Patients and Methods / Material and Methods: In a phase 3, 54-week, open-label (IRB-approved) study in patients with advanced PD, LCIG was administered continuously 16 hours/day; adjunctive therapies were allowed after week 4. In this analysis, safety and efficacy in patients who remained on daytime LCIG monotherapy was assessed.

Results: Of 324 patients who had PEG-J placement, 248 (76.5%) were on LCIG daytime monotherapy (90 patients received no overnight oral carbidopa/levodopa; Table 1). Patients on daytime LCIG monotherapy experienced reductions in "Off" time of 4.7 vs 3.6 hours in patients receiving polytherapy. Patients experienced increases in "On" time without troublesome dyskinesia of 5.0 vs 4.1 hours with daytime LCIG monotherapy vs polytherapy (Figure). Safety for patients on LCIG daytime monotherapy vs polytherapy are described in Table 2.

Table 1. Patients on Concomitant Parkinson's Disease Therapy

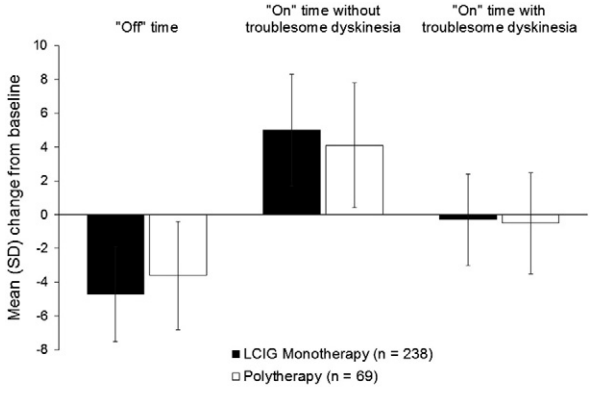
	Patients, n (%)	
Number of PD Medications	Baseline (N = 354)[a]	Post PEG-J (n = 324)
1		
Carbidopa/levodopa only	94 (26.6)	–
LCIG only	–	90 (27.8)
2		
Carbidopa/levodopa + 1 adjunctive tx	112 (31.6)	–
LCIG + nighttime carbidopa/levodopa[b]	–	158 (48.8)
LCIG + other adjunctive tx[b]	–	11 (3.4)
≥ 3		
Carbidopa/levodopa + ≥ 2 adjunctive tx	147 (41.5)	–
LCIG + ≥ 2 adjunctive tx[b]	–	65 (20.1)

[a]One patient's baseline PD medications were not recorded because of a data capturing issue.
[b]LCIG is a 16-hour infusion and nighttime oral therapy was permitted after week 4.
LCIG = levodopa-carbidopa intestinal gel; tx = treatment.

Table 2. Adverse Events

	Patients, n (%)	
Preferred Term[a]	Daytime Monotherapy (n = 248)	Polytherapy (n = 76)
Any adverse event	225 (90.7)	73 (96.1)
Non-procedure/device-related adverse events (> 10% of patients in any group)		
Nausea	39 (15.7)	15 (19.7)
Fall	39 (15.7)	10 (13.2)
Insomnia	34 (13.7)	10 (13.2)
Constipation	32 (12.9)	15 (19.7)
Urinary tract infection	27 (10.9)	10 (13.2)
Weight decreased	22 (8.9)	9 (11.8)
Parkinson's disease[b]	19 (7.7)	10 (13.2)
Vomiting	19 (7.7)	9 (11.8)
Depression	18 (7.3)	8 (10.5)
Back pain	17 (6.9)	8 (10.5)
Dyskinesia	16 (6.5)	15 (19.7)

[a]A single event could be coded to >1 preferred term.
[b]Refers to a reemergence of Parkinson's disease symptoms.



Mean (SD) change from baseline in "Off" and "On" times as assessed by a Parkinson's disease diary. SD = standard deviation.

Conclusion: Daytime LCIG monotherapy and polytherapy demonstrated similar efficacy and safety profiles in advanced PD patients, suggesting that LCIG monotherapy can provide a more simplified treatment option for appropriate patients.

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FREE PAPERS: LATE BREAKING ORAL SESSION 1

Masitinib as an add-on therapy to riluzole is safe and effective in the treatment of amyotrophic lateral sclerosis (ALS)

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Background: Masitinib, an oral tyrosine kinase inhibitor, appears unique among other ALS-developmental drugs, exerting neuroprotection by targeting microglia, macrophage and mast cell activity, in both central and peripheral nervous systems.

Objective: Evaluate masitinib plus riluzole (100mg/kg) in ALS.

Patients and Methods / Material and Methods: ALS patients received riluzole plus oral masitinib 4.5 mg/kg/day (M4.5) (n = 106) or placebo (n = 114) over 48 weeks. Primary endpoint was absolute change in ALSFRS-$R_{[W0–W48]}$ (ΔALSFRS-R) in patients with baseline ALSFRS-R progression rate of <1.1 points/month (referred to as 'Normal Progressors'). Secondary endpoints included time-to-event analysis (PFS, defined as an ALSFRS-R deterioration of >9 points from baseline or death), ALSAQ40, and FVC.

Results: Masitinib showed significant benefit in ΔALSFRS-R over placebo with a least-square means difference (ΔLSM) of 3.4 (P = 0.0158), corresponding to a clinically meaningful retardation of 27%. All sensitivity analyses were positive, with P<0.02 according to imputation (ITT) methodology. Masitinib also demonstrated benefit over placebo in the secondary variables, significantly improving median PFS by 25% (20 vs. 16 months, P = 0.0159); ALSAQ40 by 28.5% (ΔLSM of 19.4 vs. 27.2, P = 0.0078); and FVC by 22% (ΔLSM of 26.0 vs. 33.4, P = 0.0332). Post-hoc analysis indicated enhanced treatment-effect (42% retardation) is possible with early treatment (<24-month duration of illness). Common (>10%) adverse events (AEs) with masitinib in this patient cohort were rash, nausea, diarrhoea, and weight loss. Frequency of AEs, serious AEs, and severe AEs (placebo versus M4.5) was respectively: 79% vs.90%, 20% vs. 28%, and 18% vs. 24%.

Conclusion: Masitinib 4.5 mg/kg/day demonstrated a significant benefit with acceptable safety in ALS patients with a baseline ALSFRS-R progression rate of <1.1 points/month.

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FREE PAPERS: LATE BREAKING ORAL SESSION 1

Eculizumab for Guillain-Barre syndrome: Randomized clinical trial (JET-GBS study)

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