

Clinical Trials for Parkinson's Disease Drug Therapies: What Happened During Q1 2023?

Q1 2023 Trial Status Headlines (ref. dashboards 1-3)

What trials have . . .

Begun recruiting or been newly listed this quarter?

Recruiting began for three trials:

- Phase 2 trial of Intracellular Therapies' PDE-1 inhibitor lenrispodun as an adjunctive therapy for motor fluctuations
- Phase 2 trial of Kainos Medicine's FAF 1 inhibitor KM819
- Phase 1 trial of Shanghai iCELL Biotechnology's human amniotic epithelial stem cells

Six other trials were newly listed but not yet recruiting at quarter end -- most notable is the Ambroxol Phase 3 study on slowing disease progression.

Completed enrollment?

Six trials completed enrollment including two Phase 2 trials from the UCB & Neuropore collaboration (aSN misfolding inhibitor UCB0599 & aSN antibody UCB7853). Also of note was completion of enrollment for the Phase 1 GDNF gene therapy trial from Bayer / Ask Bio

Reached clinical completion?

Another nine trials reached clinical completion including a Phase 3 trial of Pharma Two B's combination product of rasagiline & pramipexole. Amongst earlier stage trials of note were Phase 1 trials of Inhibikase Therapeutics c-Abl kinase inhibitor iKT-148009 and Vaxxinity's "endobody" to aSN

Been delayed (or accelerated)?

Delays in completion date were disclosed for 17 studies (for 10 the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov) with virtually all the delays being at least 6 months. Most notable was the entire Phase 3 program (4 studies) for Cerevel's tavapadon (a dopamine D1/5 partial agonist) which were delayed 12-16 months. In contrast, just three studies reported an accelerated completion date (by 3 to 6 months).

Completion projected within the next six-months?

Twenty-four trials are projected to complete by Q3 2023 with 12 to complete in Q2 2023

- Included are the Neurocrine Phase 3 trial of the COMT inhibitor opicapone and a large (400 patient) Norwegian trial of the supplement nicotinamide riboside
- Earlier stage highlights are a Phase 2 trial of pimavanserin for impulse control disorder and a Phase 1 stem cell trial at Memorial Sloan Kettering

Q1 2023 Trial Results Headlines (ref. dashboard 4)

What trials have . . .

Had results disclosed for the first time?

Results for eight trials were disclosed for the first time. Only one trial was positive on a primary efficacy endpoint – the Mitsubishi Tanabe / Neuroderm Phase 3 trial of ND0612 (a sub-cutaneous pump of LD/CD) which demonstrated reduced motor fluctuations relative to oral LD/CD (when used on top of otherwise optimized oral therapy).

Three smaller studies (not designed with a primary efficacy endpoint) were described as having safety supporting further development and favorable trends on secondary efficacy endpoints:

- Phase 2 study (27 patients) of bifiradol (NLX-112 from Neurolix) a selective serotonin 5HT1A full agonist. Study results indicated potential to reduce levodopa-induced dyskinesias.
- Phase 1 study (11 patients) of the GDNF gene therapy (AAV2-GDNF) from Bayer / Ask Bio suggested some symptom improvement in patients with moderate disease although not in the cohort with mild disease.
- Phase 1 study (12 patients) of a lyophilized fecal extract (PRIM-DJ2727) with trends indicating possible improvement in both GI and non-GI symptoms.

Four Phase 2 trials had negative results disclosed on their primary efficacy endpoints. For the Aptinyx NYX-458 (NMDA receptor modulator) program, the negative results signaled the end of development of this agent for cognitive impairment in PD or Lewy Body Dementia. For the other three negative Phase 2 studies, favorable data on secondary endpoints or in patient sub-groups was suggested as supporting further studies. Notable here was the Phase 2 study with Neuraly's GLP-agonist NLY-01 which did not show a benefit in the study overall but had favorable data in the sub-set of patients under 60 with early PD.

Had additional detail on results disclosed?

