Clinical Trials for Parkinson's Disease Drug Therapies: What Happened During Q2 2023?

Q2 2023 Trial Status Headlines (ref. dashboards 1-3 on pages 5-12)
What trials have . . .

Begun recruiting?

Recruiting began for ten trials including several of particular interest:

- Phase 2 trial of BIA28-6156 a Gcase activator from Bial for GBA-associated PD
- Phase 1/2 trial of UB-312 an "endobody" to aSN from Vaxinity (formerly United Neuroscience)
- Phase 1 trials of Roche's NRLP3 inhibitor (RO7486976), Herantis's peptidomimetic for CDNF (HER-096), and KetoneAid a ketone ester dietary supplement

Four other trials were newly listed but not yet recruiting at quarter end -- most notable is a re-purposing study of low-dose levetiracetam (an anti-epileptic) for PD-related psychosis.

Completed enrollment?

Four trials completed enrollment including two Phase 3 trials: A study in early PD with Neurocrine's opticapone (already approved for PD with off episodes), and an open-label extension study for the Abbvie SQ pump formulation of foslevodopa-foscarbidopa

Reached clinical completion?

Another eight trials were noted as now clinically complete (although several of them completed before Q2 but sponsors were apparently delayed in updating clinicaltrials.gov). One study that did complete during Q2 was United College London's Phase 3 trial of the anti-depressants nortriptyline & escitalopram in PD

Been delayed (or accelerated)?

Delays in completion date were disclosed for 8 studies (for 4 the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov) with virtually all the delays being at least 8 months. Most notable were the previously mentioned opicapone Phase 3 trial in early PD (8-month delay) and Sun Pharma's Phase 2 trial of the Bcr/Abl kinase inhibitor K0706 (12-month delay). In contrast, just three studies reported an accelerated completion date and two of these reflected changes in development strategy (e.g., Biogen's decision to close the BIIB122 study in LRRK2 patients).

Completion projected within the next six-months?

Twenty-nine trials are projected to complete by Q4 2023 with 12 to complete in Q3 2023. This group has many interesting studies including:

- Phase 3 trials of two approved agents for new uses in PD -- rivastigmine for fall prevention and solifenacin for urinary symptoms
- Addex Therapeutics Phase 2-3 trial of the mGluR5 modulator dipraglurant for levodopa-induced dyskinesia (LID)
- Phase 2 trials of SAGE-718 an NMDA receptor modulator for cognitive impairment, iKT-148009 a c-Abl kinase inhibitor being studied in early PD, and CPL500036 a PDE 10A inhibitor for LID
- A Phase 1 study of UCB7853 an aSN antibody from UCB and Neuropore.

Q2 2023 Trial Results Headlines (ref. dashboard 4 on pages 13-17)
What trials have . . .

Had results disclosed for the first time?

Results for seven trials were disclosed for the first time. None had a primary efficacy endpoint (e.g., the primary endpoints were safety-related), but results were viewed as favorable for six of the trials (the seventh was terminated early due to poor enrollment).

Highlights included four Phase 1 studies with novel therapies:

- Bayer's bemdaneproce (human embryonic stem cell derived neural precursor cells) demonstrated feasibility of transplantation, evidence of cell survival and engraftment in the brain through one year. A Phase 2 study is now planned.
- Vaxinity's UB-312 (endobody to aSN) was well tolerated and induced anti-aSN antibodies which penetrated the CSF and slowed seeding of aSN. A Phase 1/2 trial is now recruiting.
- AstaZeneca & Takeda's MEDI1341 (aSN antibody) was well-tolerated with dose-dependent suppression of free aSN in the CSF.
- Inhibikase Therapeutics' iKT-148009 (c-Abl kinase inhibitor) showed encouraging efficacy signals and safety & PK results supported including a higher 200mg dose in an ongoing Phase 2 study.

Had additional detail on results disclosed?

