Disease	40	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 In Ct.Gov	Not Yet Recruiting
NCT06460038	Tenaponer	Ardelyx, Inc.	Sodium/hydrogen exchange 3 (NHE3) inhibitor	Phase 2	Tenapanor in Synucleinopathy-Related Constipation	30	Not In Ct.Gov	Not Yet 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 In Ct.Gov	Not Yet Recruiting
NCT06480461	VGN-R09b	Shanghai Vitalgen BioPharma Co., Ltd.	AAV based AADC gene therapy	Phase 1| Phase 2	A Trial to Evaluate Safety and Efficacy of a Product Named VGN-R09b in Patients With Parkinson's Disease	39	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 Yet Recruiting	Recruiting
NCT06356662	Tenofovir disoproxil	The Fourth Affiliated Hospital of Zhejiang University School of Medicine	Triple antiviral combination product	Phase 1	Tenofovir Disoproxil Fumarate in the Treatment of Parkinson's Disease	60	Not In Ct.Gov	Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT06453551	TRN501	SNLD, Ltd.	Thyroid Hormone Receptor beta agonist	Phase 1	A Phase I Study of TRN501 in Healthy Volunteers	72	Not In Ct.Gov	Recruiting
NCT03575195	Rifaximin	Taipei Medical University	Antibiotic	Phase 1| Phase 2	Microbiota Intervention to Change the Response of Parkinson's Disease	86	Recruiting	Suspended
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	Not Yet Recruiting	Suspended
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	41	Active Not Recruiting	Terminated
NCT04277247	Botulinum Toxin	Calgary University/ Allergan	Botulinum toxin type A	Phase 2| Phase 3	Botulinum Toxin Type A for Foot Dystonia-associated Pain in Parkinson's Disease	40	Recruiting	Unknown
NCT04802733	Bemdaneprocel (BRT-DA01)	Bayer (was BlueRock Therapeutics)	Human ESC-derived neural precursor cells	Phase 1	Phase 1 Safety and Tolerability Study of MSK-DA01 Cell Therapy for Advanced Parkinson's Disease	12	Active Not Recruiting	Unknown
NCT04857359	Dipraglurant	Addex Therapeutics	mGluR5 negative allosteric modulator	Phase 2| Phase 3	Dipraglurant (ADX48621) for the Treatment of Patients With Parkinson's Disease Receiving Levodopa-based Therapy	140	Recruiting	Unknown

Clinical Trials of Parkinson's Disease Drug Therapies

Change in Completion Date Dashboard: Q2 2024

posted on ClinicalTrials.gov between April 1, 2024, and June 30, 2024

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT05894343	AAV-GAD	MeiraGTx	Gene therapy	Phase 1| Phase 2	Long-term Follow-up of Glutamic Acid Decarboxylase (GAD) Gene Transfer in Parkinson's Disease	14	1-May-2028	1-Oct-2029	518
NCT06189170	KP405	Kariay Pharmaceutticals	Dual incretin agonist	Early Phase 1	Phase I Study to Evaluate KP405 in Healthy and Parkinson's Disease Patients	88	31-Dec-2024	31-Dec-2025	365
NCT04750226	Foslevodopa/foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/ Carbidopa prodrug	Phase 3	Study To Assess Adverse Events and Change in Disease Activity Of 24-hour Continuous Subcutaneous Infusion Of ABBV-951 In Adult Participants With Advanced Parkinson's Disease	118	16-May-2025	1-Apr-2026	320
NCT04379050	Foslevodopa/foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/ Carbidopa 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	19-Jun-2025	1-Apr-2026	286
NCT05642442	Suvecaltamide	Jazz Pharmaceuticals	Selective modulator of T-type calcium channels	Phase 2	A Study of Suvecaltamide in Adults With Moderate to Severe Residual Tremor in Parkinson's Disease	160	1-May-2024	31-Dec-2024	244
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-Sep-2024	184
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	11-Apr-2024	7-Oct-2024	179
NCT05297201	CPL500036	Celon Pharma	PDE 10A inhibitor	Phase 2	Efficacy, Safety and Pharmacokinetic Study of CPL500036 in Patients With Levodopa Induced Dyskinesia	108	1-Jun-2024	1-Nov-2024	153

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT04251585	Nasal insulin	Multiple development programs	Intra-nasal insulin	Phase 2	Intranasal Insulin in Parkinson's Disease	30	1-Mar-2024	1-Jun-2024	92
NCT05677633	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Validation Following Sargramostim Treatment in Parkinson's Disease	11	1-Feb-2024	12-Apr-2024	71
NCT05634876	UB-312	Vaxxinity (was United Neuroscience)	"Endobody" to aSN	Phase 1| Phase 2	UB-312 in Patients With Synucleinopathies	8	1-Apr-2025	1-May-2025	30