Additional results were disclosed for ten trials for which at least top-line results had been previously reported. Notable was a peer-reviewed manuscript on the Phase 1 study with DNL-151 (LRRK2 inhibitor from Denali Therapeutics & Biogen) which led to the ongoing Phase 2 program for this agent. Also of interest was a conference presentation on CVN424 (selective GPR6 inverse agonist from Cerevance) for a large (132 patient) Phase 2 study showing reduced motor fluctuations. Further studies with this agent are also ongoing.

Clinical Trials of Parkinson's Disease Drug Therapies

Trial Change in Status* Dashboard: Q1 2023

*Registered, Started or Finished Recruiting, Completed
 posted on ClinicalTrials.gov between Jan. 1, 2023, and Mar. 31, 2023

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
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	450	Recruiting	Active, not recruiting
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	Recruiting	Active, not recruiting
NCT04167540	AAV2-GDNF	Bayer (was Ask Bio)	GDNF gene therapy	Phase 1	GDNF Gene Therapy for Parkinson's Disease	11	Recruiting	Active, not recruiting
NCT03968133	Ecologic BARRIER 849 (Probiotic)	British Columbia University	Probiotic	Phase 2	Treating Anxiety in Parkinson's Disease With a Multi-Strain Probiotic	61	Recruiting	Active, not recruiting
NCT03683225	CTC-413	Chase Therapeutics	Extended-release pramipexole	Phase 2	A Study to Evaluate in Patients With Parkinsonian Type Disorders	24	Unknown status	Active, not recruiting
NCT03667404	Resistant maltodextrin	Northwestern University	Prebiotic non-digestible fiber	Phase 2	Resistant Maltodextrin for Gut Microbiome in Parkinson's Disease: Safety and Tolerability Study	30	Recruiting	Active, not recruiting
NCT05699161	Adipose-derived Stromal Vascular Fraction Cells	National Autonomous University of Nicaragua	Autologous adipose tissue-derived stromal vascular fraction (SVF) cells	Phase 1 Phase 2	Adipose-derived Stromal Vascular Fraction Cells to Treat Parkinson	10	Not in CT.GOV	Completed
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	Recruiting	Completed
NCT05083260	NE3107	Biovie	Reduces neuroinflammation and insulin resistance	Phase 1 Phase 2	NE3107 Activity and Safety in Patients With Parkinson's Disease Using Levodopa	46	Active, not recruiting	Completed