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

- A peer-reviewed manuscript on the small Phase 2 study with ursodeoxycholic acid (UDCA) in early PD which demonstrated safety, tolerability, and favorable secondary efficacy endpoints supporting conduct of larger trials.
- A conference abstract on a Phase 2 trial of the DopaFuse oral continuous release formulation of levodopa/carbidopa (a retainer attached to teeth releases levodopa/carbidopa continuously in the back of the mouth) which showed significantly less variability in plasma levodopa and significant improvement in motor function and ADLs relative to traditional immediate-release levodopa/carbidopa.
- A conference abstract on further analysis of the Phase 2 PASADENA study with prasinezumab (Mab to aSN) in early PD that showed lower rates of motor progression and complications versus placebo after two-years of therapy (which was a secondary efficacy endpoint – one-year was the primary endpoint and at that time point a statistically significant difference in disease progression was not achieved).

Methodology

- Trial data for Parkinson's disease Phase 1, 2, and 3 trials downloaded from ClinicalTrials.gov on first and last days of quarter.
- "Status" parameter compared at beginning and end of quarter to identify trials that: Were registered, started or completed recruitment, or were completed or withdrawn during the quarter. "Primary completion date" parameter compared at beginning and end of quarter to determine trials with a change in expected primary completion date. Trials with "Primary completion date" within 6 months were also identified.
- Dashboards limited to Phase 1 to Phase 3 trials evaluating pharmaceuticals, including biologics, cell and gene therapies. The "Parkinson's Disease Drug Therapies in the Clinical Trial Pipeline" reports for 2020, 2021, 2022 and The Hope List were references in identifying pharma vs. non-pharma trials within the Phase 1-3 trials, along with some information in the "agent description" and "company/sponsor" fields.
- Dashboards on Trial Results based on alerts from PubMed.gov, review of conference abstract books, daily emails from Parkinson’s News Today, the Science of Parkinson’s Disease blog, pre-print servers, and the Parkinson’s Research Interest Group on Facebook. It is challenging to capture all results disclosures, so if anything is missing, please let us know at PDTrialTracker@outlook.com.

Clinical Trials of Parkinson's Disease Drug Therapies

Trial Change in Status* Dashboard: Q2 2023

*Registered, Started or Finished Recruiting, Completed

posted on ClinicalTrials.gov between April 1, 2023, and June 30, 2023

dashboard 1

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT05677633	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Validation Following Sargramostim Treatment in Parkinson's Disease	10	Not yet recruiting	Active, not recruiting
NCT05418673	BIIB122 (DNL151)	Biogen & Denali	LRRK2 inhibitor	Phase 3	A Study to Assess if BIIB122 Tablets Are Safe and Can Slow Worsening of Early-Stage Parkinson's Disease in Participants with Specific LRRK2 Genetic Variants Between the Ages of 30 and 80 Using the Movement Disorder Society-Unified Parkinson's Disease Rating Scale	6	Recruiting	Active, not recruiting
NCT04978597	Opicapone	Neurocrine	Catechol-O-methyltransferase (COMT) inhibitor	Phase 3	Early ParkinSon wIth L-DOPA/DDCI and OpicapoNe (EPSILON Study)	410	Recruiting	Active, not recruiting
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	Enrolling by invitation	Active, not recruiting
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	Not in CT.GOV	Completed
NCT05121831	DGX-001	Digestome Therapeutics	Vagus nerve stimulator	Phase 1	A First in Human Study to Assess the Safety, Tolerability, and Pharmacokinetics of DGX-001	68	Recruiting	Completed
NCT04571164	LY03003	Luye Pharma	Rotigotine extended release	Phase 3	A Study to Evaluate the Effectiveness and Safety of LY03003 in Patients With Early Primary PD	294	Unknown status	Completed
NCT03671785	PRIM-DJ2727	Texas University	Lyophilised fecal extract	Phase 1	Study of the Fecal Microbiome in Patients With Parkinson's Disease	15	Active, not recruiting	Completed
NCT03652870	Nortriptyline/ Escitalopram	University College London	Antidepressants	Phase 3	Antidepressants Trial in Parkinson's Disease	52	Recruiting	Completed