Results Dashboard: Q2 2024

Clinical Trials of Parkinson's Disease Drug Therapies with *Results Newly Disclosed* Between 1-April-2024 and 30-June-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
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	Press Release / Corporate Communications	Negative	Negative	Generally well tolerated	No statistically significant difference vs. placebo on primary endpoint; No further development for PD planned	https://investor.sagerx.com/news-releases/news-release-details/sage-therapeutics-announces-topline-results-phase-2-precedent
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	506	Press Release / Corporate Communications	Negative	Not reported	Not reported	Interim analysis shows no treatment benefit in PD; Closing study early	https://www.expresspharma.in/proseek-study-shows-no-treatment-benefit-of-vodobatinib-in-patients-with-early-parkinsons-disease/
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	Press Release / Corporate Communications	Positive	Positive	Generally well tolerated; Consistent with prior trials	Results demonstrate potential to provide right balance of motor control, safety & tolerability	https://investors.cerevel.com/news-releases/news-release-details/cerevel-therapeutics-announces-positive-topline-results-0
NCT05635409	STEM-PD	Lund University & University of Cambridge	Ventral midbrain dopamine-ergic progenitor (stem) cells	Phase 1	A Trial to Determine the Safety and Tolerability of Transplanted Stem Cell Derived Dopamine Neurons to the Brains of Individuals With Parkinson's Disease	8	Press Release / Corporate Communications	NA	Not reported	No concerning side effects have been reported	Low-dose group transplants completed & high-dose group ongoing. Imaging shows signs of cell survival at 6-12 mnths	https://www.lunduniversity.lu.se/article/update-stem-pd-clinical-trial-stem-cell-based-transplant-parkinsons-disease
NCT04167813	Ondansetron	University College London	Treatment for hallucina-tions	Phase 2	Trial of Ondansetron as a Parkinson's HAllucinations Treatment	168	Press Release / Corporate Communications	Not reported	Not reported	More safety issues in those who received ondansetron than placebo	DMEC halted trial due to interim safety review	https://www.parkinsons.org.uk/news/trial-ondansetron-treatment-hallucinations-parkinsons-update

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
NCT04978597	Opicapone	Neurocrine	Catechol-O-methyltransferase (COMT) inhibitor	Phase 3	Early ParkinSon wIth L-DOPA/DDCI and OpicapoNe (EPSILON Study)	410	Conference Abstract or Presentation	Positive	Favorable	Similar to placebo	Significantly improved motor impairment in levodopa-treated patients without motor complications, with no dyskinesia	https://www.sciencedirect.com/journal/parkinsonism-and-related-disorders/vol/122/suppl/C#article-24
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	Press Release / Corporate Communications	NA	Favorable	No cell therapy related AEs	Preliminary results indicated consistently significant improvements in motor scores & good safety in ongoing study	https://www.prnewswire.com/news-releases/iregene-receives-ind-approval-from-us-fda-to-start-clinical-trial-for-parkinsons-disease-302180135.html
NCT04932434	Psilocybin	UC San Francisco	Naturally occurring psychedelic prodrug	Phase 2	Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease	12	Preprint	NA	Favorable	Anxiety, nausea & increased BP	Randomized trials to examine effects of psilocybin therapy on mood dysfunction & other symptoms warranted.	https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4871260
NCT02728843	Deferiprone	ApoPharma (SKY)	Iron chelator	Phase 2	Study of Parkinson's Early Stage With Deferiprone	140	CT.GOV	Negative	Negative	Nausea, vomiting, headache, abdominal pain	Not effective and frequent dose-related GI adverse events	https://clinicaltrials.gov/study/NCT02728843?term=NCT02728843&rank=1&tab=results#results-overview
NCT04334317	TAK-071	Takeda	M1 positive allosteric modulator	Phase 2	A Study of TAK-071 in People With PD	64	CT.GOV	Negative	Negative	Dizziness	No efficacy signal, but well tolerated	https://clinicaltrials.gov/study/NCT04334317?term=NCT04334317&rank=1&tab=results#results-overview
NCT04928287	Autologous adipose derived mesenchymal stem cells	Hope Biosciences	Autologous adipose derived mesenchymal stem cells	Phase 2	Randomized, Double-Blind Clinical Trial for Parkinson's Disease (Early and Moderate)	24	CT.GOV	Negative	Mixed	Fatigue, dizziness, headache, flushing	Little evidence of efficacy, but appears tolerable	https://clinicaltrials.gov/study/NCT04928287?term=NCT04928287&rank=1&tab=results#results-overview

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
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	7	CT.GOV	NA	NA	NA	Study terminated early by sponsor (folded into Phase 2 trial in patients without LRRK2 variant)	https://clinicaltrials.gov/study/NCT05418673?term=NCT05418673&rank=1&tab=results#results-overview