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT04350177	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	Active, not recruiting	Completed
NCT04334317	TAK-071	Takeda	M1 positive allosteric modulator	Phase 2	A Study of TAK-071 in People With Parkinson Disease	64	Active, not recruiting	Completed
NCT04165837	FB-101/1ST-102	1st Biotherapeutics	c-Abl kinase inhibitor	Phase 1	Safety, Tolerability, and Pharmacokinetics of Oral FB-101 in Healthy Subjects	24	Active, not recruiting	Completed
NCT04075318	UB-312	Vaxxinity (was United Neuroscience)	"Endobody" to aSN	Phase 1	Study of UB-312 in Healthy Participants and Parkinson's Disease Patients	138	Active, not recruiting	Completed
NCT04074837	NNI-362	Neuronascent	Neurorestorative	Phase 1	Phase1a, Dose-escalation Study of NNI-362 in Healthy Aged Volunteers	56	Unknown status	Completed
NCT03329508	P2B001	Pharma Two B	Rasagiline/pramipexole combination	Phase 3	A Phase 3 Study With P2B001 in Subjects With Early Parkinson's	544	Active, not recruiting	Completed
NCT05790382	NM-101	Neuramedy Co. Ltd.	Anti-TLR2 antibody	Phase 1	Single and Multiple Ascending Dose Study to Assess Safety, Tolerability and Pharmacokinetics of NM-101	56	Not in CT.GOV	Not yet recruiting
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	Not in CT.GOV	Not yet recruiting
NCT05778695	KetoneAid	University of Michigan	Ketone ester (KE) dietary supplement	Phase 1	Brain Small Chain Fatty Acid Metabolism in Parkinson Disease: Ketones	30	Not in CT.GOV	Not yet recruiting
NCT05778617	Ambroxol	Lawson Health Research Institute	Cough medicine, Gcase enhancer	Phase 3	Ambroxol to Slow Progression in Parkinson Disease	330	Not in CT.GOV	Not yet recruiting
NCT05709301	Donepezil	Oregon Health & Science University	Cholinesterase inhibitor	Phase 2	Randomized Clinical Trial of Donepezil for the Treatment of Mild Cognitive Impairment in Parkinson's Disease	120	Not in CT.GOV	Not yet recruiting
NCT05677633	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Validation Following Sargramostim Treatment in Parkinson's Disease	10	Not in CT.GOV	Not yet recruiting
NCT05766813	ITI-214 (lenrispodun)	Intra-cellular Therapies	PDE-1 inhibitor	Phase 2	Lenrispodun as Adjunctive Therapy in the Treatment of Patients With Motor Fluctuations Due to Parkinson's Disease	132	Not in CT.GOV	Recruiting
NCT05691114	Human Amniotic Epithelial Stem Cells	Shanghai iCELL Biotechnology Co., Ltd	Human Amniotic Epithelial Stem Cells	Phase 1	Precise Transplantation of Human Amniotic Epithelial Stem Cells Into Lateral Ventricle for Parkinson's Disease	18	Not in CT.GOV	Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
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	330	Not in CT.GOV	Recruiting
NCT04220762	WIN-1001X	Medi Help Line	Herbal mixture	Phase 2	A Study to Determine the Dose of WIN-1001X by Evaluating Efficacy and Safety in Early Parkinson's Disease Patients	188	Recruiting	Unknown status
NCT04146519	Autologous Mesenchymal stem cells	Belarussian Medical Academy	Mesenchymal stem cells	Phase 2 Phase 3	Parkinson's Disease Therapy Using Cell Technology	50	Recruiting	Unknown status
NCT04097080	NBTX-001	Nobilis Therapeutics	Inhaled xenon	Phase 1	Comparative Controlled Study of Analgesic, Antiasthenic and Anti-Anxiety Effects of Xenon in Patients With Parkinson's Disease	60	Recruiting	Unknown status

Clinical Trials of Parkinson’s Disease Drug Therapies
Change in Completion Date Dashboard: Q1 2023
 posted on ClinicalTrials.gov between Jan. 1, 2023, and Mar. 31, 2023

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT03683225	CTC-413	Chase Therapeutics	Extended-release pramipexole	Phase 2	A Study to Evaluate CTC-413 in Patients With Parkinsonian Type Disorders	24	1-Dec-2019	30-Dec-2023	1490
NCT05543252	UCB0599	UCB and Neuropore (NPT 200-11)	Inhibitor of aSN misfolding	Phase 2	An Extension Study to Evaluate the Long-Term Efficacy, Safety and Tolerability of UCB0599 in Study Participants With Parkinson's Disease	270	28-Dec-2027	10-Dec-2029	713
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	188	12-Dec-2022	17-Jul-2024	583
NCT04976127	Talineuren	Innomedica	GM1 in liposomes	Phase 1	Safety Evaluation of Intravenous Talineuren (TLN) in Parkinson's Disease-affected Patients	22	1-Dec-2022	1-Jun-2024	548
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	368	1-Feb-2023	1-Jun-2024	486
NCT04223193	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Flexible-Dose Trial in Early Parkinson's Disease (PD)	296	1-Jul-2023	1-Oct-2024	458
NCT04760769	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Open-label Trial in Parkinson's Disease (PD)	800	1-Nov-2024	1-Jan-2026	426
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-2023	1-Dec-2024	366
NCT04201093	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Fixed-Dose Trial in Early Parkinson's Disease (PD)	522	1-Sep-2023	1-Sep-2024	366
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-2022	1-Dec-2023	365