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
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	Unknown status	Completed
NCT02617017	Buspirone	Oregon Health & Science University	Serotonin 1A agonist + amantidine	Phase 3	Buspirone Treatment of Iatrogenic Dyskinesias in Advanced Parkinson' Disease	99	Unknown status	Completed
NCT01898390	TRANSEURO (hfVM)	Transeuro	Fetal stem cells	NA	TRANSEURO Open Label Transplant Study in Parkinson's Disease	13	Unknown status	Completed
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	Not in CT.GOV	Enrolling by invitation
NCT05882487	KL002	R&D Kanglin Biotech	Intraputaminal injection with undisclosed MOA	Early Phase 1	Safety and Efficacy Study of KL002 in the Treatment of Advanced Primary PD	9	Not in CT.GOV	Not yet recruiting
NCT05824728	AGB101	AgeneBio	Low dose levetiracetam (anti-epileptic)	Phase 2	Clinical Trial Evaluating the Efficacy and Safety of AGB101 for Treatment of Parkinson's Disease Related Psychosis	30	Not in CT.GOV	Not yet recruiting
NCT05822739	BBM-P002	Belief BioMed	AAV based gene therapy (unspecified)	Early Phase 1	Safety and Efficacy Study of Parkinson's Disease Gene Therapy Drug (BBM-P002)	6	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 in CT.GOV	Not yet recruiting
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	Not in CT.GOV	Recruiting
NCT05915247	HER-096	Herantis	Peptidomimetic for cerebral dopamine neurotrophic factor	Phase 1	Single Ascending Doses of HER-096 in Healthy Subjects	60	Not in CT.GOV	Recruiting
NCT05901818	iNSC-DAP	Xuanwu Hospital, Beijing	Autologous induced neural stem cell-derived DA precursor cells	Phase 1	Safety and Efficacy of Autologous iNSC-DAP in the Treatment of Parkinson's Disease	10	Not in CT.GOV	Recruiting
NCT05887466	A9-DPC	S.Biomedics Co., Ltd.|Yonsei University	ESC-derived Dopamine Progenitor Cell Therapy	Phase 1 |Phase 2	Study to Evaluate the Safety and Efficacy of ESC-derived Dopamine Progenitor Cell Therapy in PD Patients	12	Not in CT.GOV	Recruiting

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Status	New Status
NCT05830396	Ambroxol	Lawson Health Research Institute	Cough medicine, Gcase enhancer	Phase 2 |Phase 3	GRoningen Early-PD Ambroxol Treatment	80	Not in CT.GOV	Recruiting
NCT05819359	BIA28-6156/LTI-291	Bial (acquired Lysosomal Therapeutics)	Gcase activator	Phase 2	Efficacy, Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of BIA 28-6156 in GBA-PD	237	Not in CT.GOV	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 yet recruiting	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 yet recruiting	Recruiting
NCT05634876	UB-312	Vaxxinity (was United Neuroscience)	"Endobody" to aSN	Phase 1 |Phase 2	UB-312 in Patients with Synucleinopathies	8	Not yet recruiting	Recruiting
NCT04127578	PR001A	Prevail Therapeutics	AAV9 viral vector for GBA1 mutation	Phase 1 |Phase 2	Phase 1/2a Clinical Trial of PR001 (LY3884961) in Patients with Parkinson's Disease With at least One GBA1 Mutation (PROPEL)	20	Active, not recruiting	Recruiting
NCT03938922	ENT-01 (Kenterin)	Enterin	Displaces aSN aggregates	Phase 1	A Study to Evaluate ENT-01 for the Treatment of Parkinson's Disease Dementia	40	Unknown status	Suspended
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)	28	Completed	Terminated
NCT04593511	LY03009	Luye Pharma	Monthly injection for dopaminergic stimulation	Phase 1	to Evaluate the Safety, Tolerability and Pharmacokinetics of Four Formulations of LY03009 in Healthy Volunteers	40	Enrolling by invitation	Unknown status
NCT04269642	PT 320 (ER exenatide)	Peptron	SR Exenatide 2 weeks	Phase 2	SR-Exenatide (PT320) to Eveluate Efficacy and Safety in Patients with Early Parkinson's Disease	99	Active, not recruiting	Unknown status