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-April-2024 and 30-June-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
NCT01621581	AB-1005 (AAV2-GDNF)	Bayer/ Ask Bio (was Brain Neurotherapy Bio)	GDNF gene therapy	Phase 1	AAV2-GDNF for Advanced Parkinson s Disease	25	Peer-reviewed Manuscript	NA	Favorable	Not reported	Autopsy of patient 4-yrs post infusion showed increased putaminal GDNF gene expression and other effects suggesting regenerative potential	https://movementdisorders.onlinelibrary.wiley.com/doi/full/10.1002/mds.29820?campaign=wolearlyview
NCT03100149	Prasinezumab (RO7046015/ PRX002)	Roche/ Prothena	Immuno-therapy (Mab to aSN)	Phase 2	A Study to Evaluate the Efficacy of Prasinezumab (RO7046015/PRX002) in Participants With Early Parkinson's Disease	316	Peer-reviewed Manuscript	Negative	Negative	Not reported	Might reduce motor progression to a greater extent in individuals with more rapidly progressing PD	https://www.nature.com/articles/s41591-024-02886-y#Abs1
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 vs. real-world data (PPMI) in open-label extension	Not reported	Progression was relatively small compared to the RWD-PPMI cohort; Confirmation needed in randomized controlled trial	https://www.aan.com/msa/Public/Events/AbstractDetails/55527
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	Favorable vs. real-world data (PPMI) in open-label extension	Not reported	Exploratory analysis, which requires confirmation, suggests effect of prasinezumab in slowing motor progression may be sustained long-term	https://www.researchsquare.com/article/rs-4232431/v1
NCT03419806	Infudopa (DIZ102)	Dizlin	Sub-cutaneous L-DOPA	Phase 1	Study Comparing Intravenous and Subcutaneous Infudopa With Intestinal Duodopa in Patients With Parkinson's Disease	25	Peer-reviewed Manuscript	NA	Favorable	Not reported	Patients responded equally well to all treatments; Results do not indicate high plasma carbidopa levels hamper motor efficacy of levodopa	https://movementdisorders.onlinelibrary.wiley.com/doi/full/10.1002/mdc3.14138?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
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	Peer-reviewed Manuscript	Positive	Mix of neutral & favorable	Nausea & vomiting	Less progression than placebo at 12 months but associated with GI side effects; Longer & larger trials needed	https://www.nejm.org/doi/10.1056/NEJMoa2312323?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
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	CT.GOV	NA	Not reported	Nasopharyn-gitis	Favorable trend on primary endpoint	https://clinicaltrials.gov/study/NCT03815916?term=NCT03815916&rank=1&tab=results#results-overview
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	No differences among sub-groups	Treatment effect was homogenous across different analyzed subgroups	https://www.aan.com/msa/Public/Events/AbstractDetails/55515
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	Peer-reviewed Manuscript	NA	No difference from placebo	Mostly mild & transient	Anti-aSyn antibodies in serum & CSF confirm immune-genicity and support further development	https://www.nature.com/articles/s41591-024-03101-8
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	Transient peri-operative events	Well tolerated; Demonstrating general stability in Mild Cohort & possible clinical benefit in Moderate Cohort	https://www.askbio.com/askbio-presents-18-month-phase-ib-trial-results-of-ab-1005-gene-therapy-for-patients-with-parkinsons-disease/
NCT04778176	DopaFuse	SynAgile	Continuous delivery of L-DOPA/ Carbidopa	Phase 2	Assessing the Pharmacokinetics, Safety, Tolerability and Efficacy of Continuous Oral Levodopa Via the DopaFuse¬Æ Delivery System in Parkinson's Disease Patients	17	Peer-reviewed Manuscript	NA	Favorable	No clinically significant AEs	Less variability in LD concentrations & reductions in OFF time compared to standard oral LD/CD therapy; well tolerated	https://movementdisorders.onlinelibrary.wiley.com/doi/abs/10.1002/mds.29824?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
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	AEs mild to moderate and not related to treatment	Well tolerated, with no major safety issues through 1 year. Exploratory clinical measures suggested improvements	https://www.sciencedirect.com/journal/parkinsonism-and-related-disorders/vol/122/suppl/C#article-24
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	Increased post-transplantation 18F-DOPA PET signal along posterior putamen surgical trajectories consistent with survival of grafts at 1 year	https://index.mirasmart.com/AAN2024/PDFfiles/AAN2024-003326.html
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	CT.GOV	NA	Favorable	Nausea & vomiting	Statistically significant efficacy on secondary endpoints & minimal discontinuations suggesting good tolerability	https://clinicaltrials.gov/study/NCT05148884?term=NCT05148884&rank=1&tab=results#results-overview
NCT06037590	Levodopa Cyclops	PureIMS, B.V.	Inhaled levodopa	Phase 1	A Pilot Comparative Bioavailability Study of Levodopa Administered Via Levodopa Cyclops,Ñ¢ Relative to INBRIJA¬Æ	26	Conference Abstract or Presentation	NA	NA	Diarrhea (1 event)	PK enables abbreviated registration path; Potential for fast relief of off episodes	https://www.sciencedirect.com/journal/parkinsonism-and-related-disorders/vol/122/suppl/C#article-24

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

Row Labels	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
NCT02617017	Buspirone	Oregon Health & Science University	Serotonin 1A agonist + amantidine	Phase 3	Buspirone Treatment of Iatrogenic Dyskinesias in Advanced PD	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 PD	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
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 & CST-107 in Subjects With Mild Cognitive Impairment or Mild Dementia Due to PD or Alzheimer's Disease	64	1-Dec-2023	1-Feb-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.