



Newron Pharmaceuticals S.p.A.

Investor and analyst call

Safinamide phase III results

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Moderators:

Luca Benatti, CEO

Ravi Anand, CMO

European dial-in: +39 02 802 09 11

UK dial-in: +44 (0)208 79 29 750

USA toll free number: +1 866 23 96 425

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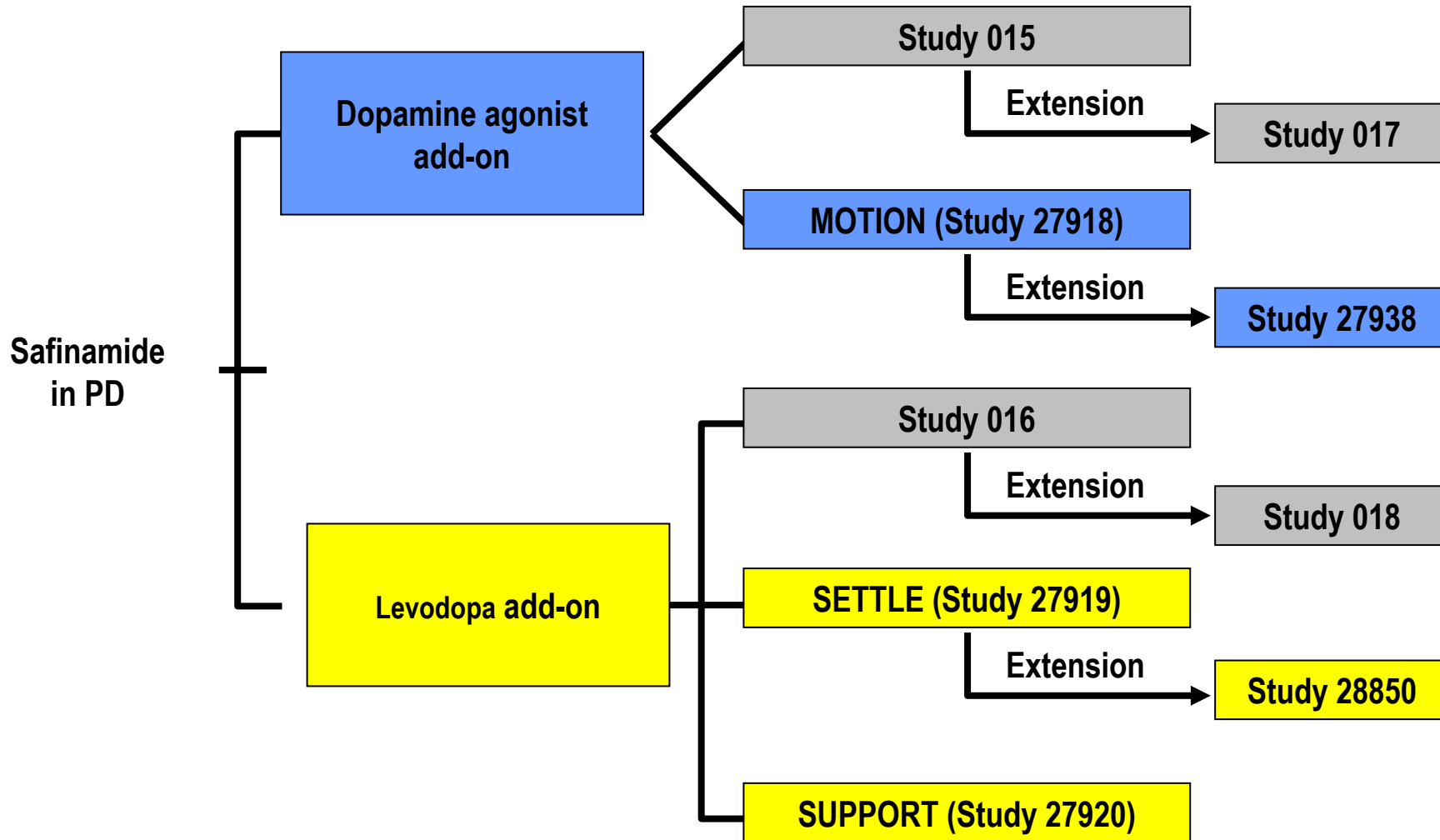
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Safinamide background

- Safinamide is being developed for the treatment of the signs and symptoms of idiopathic Parkinson's disease, as adjunctive therapy for patients currently treated with dopamine agonists and as adjunctive therapy to levodopa
- Novel chemical class (alpha amino-amide) derivative in Phase III worldwide
- Enhances brain dopamine by highly selective MAO-B inhibition and dopamine re-uptake inhibition; antagonises stimulated release of glutamate
- High bioavailability, absorption unaffected by food, linear kinetics, and half-life of 21-24 h
- No tyramine potentiation in animal or human studies to date; all therapeutic studies performed without any tyramine restriction
- Merck Serono has exclusive worldwide rights to develop, manufacture and commercialize safinamide in Parkinson's disease, Alzheimer's disease and other therapeutic applications, as per the agreement signed with Newron in 2006