Clinical Trials of Parkinson's Disease Drug Therapies

Change in Completion Date Dashboard: Q2 2023

posted on ClinicalTrials.gov between April 1, 2023, and June 30, 2023

dashboard 2

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
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	23-Oct-2024	511
NCT04127578	PR001A	Prevail Therapeutics	AAV9 viral vector for GBA1 mutation	Phase 1|Phase 2	Phase 1/2a Clinical Trial of PR001 (LY3884961) in Patients with Parkinson's Disease With at least One GBA1 Mutation (PROPEL)	20	1-Apr-2028	1-Jun-2029	426
NCT03655236	K0706/SCC - 138	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	504	1-Mar-2023	1-Mar-2024	366
NCT02579473	SER-214 (Rotigotine polymer conjugate)	Serina Therapeutics	Continuous delivery of rotigotine	Phase 1	A Study of Weekly Subcutaneous Injections of SER-214 in Subjects with Parkinson's Disease (PD), to Determine the Safety, Tolerability and Pharmacokinetic (PK) Profile of SER-214	20	31-Dec-2022	31-Dec-2023	365
NCT05603715	Pyridostigmine	University of Vermont	Cholinesterase inhibitor	Phase 2	Pyridostigmine for the Treatment of Constipation in Parkinson Disease	16	1-Feb-2023	1-Feb-2024	365
NCT05297201	CPL500036	Celon Pharma	PDE 10A inhibitor	Phase 2	Efficacy, Safety and Pharmacokinetic Study of CPL500036 in Patients with Levodopa Induced Dyskinesia	108	1-Feb-2023	1-Nov-2023	273
NCT04978597	Opicapone	Neurocrine	Catechol-O-methyltransferase (COMT) inhibitor	Phase 3	Early ParkinSon wIth L-DOPA/DDCI and OpicapoNe (EPSILON Study)	410	1-May-2023	1-Jan-2024	245

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Prior Primary Completion Date	New Primary Completion Date	Change (Days)
NCT04777331	Prasinezumab (RO7046015/PRX002)	Roche/Prothena	Immunotherapy (Mab to aSN)	Phase 2	A Study to Evaluate the Efficacy and Safety of Intravenous Prasinezumab in Participants with Early Parkinson's Disease	575	10-Jul-2024	20-Sep-2024	72
NCT04542499	Tavapadon (PF-06649751)	Cerevel	Dopamine D1/5 partial agonist	Phase 3	Flexible-Dose, Adjunctive Therapy Trial in Adults with Parkinson's Disease with Motor Fluctuations	500	1-Jun-2024	1-Mar-2024	-92
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-2023	1-Sep-2019	-1461
NCT05418673	BIIB122 (DNL151)	Biogen & Denali	LRRK2 inhibitor	Phase 3	A Study to Assess if BIIB122 Tablets Are Safe and Can Slow Worsening of Early-Stage Parkinson's Disease in Participants with Specific LRRK2 Genetic Variants Between the Ages of 30 and 80 Using the Movement Disorder Society-Unified Parkinson's Disease Rating Scale	6	15-Jan-2031	1-Aug-2023	-2724

