# 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 |
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| 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 Neurother-apy 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://cslide.ctimeetingtech.com/adpd23/attendee/confcal/session/calendar/2023-04-01 |
| 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 | 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/neurolixis-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 |

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| 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-2023and 31-Mar-2023

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| NCT05083260 | NE3107 | Biovie | Reduces neuroinfla-mation and insulin resistance | Phase 1 Phase 2 | NE3107 Activity and Safety in Patients With Parkinson's Disease Using Levodopa | 46 | 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.issuerdirect.com/news-release.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-methyl-transferase (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 |

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| NCT03329508 | P2B001 | Pharma Two B | Rasagiline/ pramiprex-ole 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) aggrega-tion inhibitor | Phase 1 Phase 2 | Posiphen¬Æ 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 neuro-trophic 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://cslide.ctimeetingtech.com/adpd23/attendee/confcal/session/calendar/2023-04-01 |
| NCT03829657 | Ampreloxetine (TD- 9855) | Theravance | Norepi-nephrine 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 |