Safinamide - Clinical Development Plan





Safinamide Study 016

A PHASE III, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO DETERMINE THE **EFFICACY AND SAFETY** OF A LOW (50 MG/DAY) AND HIGH (100 MG/DAY) DOSE OF SAFINAMIDE, AS ADD-ON THERAPY, IN PATIENTS WITH IDIOPATHIC PARKINSON'S DISEASE WITH MOTOR FLUCTUATIONS, TREATED WITH A STABLE DOSE OF LEVODOPA AND WHO MAY BE RECEIVING CONCOMITANT TREATMENT WITH STABLE DOSES OF A DOPAMINE AGONIST, AND/OR AN ANTICHOLINERGIC

Add-on to L-dopa in mid-to-late stage PD

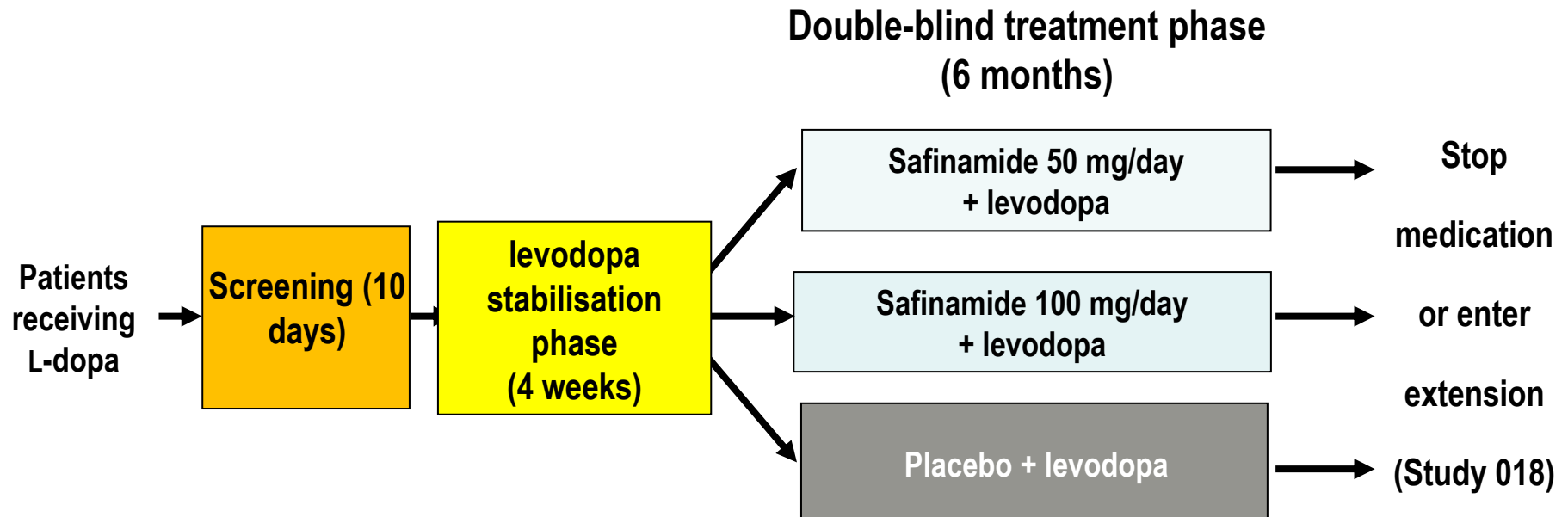
Study 016 – Design



- Double-blind, placebo-controlled, parallel-group, randomised, multi-centre multi-national, Phase III trial
- Comparing two doses of safinamide (50 and 100 mg/day, p.o.) versus placebo
- Once per day administration in the morning
- 669 subjects randomized across 55 sites in Europe and Asia
- Eligible patients will be treated for a total of 2 years
 - This will be achieved by the patients participating in the two protocols:
 - Study 016: duration of treatment is 24 weeks
 - Study 018 duration of treatment is 18 months
- Data from the first 6 months of treatment being analyzed separately, and the blind will be maintained throughout the additional 18 months of treatment

Add-on to levodopa in mid-to-late stage PD

Study 016 - Design



Add-on to L-dopa in mid-to-late stage PD

Study 016 – Objectives



- To evaluate the efficacy and safety of safinamide 50 and 100 mg/day, compared to placebo, in patients with Parkinson's disease with motor fluctuations and currently receiving an 'optimized' PD treatment with levodopa and other PD therapies (dopamine agonists, anticholinergics, amantadine).