Clinical Trials of Parkinson's Disease Drug Therapies
with Primary Completion Date within 6 months of 30-June-2023

trial data: ClinicalTrials.gov

dashboard 3

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
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 hAESCs 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
NCT05418673	BIIB122 (DNL151)	Biogen & Denali	LRRK2 inhibitor	Phase 3	A Study to Assess if BIIB122 Tablets Are Safe and Can Slow Worsening of Early-Stage Parkinson's Disease in Participants with Specific LRRK2 Genetic Variants Between the Ages of 30 and 80 Using the Movement Disorder Society-Unified Parkinson's Disease Rating Scale	6	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
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

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
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
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	90	30-Sep-2023	31-Oct-2023
NCT03790670	Leukine (sargramostim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Assessments of Leukine During Treatment of Parkinson's Disease	7	30-Oct-2023	30-Dec-2024
NCT05297201	CPL500036	Celon Pharma	PDE 10A inhibitor	Phase 2	Efficacy, Safety and Pharmacokinetic Study of CPL500036 in Patients with Levodopa Induced Dyskinesia	108	1-Nov-2023	1-Dec-2023
NCT05915247	HER-096	Herantis	Peptidomimetic for cerebral dopamine neurotrophic factor	Phase 1	Single Ascending Doses of HER-096 in Healthy Subjects	60	1-Nov-2023	1-Nov-2023
NCT02616120	SQJZ herbal mixtures	Dongzhimen Hospital, Beijing	Herbal mixture	Phase 2	Effect of SQJZ Herbal Mixtures on Non-motor Symptoms of Parkinson's Disease	240	1-Dec-2023	1-Dec-2023
NCT02914366	Ambroxol	Lawson Health Research Institute	Cough medicine, Gcase enhancer	Phase 2	Ambroxol as a Treatment for Parkinson's Disease Dementia	55	1-Dec-2023	1-Dec-2023
NCT03562494	VY-AADC02	Neurocrine Biosciences| Voyager Therapeutics	AADC gene therapy	Phase 2	VY-AADC02 for Parkinson's Disease with Motor Fluctuations (RESTORE-1)	85	1-Dec-2023	1-Dec-2023
NCT03575195	Rifaximin	Taipei Medical University	Antibiotic	Phase 1|Phase 2	Microbiota Intervention to Change the Response of Parkinson's Disease	86	1-Dec-2023	1-Dec-2023
NCT03956979	JM-010 (Buspirone/ Zolmitriptan)	Contera Pharma/Bukwang	Serotonin 1 receptor agonist combination (buspirone and zolmitriptan)	Phase 2	A Study in Parkinson's Disease in Patients with Moderate to Severe Dyskinesia	81	1-Dec-2023	1-Dec-2023