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-2022	1-Dec-2023	365
NCT03575195	Rifaximin	Taipei Medical University	Antibiotic	Phase 1 Phase 2	Microbiota Intervention to Change the Response of Parkinson's Disease	86	1-Dec-2022	1-Dec-2023	365
NCT03149809	Solifenacin	Astellas Pharma	Antimuscarinic bladder relaxant	Phase 3	Behavioral or Solifenacin Therapy for Urinary Symptoms in Parkinson Disease	90	30-Dec-2022	31-Aug-2023	244
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	1-Dec-2022	15-Jun-2023	196
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-Sep-2023	1-Mar-2024	182
NCT03968133	Ecologic BARRIER 849 (Probiotic)	British Columbia University	Probiotic	Phase 2	Treating Anxiety in Parkinson's Disease With a Multi-Strain Probiotic	61	1-Dec-2022	31-May-2023	181
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	21-Oct-2022	1-Nov-2022	11
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	450	18-Jul-2024	11-Apr-2024	-98
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	24-Nov-2023	21-Jul-2023	-126
NCT05634876	UB-312	Vaxxinity (was United Neuroscience)	"Endobody" to aSN	Phase 1 Phase 2	UB-312 in Patients With Synucleinopathies	8	1-Oct-2025	1-Apr-2025	-183

**Clinical Trials of Parkinson’s Disease Drug Therapies
with Primary Completion Date within 6 months of 31-Mar-2023**

trial data: ClinicalTrials.gov

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
NCT04831281	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	1-Apr-2023	1-May-2023
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-May-2023
NCT04802733	MSK-DA01	Memorial Sloan Kettering Cancer Center	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	1-May-2023	1-May-2024
NCT04978597	Opicapone	Neurocrine	Catechol-O-methyltransferase (COMT) inhibitor	Phase 3	Early ParkinSon with L-DOPA/DDCI and OpicapoNe (EPSILON Study)	324	1-May-2023	1-May-2023
NCT03568968	Nicotinamide riboside	Haukeland University Hospital	Nicotinamide riboside	Not Applicable	A Randomized Controlled Trial of Nicotinamide Supplementation in Early Parkinson's Disease	400	15-May-2023	15-Mar-2024
NCT03947216	Pimavanserin	Strasbourg University Hospital	Inverse agonist/antagonist of 5HT2a receptors	Phase 2	Randomized Placebo Controlled Trial Evaluating the Efficacy of Pimavanserin, a Selective Serotonin 5-HydroxyTryptamine-2A (5HT2A) Inverse Agonist, to Treat Impulse Control Disorders in Parkinson's Disease.	130	31-May-2023	31-Jul-2023
NCT03968133	Ecologic BARRIER 849 (Probiotic)	British Columbia University	Probiotic	Phase 2	Treating Anxiety in Parkinson's Disease With a Multi-Strain Probiotic	61	31-May-2023	1-Dec-2023
NCT04251585	Nasal insulin	HealthPartners Institute	Intra-nasal insulin	Phase 2	Intranasal Insulin in Parkinson's Disease	30	1-Jun-2023	1-Jul-2023
NCT04643327	Levetiracetam	Queensland University	Anti-epileptic	Phase 2	Uncovering a Novel Therapeutic Target to Reduce Dementia Risk in Parkinson's Disease	28	1-Jun-2023	1-Dec-2023
NCT05104463	CST-103 and CST-107	CuraSen Therapeutics	Restores brain homeostasis	Phase 2	A Study of CST-2032 and CST-107 in Subjects With Mild Cognitive Impairment or Mild Dementia Due to Parkinson's or Alzheimer's Disease	60	1-Jun-2023	1-Dec-2023