Study 016 - Key Inclusion Criteria



- Male or female, aged 30-80 years
- Diagnosis of idiopathic Parkinson's Disease of > 3 yrs
- Hoehn and Yahr stage of I-IV during an "off" phase
- Levodopa responsive and receiving a stable dose of levodopa at Screening
 - 4-10 doses per day
 - Any levodopa preparation (plus benserazide/carbidopa)
 - COMT inhibitors permitted (including Stalevo®)
- Patients may be receiving concomitant treatment with stable doses of a dopamine agonist and/or an anticholinergic and/or amantadine
- Motor fluctuations with >1.5 hours OFF time during day
- Ability to maintain diary (18 hours) with help of caregiver
- Complete ophthalmologic screening

Study 016 - Key exclusion criteria



- Late-stage PD with severe, disabling peak-dose or biphasic dyskinesia, or wide/unpredictable fluctuations.
- Previous stereotactic surgery to treat PD.
- History of psychosis or score ≥ 3 on the UPDRS Section I, Item 2 (thought disorder) or 3 (depression).
- GRID-HAM-D total score > 17 .
- Evidence of dementia or cognitive dysfunction: Mini Mental State Examination < 22 , or UPDRS Section I, Item 1 score ≥ 3 .
- Active retinopathy.

Study 016

Efficacy Variables



Primary efficacy variable:

- Increase in mean daily “on” time (“on” time without dyskinesia plus “on” time with minor dyskinesia) during 18-hr diary recording period

Secondary efficacy variables

- Decrease in total daily “off” time, as measured by diary cards
- Decrease in mean “off” time following first morning dose of levodopa
- Change in cognition (cognitive test battery)*
- Improvement in the Dyskinesias Rating Scale during “on” phase
- UPDRS Section II during “on” phase – mean change from baseline to endpoint
- UPDRS Section III during “on” phase – mean change from baseline to endpoint
- CGI - Change from baseline - mean score in the course of the study
- CGI- Severity of illness – mean change from baseline to endpoint
- Mean percent change in levodopa dose (change from baseline to endpoint) *

Tertiary efficacy variables:

- Hoehn and Yahr staging *
- GRID-HAMD (17-item) total score - mean change from baseline to endpoint
- MMSE - mean change from baseline to endpoint *
- PDQ-39 - mean change from baseline to endpoint.

* *To be reported later*

Add-on to L-dopa in mid-to-late stage PD

Study 016 – Safety assessments



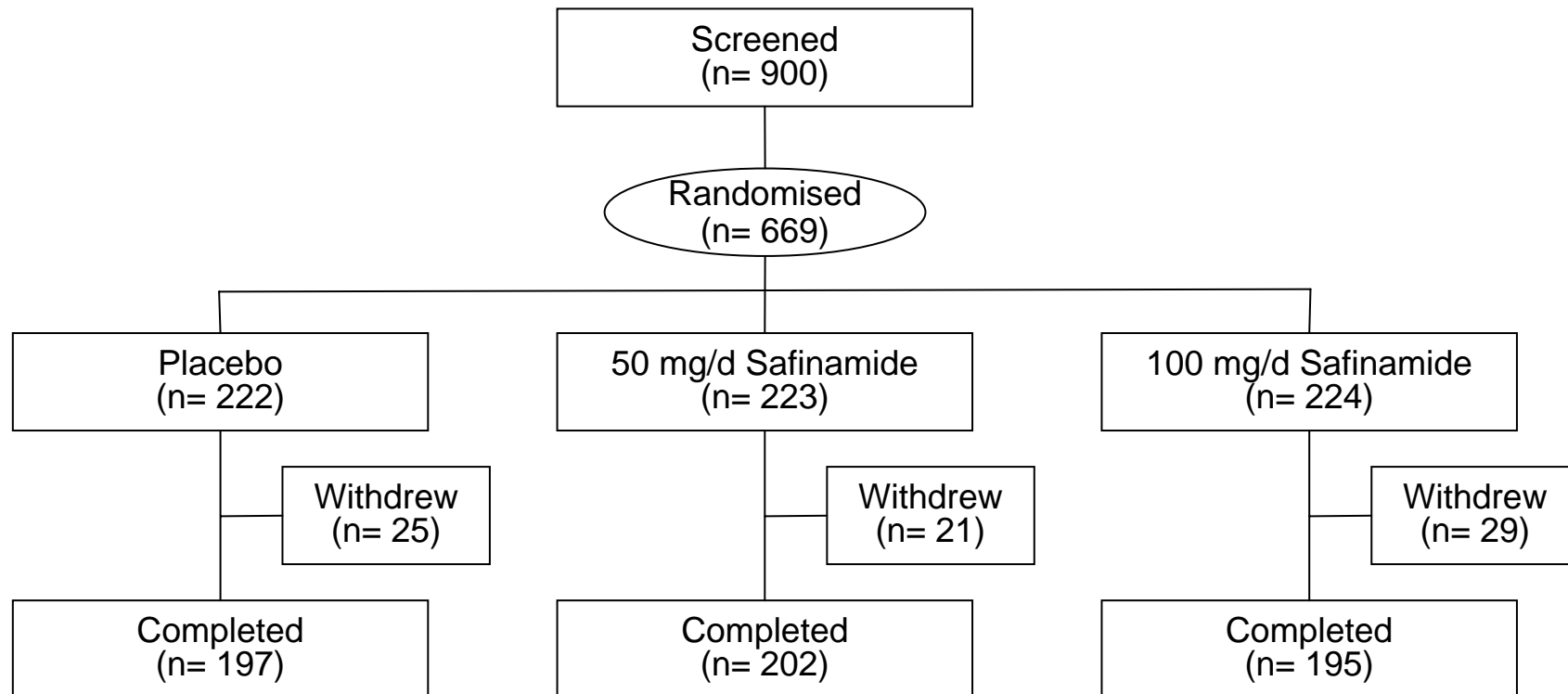
- Adverse events
- Vital signs (systolic/diastolic blood pressure, pulse, body weight, body temperature, respiratory rate)
- Laboratory evaluations (blood chemistry, hematology, urinalysis)
- Electrocardiogram (ECG) –12-lead, standard
- Physical examination/ Neurological examination
- Ophthalmological examination – including funduscopy, corrected visual acuity, color vision, and visual field