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Primary Completion Date	Completion Date
NCT04147949	AV-101 (L-4-chlorokyurenine or 4-Cl-KYN)	VistaGen Therapeutics	NMDAR GlyB modulator	Phase 2	AV-101 (L-4-chlorokynurenine) in Parkinson's Disease Subjects with Levodopa-Induced Dyskinesia	20	1-Dec-2023	1-Apr-2024
NCT04167540	AAV2-GDNF	Ask Bio (was Brain Neurotherapy Bio)	GDNF gene therapy	Phase 1	GDNF Gene Therapy for Parkinson's Disease	11	1-Dec-2023	1-Jun-2027
NCT04935762	CST-103 and CST-107	CuraSen Therapeutics	Restores brain homeostasis	Phase 2	A Study of CST-103 Co-administered with CST-107 in Subjects with Parkinson's Disease Having Freezing of Gait (CLIN-012)	25	1-Dec-2023	1-Mar-2024
NCT05116813	Dipraglurant	Addex Therapeutics	mGluR5 negative allosteric modulator	Phase 2|Phase 3	Open-label Safety Study of Dipraglurant (ADX48621) in Patients with Parkinson's Disease Receiving Levodopa-based Therapy	140	1-Dec-2023	1-Dec-2023
NCT03976349	BIIB094	Biogen/Ionis	Antisense oligo to LRRK2	Phase 1	A Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of BIIB094 in Adults with Parkinson's Disease	82	2-Dec-2023	2-Dec-2023
NCT03683225	CTC-413	Chase Therapeutics	Extended-release pramipexole	Phase 2	A Study to Evaluate in Patients with Parkinsonian Type Disorders	24	30-Dec-2023	30-Dec-2023
NCT02579473	SER-214 (Rotigotine polymer conjugate)	Serina Therapeutics	Continuous delivery of rotigotine	Phase 1	A Study of Weekly Subcutaneous Injections of SER-214 in Subjects with Parkinson's Disease (PD), to Determine the Safety, Tolerability and Pharmacokinetic (PK) Profile of SER-214	20	31-Dec-2023	31-Dec-2023
NCT02864004	Apomorphine (pump)	Supernus/US Worldmeds	Apomorphine infusion	Phase 3	Apomorphine Pump in Early Stage of Parkinson's Disease (EARLY-PUMP)	192	31-Dec-2023	30-Jun-2025
NCT03309514	Neural Stem Cell-Derived Neurons	NeuroGeneration	Neural stem cell derived neurons	Phase 1|Phase 2	Transplantation of Neural Stem Cell-Derived Neurons for Parkinson's Disease	0	31-Dec-2023	30-Jun-2024

Results Dashboard: Q2 2023

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

dashboard 4

ClinicalTrials.gov identifier (NCT)	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Type of Disclosure	Primary Efficacy Endpoint	Secondary Efficacy Endpoints	Safety	Conclusions	Reference
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	Press Release / Corporate Communications	NA	Not reported	Generally safe and well tolerated	Well-tolerated & induced anti-aSyn antibodies which penetrate CSF & slow seeding of aSyn	https://ir.vaxxinity.com/news-releases/news-release-details/vaxxinity-announces-ub-312-successfully-met-primary-objectives
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	Press Release / Corporate Communications	NA	Not reported	Well tolerated	Demonstrated feasibility of transplantation & evidence of cell survival & engraftment in the brain through one year; Phase 2 planned	https://www.bayer.com/media/en-us/bluerocks-neuronal-stem-cell-therapy-for-parkinsons-disease-is-first-to-show-positive-results-in-phase-i-clinical-study/
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	Press Release / Corporate Communications	NA	Favorable	No AEs of clinical significance	Encouraging efficacy observations; Safety &PK support inclusion of 200mg dose in ongoing Phase 2 study	https://www.prnewswire.com/news-releases/inhibikase-therapeutics-provides-safety-and-functional-update-on-its-phase-11b-101-trial-and-its-phase-2-ikt-148009-201-trial-in-parkinsons-disease-301807589.html
NCT03877510	IPX203	Amneal (was Impax Pharma)	L-DOPA/ carbidopa extended release	Phase 3	Open Label Extension (OLE) Study of the Safety and Clinical Utility of IPX203 in Parkinson's Disease (PD) Participants with Motor Fluctuations	419	Conference Abstract or Presentation	NA	Favorable	Well tolerated (low rates of dyskinesia & falls)	Favorable safety & tolerability profile; efficacy maintained from baseline to end of study	https://www.aan.com/MSA/Public/Events/AbstractDetails/52886
NCT03272165	MEDI1341	Astra Zeneca / Takeda	aSN antibody	Phase 1	Single Ascending Dose Study of MEDI1341 in Healthy Volunteers	50	Conference Abstract or Presentation	NA	NA	No clinically significant safety findings	Well tolerated with dose-dependent changes in serum concentrations	https://index.mirasmart.com/aan2023/PDFfiles/AAN2023-002469.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
NCT04449484	MEDI1341	Astra Zeneca / Takeda	aSN antibody	Phase 1	Multiple Ascending Dose Study of MEDI1341 in Patients with Parkinson's Disease	25	Conference Abstract or Presentation	NA	NA	No clinically significant safety findings	Well tolerated with dose-dependent suppression of free aSyn in CSF	https://index.mirasmart.com/aan2023/PDFfiles/AAN2023-002469.html
NCT03971617	Hydrogen	Stony Brook University	Antioxidant	Phase 2-Phase 3	Clinical Trial to Evaluate the Safety and Tolerability of Hydrogen in Patients with Parkinson's Disease	2	CT.GOV	NA	NA	Not reported	Terminated due to poor enrollment	https://classic.clinicaltrials.gov/ct2/show/results/NCT03971617?term=NCT03971617&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.