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
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	15-Jun-2023	1-Aug-2023
NCT03413384	Ceftriaxone	Brainx	Ceftriaxone	Phase 2	To Assess the Efficacy and Safety of Ceftriaxone in Patients With Mild to Moderate Parkinson's Disease Dementia	106	30-Jun-2023	31-Dec-2023
NCT03446807	Droxidopa	Loma Linda University/Lundbeck	L-threo-dihydroxyphenylserine	Phase 2	Safety and Efficacy of Droxidopa for Fatigue in Patients With Parkinsonism	0	1-Jul-2023	1-Jul-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	21-Jul-2023	21-Jul-2023
NCT05435755	Human Amniotic Epithelial Stem Cells	Shanghai iCELL Biotechnology Co., Ltd	Human Amniotic Epithelial Stem Cells	Early Phase 1	Precise Transplantation of hAESC's Into the Ventricle for Parkinson's Disease.	12	30-Jul-2023	30-Aug-2023
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	1-Aug-2023	1-Aug-2023
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-Aug-2023	2-Aug-2023
NCT04226248	Rivastigmine	Bristol University	Cholinesterase inhibitor	Phase 3	CHIEF PD (CHolinesterase Inhibitor to prEvent Falls in Parkinson's Disease)	600	30-Aug-2023	30-Nov-2023
NCT03149809	Solifenacin	Astellas Pharma	Antimuscarinic bladder relaxant	Phase 3	Behavioral or Solifenacin Therapy for Urinary Symptoms in Parkinson Disease	90	31-Aug-2023	30-Sep-2023
NCT02726386	ND0612	Mitsubishi Tanabe/Neuroderm	Sub-cutaneous L-DOPA	Phase 2	A Clinical Study in Advanced Parkinson's Disease Investigating the Long Term Safety of ND0612 Administered as a Continuous SC Infusion	210	1-Sep-2023	1-Oct-2023
NCT04332276	DIVE	Lille University Hospital/InBrain Pharma	Intra-cerebroventricular dopamine	Phase 1 Phase 2	Dopaminergic restauration by intraVentriculaire Administration	20	1-Sep-2023	1-Sep-2023
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	76	1-Sep-2023	1-Sep-2023

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
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	20	30-Sep-2023	30-Sep-2023
NCT05424276	iKT-148009	Inhibikase Therapeutics	c-Abl kinase inhibitor	Phase 2	A Randomized, Double-Blind, Placebo-Controlled Trial of iKT-148009 in Untreated Parkinson's Disease	120	30-Sep-2023	31-Oct-2023

Results Dashboard: Q1 2023

Clinical Trials of Parkinson's Disease Drug Therapies with Results Newly Disclosed Between 1-Jan-2023 and 31-Mar-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
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	Press Release / Corporate Communications	Positive	Favorable	Infusion site hematoma, infection & erythema	Confirmed potential as effective treatment for patients with motor fluctuations, despite optimization of oral therapies	https://www.prnewswire.com/news-releases/neuroderm-announces-highly-positive-results-from-the-pivotal-phase-iii-boundless-trial-evaluating-nd0612-in-parkinsons-disease-patients-with-motor-fluctuations-301715848.html
NCT04167540	AAV2-GDNF	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 in moderate cohort	Well tolerated; AEs primarily peri-operative or related to underlying PD	Favorable safety profile, stabilization in the Mild Cohort & possible motor improvements in the Moderate Cohort. Further longitudinal evaluation needed & controlled study planned	https://slide.ctimeetingtech.com/adpd23/attendee/confcal/session/calendar/2023-04-01
NCT05148884	NLX-112 (befiradol)	Neurolix	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	Press Release / Corporate Communications	NA	Favorable	Good safety & favorable tolerability	Findings indicate NLX-112 can be safely administered to people with PD and alleviates their troublesome LID; Larger Phase 2b study planned	https://www.einnews.com/pr_news/622375270/neurolix-announces-positive-ph2a-proof-of-concept-on-nlx-112-in-levodopa-induced-dyskinesia-in-parkinson-s-disease
NCT03671785	PRIM-DJ2727	Texas University	Lyophilised fecal extract	Phase 1	Study of the Fecal Microbiome in Patients With Parkinson's Disease	12	Peer-reviewed Manuscript	NA	Favorable	Non-severe transient upper GI symptoms	Increased microbiome diversity; reduced constipation, improved gut transit & intestinal motility; improved subjective motor & non-motor symptoms	https://www.frontiersin.org/articles/10.3389/fneur.2023.1104759/full