Safety of patients treated with safinamide was monitored by an Independent International Safety Monitoring Board



Safinamide Study 016: Results

Study 016 - Subject Disposition





Study 016 – Safety results

Study 016 - Treatment-Emergent Adverse Events Incidence > 5 % at least in one treatment group



AE (preferred term) reported at least in one treatment group > 5 %	Placebo		Safinamide			
			50 mg/day		100 mg/day	
	n	%	n	%	n	%
Dyskinesia	27	12.20	46	20.60	40	17.90
Cataract	15	6.80	9	4.00	14	6.30
Headache	10	4.50	12	5.40	11	4.90
Back pain	13	5.90	10	4.50	11	4.90
Parkinson's disease	18	8.10	11	4.90	9	4.00
Depression	11	5.0	2	0.9	4	1.8



Study 016 – Efficacy results

Study 016 – Demographics Characteristics



	Placebo (n=222)	Safinamide 50 mg/day (n=223)	Safinamide 100 mg/day (n=224)
Mean age (years) (SD)	59.4 (9.41)	60.1 (9.67)	60.1 (9.19)
Gender Male (%)	72.1%	70.4%	72.8%
Race			
Asian	180 (81.1%)	180 (80.7%)	179 (79.9%)
White	42 (18.9%)	43 (19.3%)	45 (20.1%)
Disease Duration (years) (SD)	8.29 (3.759)	7.88 (3.976)	8.15 (3.788)

Study 016 – Baseline Characteristics



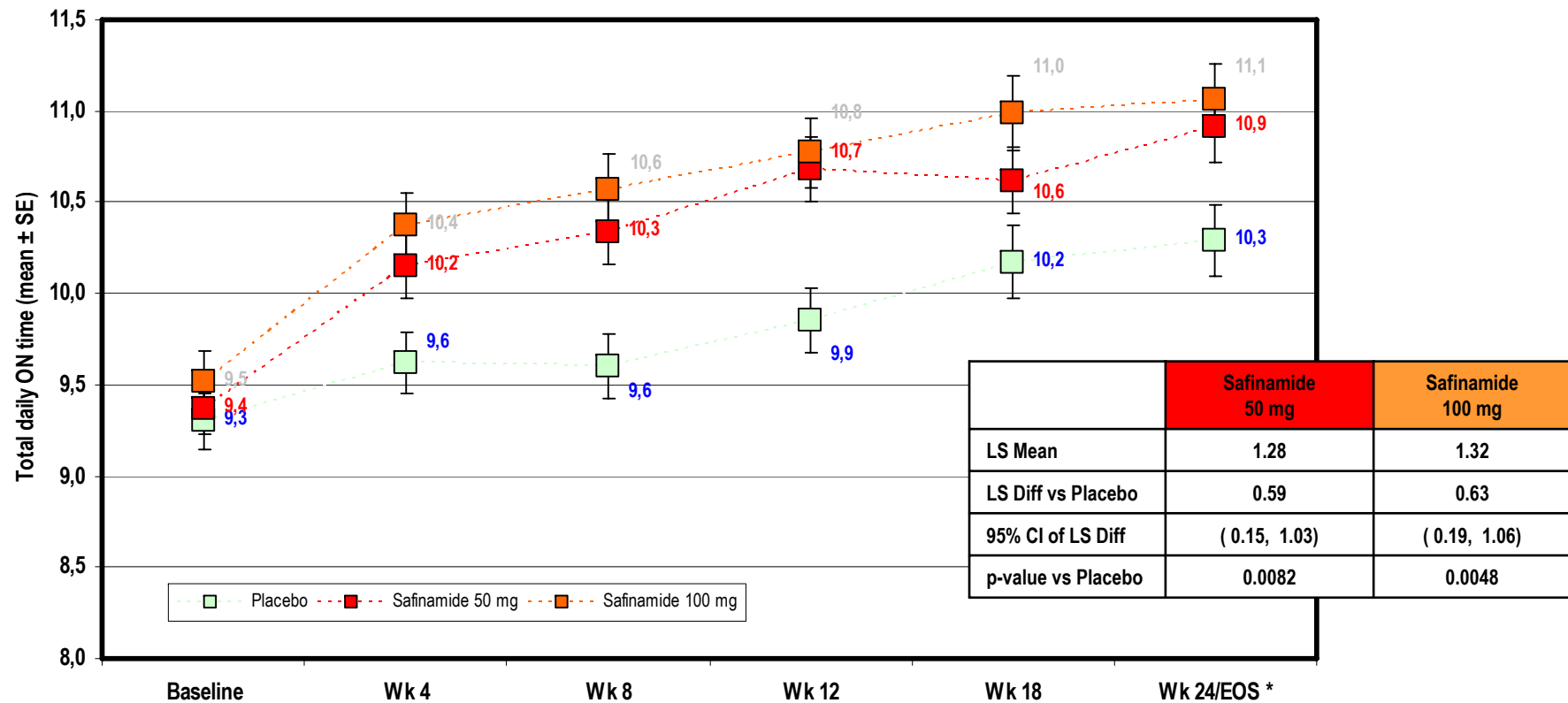
	Placebo (n=222)	Safinamide 50 mg/day (n=223)	Safinamide 100 mg/day (n=224)
Baseline OFF time (hours) (SD)	5.3 (2.06)	5.2 (2.08)	5.2 (2.16)
Baseline 'ON' time (hours) (SD)	9.30 (2.155)	9.37 (2.259)	9.52 (2.426)
Baseline UPDRS Part III 'ON' (SD)	28.7 (12.03)	27.3 (12.67)	28.3 (13.30)
PD Treatment			
Levodopa*	222 (100.0%)	223 (100.0%)	224 (100.0%)
Dopamine Agonist	136 (61.3%)	142 (63.7%)	128 (57.1%)
Anticholinergic	86 (38.7%)	73 (32.7%)	85 (37.9%)
Entacapone	56 (25.2%)	52 (23.3%)	55 (24.65)
Stalevo	33 (14.9%)	30 (13.5%)	36 (16.1%)
Amantadine	32 (14.4%)	29 (13.0%)	30 (13.4%)