Clinical Trials of Parkinson's Disease Drug Therapies with *Additional Results Disclosed* Between 1-April-2023and 30-June-2023

NCT Number	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/ pramiprexole combination	Phase 3	A Phase 3 Study with P2B001 in Subjects with Early Parkinson's	544	Conference Abstract or Presentation	Positive	Favorable	Lower rates of somnolence & orthostatic hypotension than Prami-ER	Once daily option (without titration) for early PD with comparable efficacy to Prami-ER but reduced sleep-related & dopaminergic side effects	https://index.mirasmart.com/aan2023/PDFfiles/AAN2023-003733.html
NCT03329508	P2B001	Pharma Two B	Rasagiline/pramiprexole combination	Phase 3	A Phase 3 Study with P2B001 in Subjects With Early Parkinson's	544	Conference Abstract or Presentation	Positive	Favorable	Nausea, fatique, somnolence & dizziness	Similar efficacy to ER-PPX but with significantly less new-onset excessive daytime sleepiness	https://index.mirasmart.com/aan2023/PDFfiles/AAN2023-002396.html
NCT04380142	Foslevodopa/ foscarbidopa (ABBV-951)	Abbvie	Sub-cutaneous L-DOPA/Carbidopa prodrug	Phase 3	Study Comparing Continuous Subcutaneous Infusion Of ABBV-951 With Oral Carbidopa/Levodopa Tablets for Treatment Of Motor Fluctuations In Adult Participants With Advanced Parkinson's Disease	174	Conference Abstract or Presentation	Positive	Favorable	Infusion site erythema, pain, cellulitis & edema	AEs & discontinuations higher during 4-week optimization vs. 8-week maintenance period; Maybe due to dose titration & acclimation to pump	https://index.mirasmart.com/aan2023/PDFfiles/AAN2023-000004.html
NCT03790670	Leukine (sargramos-tim)	Nebraska University	Recombinant GM-CSF	Phase 1	Biomarker Assessments of Leukine During Treatment of Parkinson's Disease	7	Peer-reviewed Manuscript	NA	Favorable	injection-site reactions, elevated total WBCs & bone pain	Affirmed long-term safety as well as immune & anti-inflammatory responses reflecting clinical stability. Phase 2 planned.	https://translationalneurodegeneration.biomedcentral.com/articles/10.1186/s40035-023-00361-1
NCT03840005	UDCA (Ursodeoxy-cholic acid)	Minnesota University	Improves mitochon-drial function	Phase 2	Trial of Ursodeoxycholic Acid (UDCA) for Parkinson's Disease: The "UP" Study	31	Peer-reviewed Manuscript	NA	Favorable	Mild, transient GI AEs	Safe & well tolerated in early PD; Larger trials needed to evaluate disease-modifying effect	https://movementdisorders.onlinelibrary.wiley.com/doi/10.1002/mds.29450