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
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	Press Release / Corporate Communications	Negative	Favorable	Reduced mobility during first month	Potential to become effective treatment for levodopa-induced dyskinesia	https://finance.yahoo.com/news/irlab-announces-top-line-results-202500772.html
NCT04154072	NLY-01 (pegylated exenatide)	Neuraly/ Johns Hopkins	GLP-1 agonist	Phase 2	A Clinical Study of NLY01 in Patient's With Early Parkinson's Disease	255	Press Release / Corporate Communications	Negative	Not reported	Safe and well tolerated	Beneficial effect in patients under 60 may represent interest for further evaluation in younger patients	https://www.businesswire.com/news/home/20230327005069/en/Neuraly-Announces-Topline-Results-from-Phase-2-Trial-of-NLY01-in-Parkinsons-Disease
NCT03440112	Transdermal flumazenil	Michigan University	GABA-A modulator	Phase 1 Phase 2	Modulation of GABA-A Receptors in Parkinson Disease-Transdermal Flumazenil Arm	34	CT.GOV	Negative	Favorable	No AEs reported	Significantly improved balance vs. placebo	https://www.clinicaltrials.gov/ct2/show/results/NCT03440112?term=NCT03440112&draw=2&rank=1
NCT04148391	NYX-458	Aptinyx	NMDA receptor modulator	Phase 2	NYX-458 in Subjects With Mild Cognitive Impairment or Mild Dementia Due to Parkinson's Disease or Lewy Body Dementia (Cognition, Memory, Attention, Thinking)	99	Press Release / Corporate Communications	Negative	Negative	Well tolerated	Results do not support further development	https://ir.aptinyx.com/press-releases/news-details/2023/Aptinyx-Reports-Results-from-Phase-2-Study-of-NYX-458-in-Cognitive-Impairment-Associated-with-Parkinsons-Disease-and-Dementia-with-Lewy-Bodies-and-Provides-Pipeline-and-Corporate-Update/default.aspx

Clinical Trials of Parkinson's Disease Drug Therapies with Additional Results Disclosed Between 1-Jan-2023 and 31-Mar-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
NCT05083260	NE3107	Biovie	Reduces neuroinflammation and insulin resistance	Phase 1 Phase 2	NE3107 Activity and Safety in Patients With Parkinson's Disease Using Levodopa	46	Press Release / Corporate Communications	NA	Favorable	Not reported	Encouraging efficacy signal as measured by morning on/off state; Preparing to launch Phase 3	https://feeds.issuereirect.com/news-releases.html?newsid=8889777766147180
NCT04056689	DNL-151	Denali Therapeutics	LRRK2 inhibitor	Phase 1	Study to Evaluate DNL151 in Subjects With Parkinson's Disease	36	Peer-reviewed Manuscript	NA	NA	Headache, hypotension	Safety, PK (including CSF penetration) & PD (LRRK2 inhibition) support further development	https://movementdisorders.onlinelibrary.wiley.com/doi/10.1002/mds.29297
NCT03496870	Opicapone	Neurocrine	Catechol-O-methyltransferase (COMT) inhibitor	Phase 1	A Study of the Pharmacokinetics, Pharmacodynamics, and Safety of Opicapone in Subjects With Parkinson's Disease Taking Levodopa.	16	Peer-reviewed Manuscript	NA	NA	Not reported	Marked & extended COMT inhibition, which increased systemic LD exposure and decreased peak-to-trough fluctuations	https://pubmed.ncbi.nlm.nih.gov/36688497/
NCT04575259	ANAVEX 2-73	Anavex Life Sciences	Targets sigma receptors	Phase 2	OLE Study for Patients With Parkinson's Disease With Dementia Enrolled in Study ANAVEX2-73-PDD-001	132	Press Release / Corporate Communications	NA	Favorable	Generally safe and well tolerated	Clinical symptoms consistently improved during the 48 wk extension phase; Potential capability to slow and potentially reverse the symptoms of PD	https://www.anavex.com/post/anavex-2-73-blarcamesine-shows-clinical-benefit-in-long-term-48week-phase-2-extension-study-in-pdd
NCT04191577	CVN424	Cerevance	Selective GPR6 Inverse Agonist	Phase 2	Study of CVN424 in Parkinson's Disease Patients With Motor Fluctuations	141	Conference Abstract or Presentation	Positive	Favorable	Headache, nausea, and vomiting	Generally safe & well-tolerated; clinically meaningful improvement in motor fluctuations. Further trials ongoing.	https://cslide.ctimeetingtech.com/adpd23/attendee/confcal/session/calendar/2023-04-01
NCT03670953	IPX203	Amneal (was Impax Pharma)	L-DOPA/carbidopa extended release	Phase 3	A Study to Evaluate the Safety and Efficacy of IPX203 in Parkinson's Disease Participants With Motor Fluctuations	630	CT.GOV	Positive	Favorable	Nausea, anxiety, dizziness	Longer "Good On" and decreased daily fluctuations vs. IR CD-LD	https://www.clinicaltrials.gov/ct2/show/results/NCT03670953?term=NCT03670953&draw=2&rank=1