*Includes various formulations of levodopa including Sinemet (Immediate Release/Controlled Release) and Madopar

Study 016: Primary efficacy variable – ON* time



Summary of Total Daily 'ON' Time and Change from Baseline
On Treatment - Repeated Measures
ITT Population

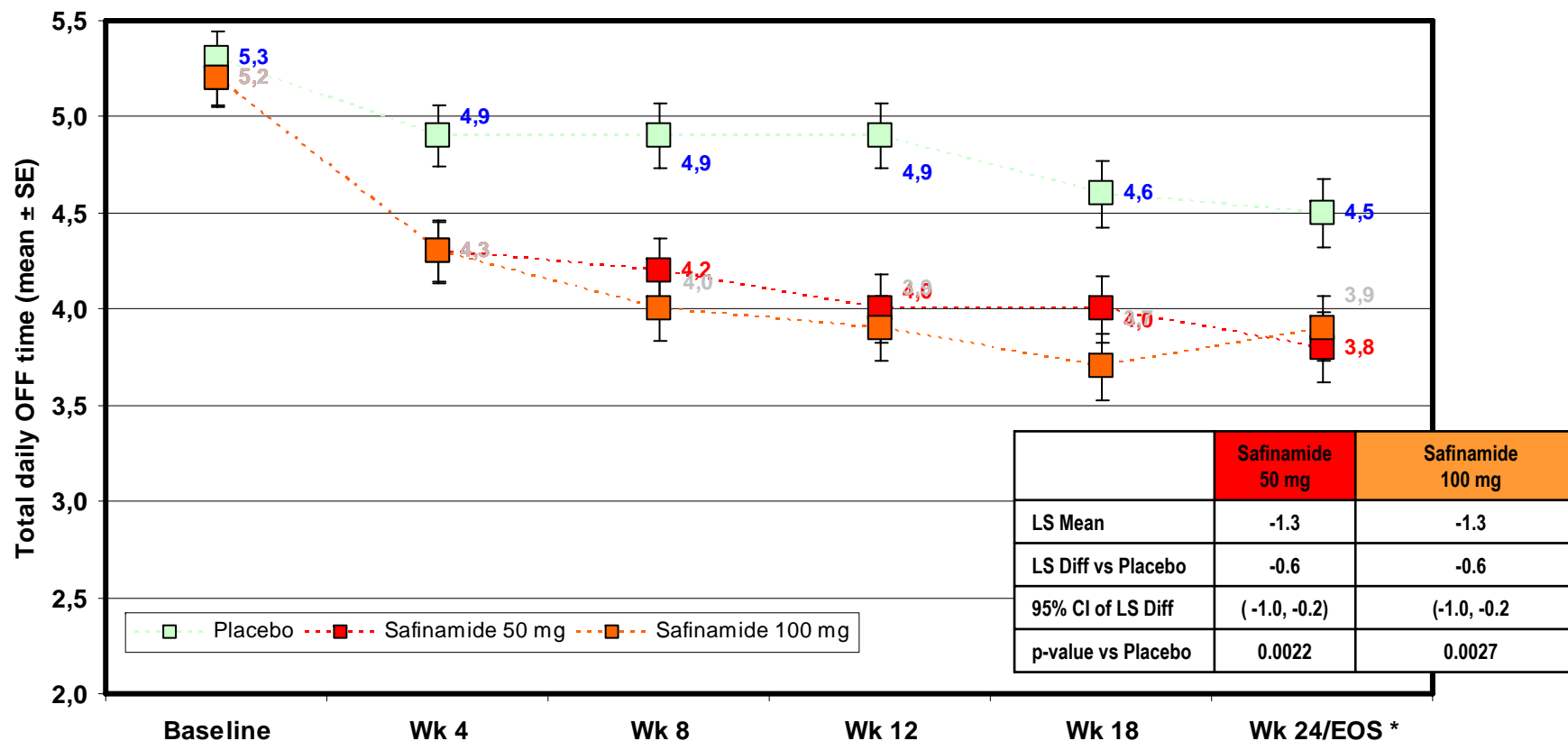


*ON Time = ON time without dyskinesia + ON time with minor dyskinesia

Study 016: Total daily OFF time



Summary of Total Daily 'OFF' Time and Change from Baseline
On Treatment - Repeated Measures
ITT Population



Diary categories



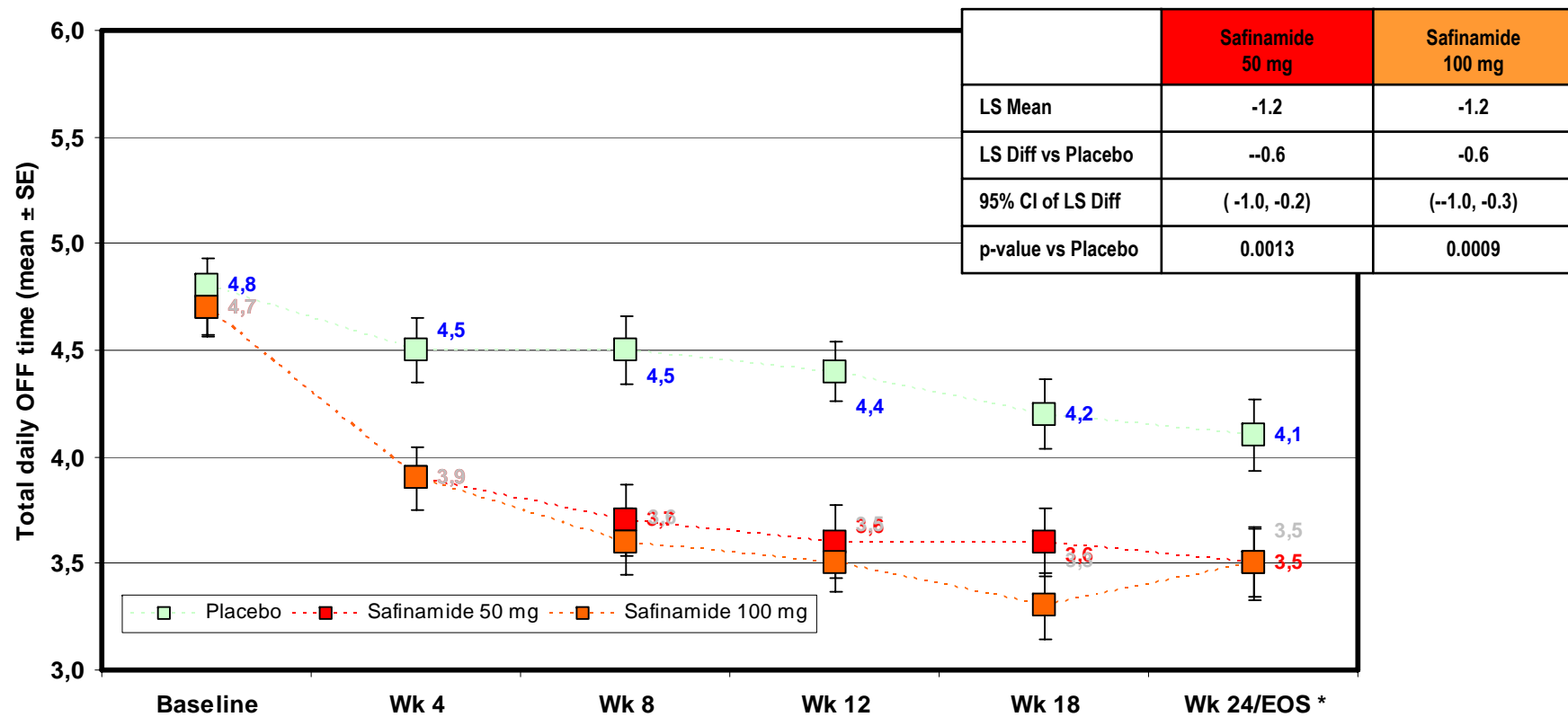
Characteristic recorded	Safinamide 50 mg/day	Safinamide 100 mg/day
'ON' time without dyskinesia LS means difference vs placebo (hours) p-value	0.5 0.0367	0.7 0.0070
'ON' time with minor dyskinesia LS means difference vs placebo (hours) p-value	0.0 0.9196	-0.1 0.5881
'ON' time with troublesome dyskinesia LS means difference vs placebo (hours) p-value	0.1 0.5324	0.0 0.9931
'OFF' time LS means difference vs placebo (hours) p-value	-0.6 0.0022	-0.6 0.0027
Asleep time LS means difference vs placebo (hours) p-value	-0.1 0.5021	0.0 0.6727

LS means and p-values were calculated from an ANCOVA model based on the change from baseline to endpoint, with the baseline value as a covariate.