NCT Number	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Type of Disclosure	Primary Efficacy Endpoint	Secondary Efficacy Endpoints	Safety	Conclusions	Reference
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 E-Delivery System in Parkinson's Disease Patients	17	Conference Abstract or Presentation	NA	Favorable	No clinically significant AEs	Significantly less variability in plasma levodopa & significant improvement in motor function & ADLs	https://www.aan.com/MSA/Public/Events/AbstractDetails/55228
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	Reduced OFF time, increased ON time without troublesome dyskinesia & allowed for oral medication reduction; AEs consistent with prior studies	https://index.mirasmart.com/aan2023/PDFfiles/AAN2023-002446.html
NCT03877510	IPX203	Amneal (was Impax Pharma)	L-DOPA /carbidopa extended release	Phase 3	Open Label Extension (OLE) Study of the Safety and Clinical Utility of IPX203 in Parkinson's Disease (PD) Participants with Motor Fluctuations	419	CT.GOV	NA	Favorable	Dyskinesia, falls	Efficacy generally maintained from baseline to end of study	https://classic.clinicaltrials.gov/ct2/show/results/NCT03877510?term=NCT03877510&draw=2&rank=1
NCT01968460	P2B001	Pharma Two B	Rasagiline/ pramiprexole combination	Phase 2| Phase 3	Safety, Tolerability and Efficacy of Two Doses of Once Daily P2B001 in Subjects with Early Parkinson's Disease	149	CT.GOV	Positive	Favorable	Nausea, fatigue, somnolence & dizziness	Both doses positive on primary endpoint; higher dose more consistently positive on secondaries	https://classic.clinicaltrials.gov/ct2/show/results/NCT01968460?term=NCT01968460&draw=2&rank=1
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	At week 104 lower rates of motor progress-sion & complica-tions	Not reported	Open label extension ongoing; Will report further results on a yearly basis	https://index.mirasmart.com/aan2023/PDFfiles/AAN2023-002952.html

NCT Number	Agent	Company / Sponsor	Agent Description	Phase	Trial Title	Enrollment	Type of Disclosure	Primary Efficacy Endpoint	Secondary Efficacy Endpoints	Safety	Conclusions	Reference
NCT04476017	SAGE-718	Sage Therapeutics	NMDA receptor modulator	Phase 2	A Study to Evaluate the Safety and Tolerability of SAGE-718 in Participants with Parkinson's Disease Mild Cognitive Impairment (PD-MCI)	18	CT.GOV	NA	Not reported	No AEs that occurred in >1 subject	Generally well tolerated	https://classic.clinicaltrials.gov/ct2/show/results/NCT04476017?term=NCT04476017&draw=2&rank=1&view=results
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	Peer-reviewed Manuscript	NA	Favorable	Poorly tolerated in 33% of patients	Engagement of blood-based therapeutic targets & improvements in MRI disease-progression biomarkers	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10196787/
NCT02969369	SEP-363856	Sunovion (part of Sumitomo Dainippon)	Serotonin 1 receptor agonist	Phase 2	A Study to Evaluate the Efficacy, Safety and Tolerability of SEP-363856 in Subjects with Parkinson's Disease Psychosis	39	CT.GOV	Negative	Favorable	Hallucina-tions, confusion, falls & dizziness	Generally well tolerated with favorable trends on multiple efficacy endpoints	https://classic.clinicaltrials.gov/ct2/show/results/NCT02969369?term=NCT02969369&draw=2&rank=1
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	CT.GOV	NA	Not reported	Infusion site hematoma, infection & erythema	About 55% completed 12-month study; about 20% discontinued due to AEs	https://classic.clinicaltrials.gov/ct2/show/results/NCT02726386?term=NCT02726386&draw=2&rank=1&view=results
NCT03250117	Ropinirole	Titan Pharma-ceuticals	Ropinirole SQ implant	Phase 1| Phase 2	Relative Bioavailability Study of Ropinirole Implants in Parkinson's Patients on L-Dopa Switched from Oral Ropinirole	6	CT.GOV	NA	NA	Implant site reaction	Study terminated early by sponsor	https://classic.clinicaltrials.gov/ct2/show/results/NCT03250117?term=NCT03250117&draw=2&rank=1