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
NCT03329508	P2B001	Pharma Two B	Rasagiline/pramipexole combo	Phase 3	A Phase 3 Study With P2B001 in Subjects With Early Parkinson's	544	CT.GOV	Positive	Favorable	Nausea, fatigue, somnolence & dizziness	Met primary and multiple secondary efficacy endpoints with better tolerability than ER-PPX	https://www.clinicaltrials.gov/ct2/show/results/NCT03329508?term=NCT03329508&draw=2&rank=1
NCT04524351	Butanetap (ANVS-401, posiphen)	Annovis (was QR Pharma)	aSN (+tau +APP) aggregation inhibitor	Phase 1 Phase 2	Posiphen- π E Dose-Finding, Biomarker Study in Early Alzheimer's and Parkinson's Patients	75	CT.GOV	NA	NA	Headache, fatigue, back pain, muscle spasms	Only safety and PK results reported	https://www.clinicaltrials.gov/ct2/show/results/NCT04524351?term=NCT04524351&draw=2&rank=1
NCT03295786	CDNF (Cerebral Dopamine Neurotrophic Factor)	Herantis	Cerebral dopamine neurotrophic factor	Phase 1 Phase 2	Clinical Study to Test the Safety of CDNF by Brain Infusion in Patients With Parkinson's Disease	17	Conference Abstract or Presentation	NA	Mix of neutral & favorable	SAEs & AEs related to infusion procedure	Safe & well tolerated despite AEs & SAEs related to route of administration. Signs of potential clinical & biological response were observed in individual patients	https://slide.ctimeetingtech.com/adpd23/attendee/confcal/session/calendar/2023-04-01
NCT03829657	Amprelosetine (TD- 9855)	Theravance	Norepinephrine reuptake inhibitor	Phase 3	Phase 3 Clinical Effect Durability of TD-9855 for Treating Symptomatic nOH in Subjects With Primary Autonomic Failure	203	CT.GOV	Negative	Not reported	Headache, dizziness, constipation & UTI	Study terminated early by sponsor	https://www.clinicaltrials.gov/ct2/show/results/NCT03829657?term=NCT03829657&draw=2&rank=1

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.

Methodology

- Trial data for Parkinson's disease Phase 1, 2, 3 trials downloaded from ClinicalTrials.gov on first and last days of quarter.
- "Status" parameter compared at beg. 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 beg. 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](#) 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.