Study 016 – OFF Time after Morning Dose of Levodopa



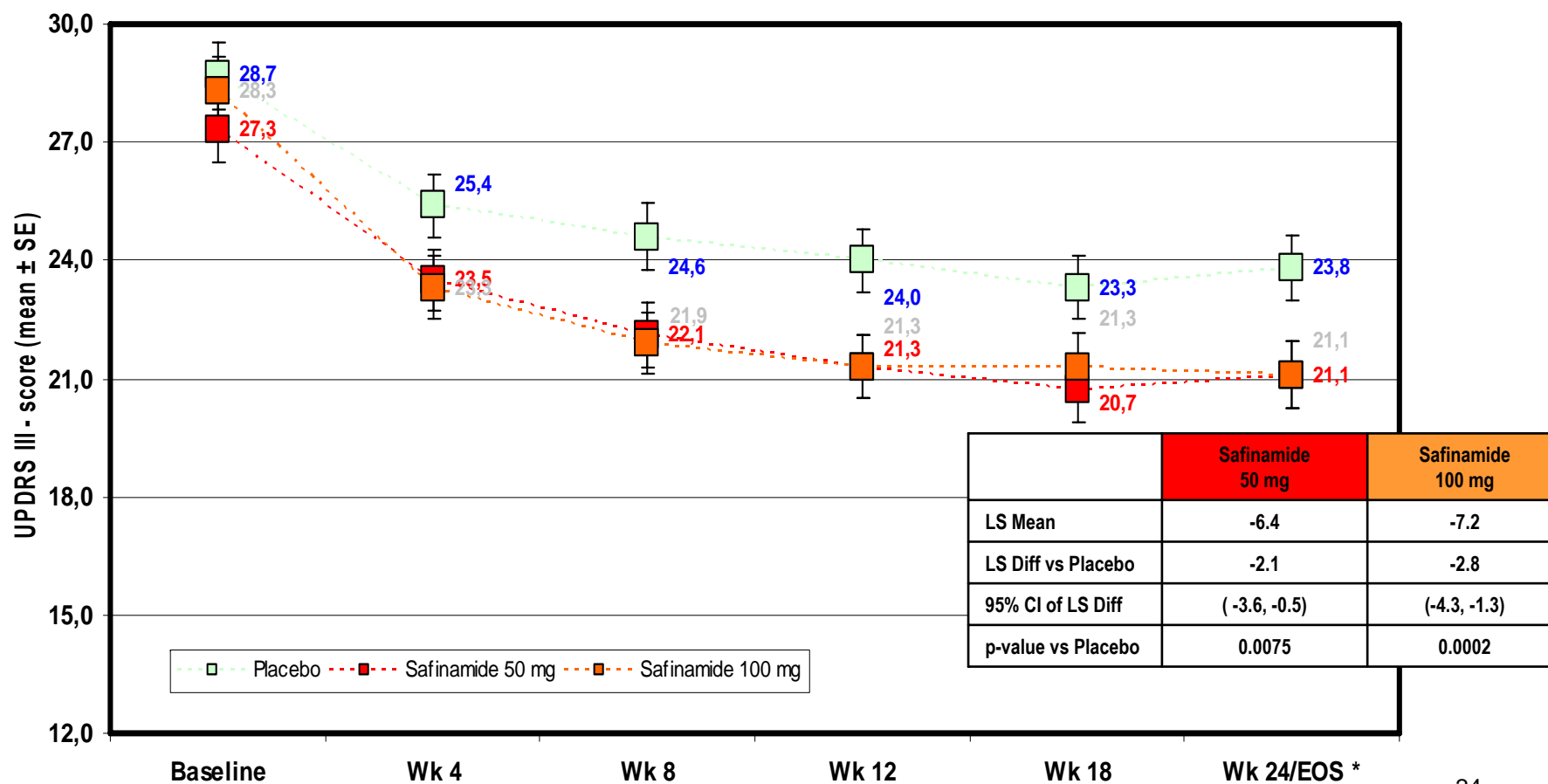
Summary of Change in Mean 'OFF' Time Following the Morning Dose of Levodopa and Change from Baseline
ITT Population



Study 016: UPDRS III during ON phase



UPDRS III - Change from baseline
ITT Population



Study 016: CGI - Change



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
Visit 4 improvement (%)	120 (53.8)	133 (59.4)	96 (43.2)
Endpoint improvement (%)	150 (67.3)	143 (63.8)	122 (55)
P-Value	0.0003	0.0097	

