Results Dashboard: Q4 2022

Clinical Trials of Parkinson's Disease Drug Therapies with Results Newly Disclosed

Between 1-Oct-2022 and 31-Dec-2022

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
NCT04778176	DopaFuse	SynAgile	Continuous delivery of LDOPA / Carbidopa	Phase 2	Assessing the Pharmacokinetics, Safety, Tolerability and Efficacy of Continuous Oral Levodopa Via the DopaFuse Delivery System in Parkinson's Disease Patients	17	Press Release / Corporate Communications	NA	Favorable	Mild & transient oro-buccal reactions	Plasma variability significantly reduced & motor complications significantly improved	https://www.globenewswire.com/news release/2022/11/04/2548477/0/en/SynAgile Corporation-Announces-Positive-Phase-2-Top-Line Results-for-DopaFuse-Levodopa-Carbidopa-Delivery System.html
NCT03881371	Safinamide	Zambon SpA	MAO-B inhibitor	Phase 3	A Study to Evaluate the Efficacy and Safety of Safinamide, as add-on Therapy, in Idiopathic Chinese Parkinson's Disease (PD) Patients With Motor Fluctuations Treated With Stable Doses of Levodopa	307	Peer-reviewed Manuscript	Positive	Favorable	No significant differences vs. placebo	As add-on to LD, significantly reduced motor fluctuations & improved motor symptoms & quality of life	CNS Drugs. 2022 Nov;36(11):1217-1227. doi: 10.1007/s40263-022-00958-6. Epub 2022 Nov 8.
NCT04111666	AL101	Alector/GSK	Increases progranulin	Phase 1	A Phase 1 First in Human Study to Assess Safety and Tolerability of AL101	88	Conference Abstract or Presentation	NA	Favorable	Generally well tolerated	PK-PD profile following single & multiple IV doses support development in AD & PD	https://www.globenewswire.com/news release/2022/11/29/2564291/0/en/Alector Presents-Results-from-First-in-Human-Phase-1- Study-of-AL101-for-the-Treatment-of Neurodegenerative-Diseases.html
NCT05083260	NE3107	Biovie	Reduces neuroinflammati on and insulin resistance	Phase 1|Phase 2	NE3107 Activity and Safety in Patients With Parkinson's Disease Using Levodopa	40	Press Release / Corporate Communications	NA	Favorable	No drug-related AEs	Probable signal of efficacy in treatment of motor symptoms should be pursued in larger study	https://www.globenewswire.com/news release/2022/12/05/2567854/0/en/BioVie Announces-Positive-Results-for-NE3107-in Parkinson-s-and-Alzheimer-s-Phase-2-Trials.html
NCT02655315	Deferiprone	ApoPharma (SKY)	Iron chelator	Phase 2	Conservative Iron Chelation as a Disease-modifying Strategy in Parkinson's Disease	372	Peer-reviewed Manuscript	Negative	Negative	Agranulo-cytosis & neutropenia	Deferiprone was associated with worse scores in measures of parkinsonism than those with placebo	https://pubmed.ncbi.nlm.nih.gov/36449420/
NCT04739423	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 Neurodegenerative Disorders	41	Press Release / Corporate Communications	NA	Favorable	Well tolerated	Congnitive findings support further development for PD patients with RBD	https://www.businesswire.com/news/home/20221219005238/en/CuraSen-Therapeutics-Announces Successful-Completion-of-Phase-2-Safety Tolerability-and-Proof-of-Concept-Study-in-Patients with-Parkinson's-Disease-or-Mild-Cognitive Impairment-MCI-with-CST-103CST-107-Treatment

NCT04369430	AKST4290-211	Alkahest	CCR3 inhibitor	Phase 2	Study Assessing Efficacy and Safety of AKST4290 in Subjects With Parkinson's Disease on Stable Dopaminergic Treatment	110	CT.GOV	Negative	Negative	Nausea & fatigue	No statistics but seems to be negative study (although still in company pipeline as of 1/1/23)	https://www.clinicaltrials.gov/ct2/show/results/NCT04369430?term=NCT04369430&draw=2&rank=1
NCT04095793	Amprelo xetine (TD 9855)	Theravance	Norepinephrin e reuptake inhibitor	Phase 3	Phase 3 Open-Label Extension Study of TD-9855 for Treating Symptomatic nOH in Subjects With Primary Autonomic Failure	110	CT.GOV	NA	NA	UTI, headache, arthralgia	Study terminated early by sponsor	https://www.clinicaltrials.gov/ct2/show/results/NCT04095793?term=NCT04095793&draw=2&rank=1
NCT03391882	APL-130277 (Kynmobi)	Sunovion (part of Sumitomo Dainippon)	Sublingual apomorphine	Phase 3	A Study of an Investigational Drug to See How it Affects the People With Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes) Compared to an Approved Drug Used to Treat People With Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes)	113	CT.GOV	Neutral	Mix of neutral & favorable	Nausea, dyskinesia, fatigue	Sub-linqual apomorphine efficacy not superior to SQ but prefered by patients	https://www.clinicaltrials.gov/ct2/show/results/NCT03391882?term=NCT03391882&draw=2&rank=1
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	Press Release / Corporate Communications	Negative	Mixed	No adverse drug reactions	Confident can increase likelihood of success by increasing cohort size & introducing prefilled syringes	https://www.koreabiomed.com/news/articleView. html?idxno=20071

Clinical Trials of Parkinson's Disease Drug Therapies with Additional Results Disclosed

Between 1-Oct-2022 and 31-Dec-2022

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
NCT03781791	ENT-01 (Kenterin)	Enterin	Displaces aSN aggregat es	Phase 2	Orally Administered ENT-01 for Parkinson's Disease Related Constipation (KARMET)	144	Peer-reviewed Manuscript	Positive	Favorable	Nausea & diarrhea	Safe and significantly improved constipation	https://www.acpjournals.org/doi/10.7326/M22- 1438#.Y2nUVllpRhU.twitter
NCT02787590	Simvastatin	Generics available	Statin	Phase 2	Simvastatin as a Neuroprotective Treatment for Moderate Parkinson's Disease	235	Peer-reviewed Manuscript	Negative	Negative	Typical statin side effects	Futile as a disease-modifying therapy in patients with PD of moderate severity	https://jamanetwork.com/journals/jamaneurology /fullarticle/2797508
NCT04912115	PT-001	Pharmather	Ketamine	Phase 2	Randomized, Double-Blind, Active Placebo-Controlled Study of Ketamine to Treat Levodopa-Induced Dyskinesia	30	Conference Abstract or Presentation	Positive	Favorable	Dissociati on & hypertens ion	Results support repurposing of sub anesthetic ketamine for LID	https://www.abstractsonline.com/pp8/#!/10619/presentation/63154

NCT04380142	Foslevodopa/ foscar bidopa (ABBV-951)	Abbvie	Sub-cutaneous LDOPA/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	Peer-reviewed Manuscript	Positive	Favorable	Infusion site erythema, pain, cellulitis & edema	Improved motor fluctuations (both on time without troublesome dyskinesia and off time). Potential non-surgical alternative for patients with advanced disease	https://pubmed.ncbi.nlm.nih.gov/36402160/
NCT00660673	Duodopa	Abbvie	Intestinal LD/CD	Phase 3	Open Label Continuation Treatment Study With Levodopa-Carbidopa Intestinal Gel in Advanced Parkinson's Disease	262	CT.GOV	NA	Favorable	Device complications & post -op infections	Supportive data on long-term safety and effectiveness in open-label setting	https://www.clinicaltrials.gov/ct2/show/results/NCT00660673?term=NCT00660673&draw=2&rank=1
NCT04524351	Butanetap (ANVS 401, posiphen)	Annovis (was QR Pharma)	aSN (+tau +APP) aggregation inhibitor	Phase 1|2	Posiphen Dose-Finding, Biomarker Study in Early Alzheimer's and Parkinson's Patients	75	Peer-reviewed Manuscript	NA	Favorable	Headache, erythema, movement disorder & muscle spasms	Well tolerated & safe; promising exploratory biomarker & efficacy measures; larger trials warranted	https://link.springer.com/article/10.14283/jpad.20 22.84