Study 016: CGI - Severity



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
Baseline (SD)	4 (0.7)	3.9 (0.7)	4 (0.7)
Endpoint (SD)	3.5 (0.9)	3.6 (0.9)	3.7 (0.8)
Change from Baseline to Endpoint (SD)	-0.4	-0.4	-0.3
LS Mean (SE)	-0.4	-0.4	-0.2
Treatment Difference (SE)	-0.2	-0.1	
95% CI of Difference	(-0.3, -0.1)	(-0.2, -0.0)	
P-Value vs Placebo	0.0038	0.0219	

Study 016: Dyskinesia Rating Scale (DRS)



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
Baseline (SD)	3.9 (3.9)	3.7 (4.1)	3.4 (3.9)
Endpoint (SD)	3.7 (3.8)	3.5 (3.9)	3.1 (3.6)
Change from Baseline to Endpoint mean	-0.2	-0.3	-0.2
P-Value vs Placebo	0.2992	0.2734	

Study 016: UPDRS II



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
Baseline (SD)	11.8 (5.7)	12.1 (5.8)	12.3 (5.9)
Endpoint (SD)	9.7 (6.0)	9.7 (6.4)	10.7 (6.3)
Change from Baseline to Endpoint (SD)	-2.0	-2.5	-1.5
LS Mean (SE)	-1.8	-2.2	-1.2
Treatment Difference (SE)	-0.6	-1.0	
95% CI of Difference	(-1.4, 0.1)	(-1.7, -0.3)	
P-Value vs Placebo	0.0742	0.006	

Study 016: UPDRS IV Total Score



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
Baseline (SD)	5.6 (2.4)	5.6 (2.7)	5.6 (2.8)
Endpoint (SD)	4.9 (2.6)	4.6 (2.7)	5.3 (3.0)
Change from Baseline to Endpoint (SD)	-0.7	-1.0	-0.4
LS Mean (SE)	-0.5	-0.8	-0.2
Treatment Difference (SE)	-0.4	-0.6	
95% CI of Difference	(-0.7, -0.0)	(-1.0, -0.3)	
P-Value vs Placebo	0.0381	0.0004	

Study 016: GRID-HAMD Total score



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
Baseline (SD)	6.0 (3.7)	6.0 (3.6)	5.9 (3.7)
Endpoint (SD)	5.3 (3.7)	5.0 (3.4)	5.7 (4.2)
Change from Baseline to Endpoint (SD)	-0.7	-0.9	-0.3
LS Mean (SE)	-0.6	-0.1	-0.3
Treatment Difference (SE)	-0.3	-0.7	
95% CI of Difference	(-0.9, 0.2)	(-1.2, -0.1)	
P-Value vs Placebo	0.2367	0.0179	

Study 016: Diary responder rate – Improvement at Endpoint in ON time with No Increase in Troublesome Dyskinesia



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
Improvement in ON time ^a , no. (%)	106 (47.5)	125 (55.8)	88 (39.6)
P-Value	0.0641	<0.0001	
Improvement in ON and OFF time no. (%)	99 (44.4)	117 (52.2)	87 (39.2)
P-Value^b	0.2069	0.0008	
<p>a Increase in ON time with no worsenig of either troublesome dyskinesia or OFF time b Increase in ON time and decrease in OFF time with no worsening of troublesome dyskinesia</p>			

Study 016: UPDRS III Responder Rate



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
> 20% Improvement no. (%)	109 (48.9)	111 (49.6)	91 (41.0)
P-Value	0.0239	0.03	
> 30% Improvement no. (%)	84 (37.7)	92 (41.1)	70 (31.5)
P-Value	0.0698	0.0095	

Study 016: Responder Rate Based on Diary^{\$} and UPDRS III Improvement



	Safinamide		Placebo
	50 mg/day	100 mg/day	
n	223	224	222
≥ 20% Improvement on UPDRS III	75 (33.63%)	77 (34.38%)	50 (22.52%)
P-Value	0.0019	0.0008	
≥ 30% Improvement on UPDRS III	60 (26.91%)	66(29.46%)	42 (18.92%)
P-Value	0.0177	0.0016	
^{\$} Increase of 'ON' Time ≥ 30 Minutes and decrease of 'OFF' Time ≥ 30 Minutes			

Study 016 Conclusions



CONCLUSIONS

- When used as add-on to stable L-dopa therapy for 24 weeks in patients with mid- to late-stage PD, safinamide 50 and 100 mg/day:
 - significantly increased total daily 'ON' time without increasing troublesome dyskinesia, indicating that safinamide improved motor fluctuations
 - significantly reduced 'OFF' time after the first morning L-dopa dose, total daily 'OFF' time, UPDRS III score during 'ON' phase, UPDRS IV scores and CGI 'Change' and 'Severity of Illness' scores
 - the clinical significance of changes associated with safinamide was reflected in the responder analysis.
 - Safinamide 100 mg/day also significantly improved activities of daily living and may also reduce depressive symptoms associated with PD.
 - Safinamide treatment was well tolerated in this study; no systematic differences were observed between the groups in the incidence of withdrawals, serious AEs or clinically notable AEs, indicative of a good safety profile for safinamide.
-
- This study had a high completion rate (89%); and of 669 patients enrolled, 544 (81%) continued into the 18-month extension study assessing dyskinesia as the primary endpoint