Newron Pharmaceuticals S.p.A.

Investor and analyst call

Safinamide

Study 018 Top-Line Results

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Moderators:
Luca Benatti, CEO
Ravi Anand, CMO

European dial-in:	+39 02 805 8811
UK dial-in:	+44 20 3147 4796
USA toll free number:	+1 866 63 203 28

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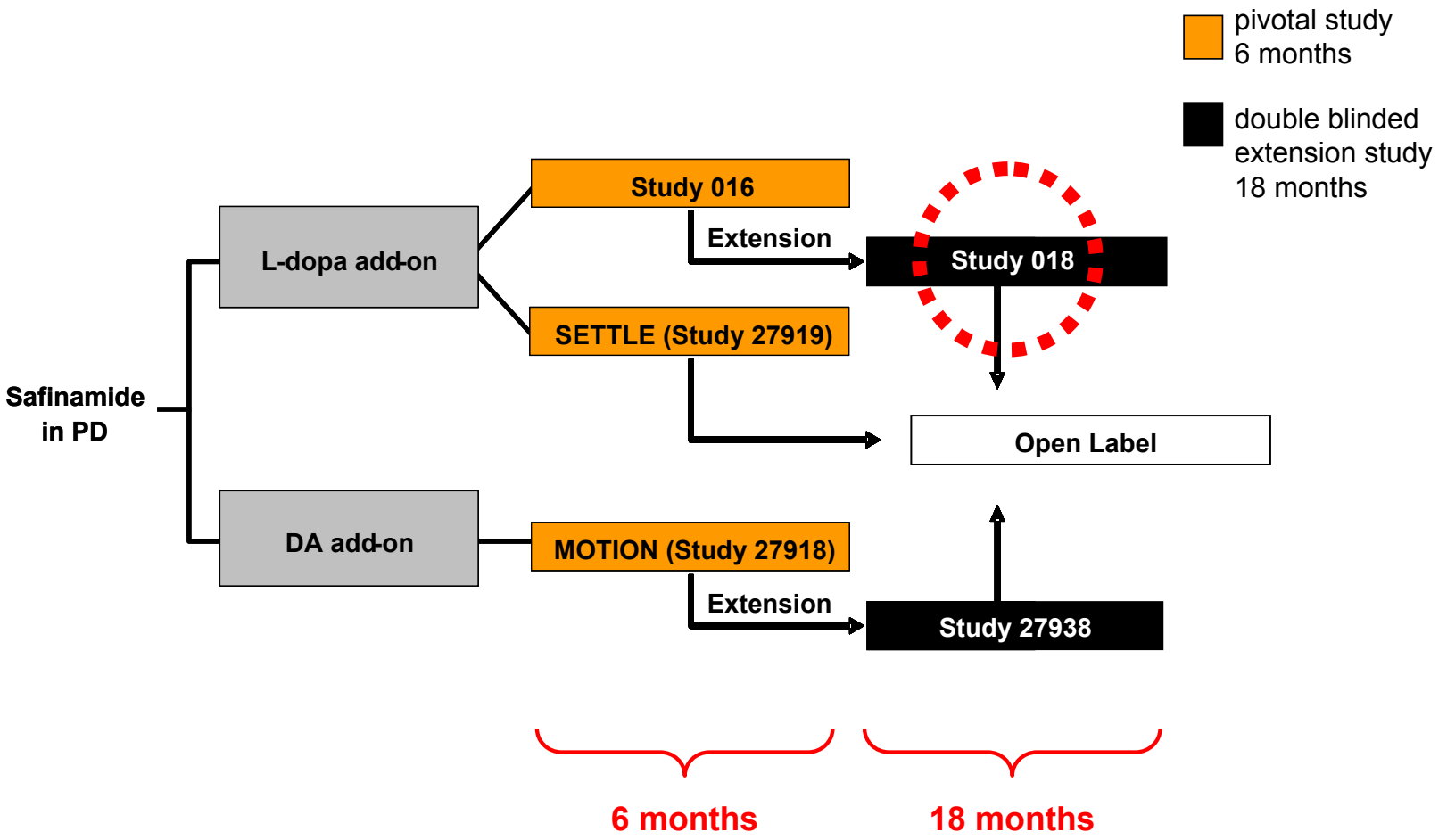
Safinamide Parkinson's disease - add-on program ongoing



Study 016 - Key inclusion criteria

- Male or female, aged 30-80 years
- Diagnosis of idiopathic Parkinson's Disease of > 3 yrs
- 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
- 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 - Baseline subject demographics and disease characteristics

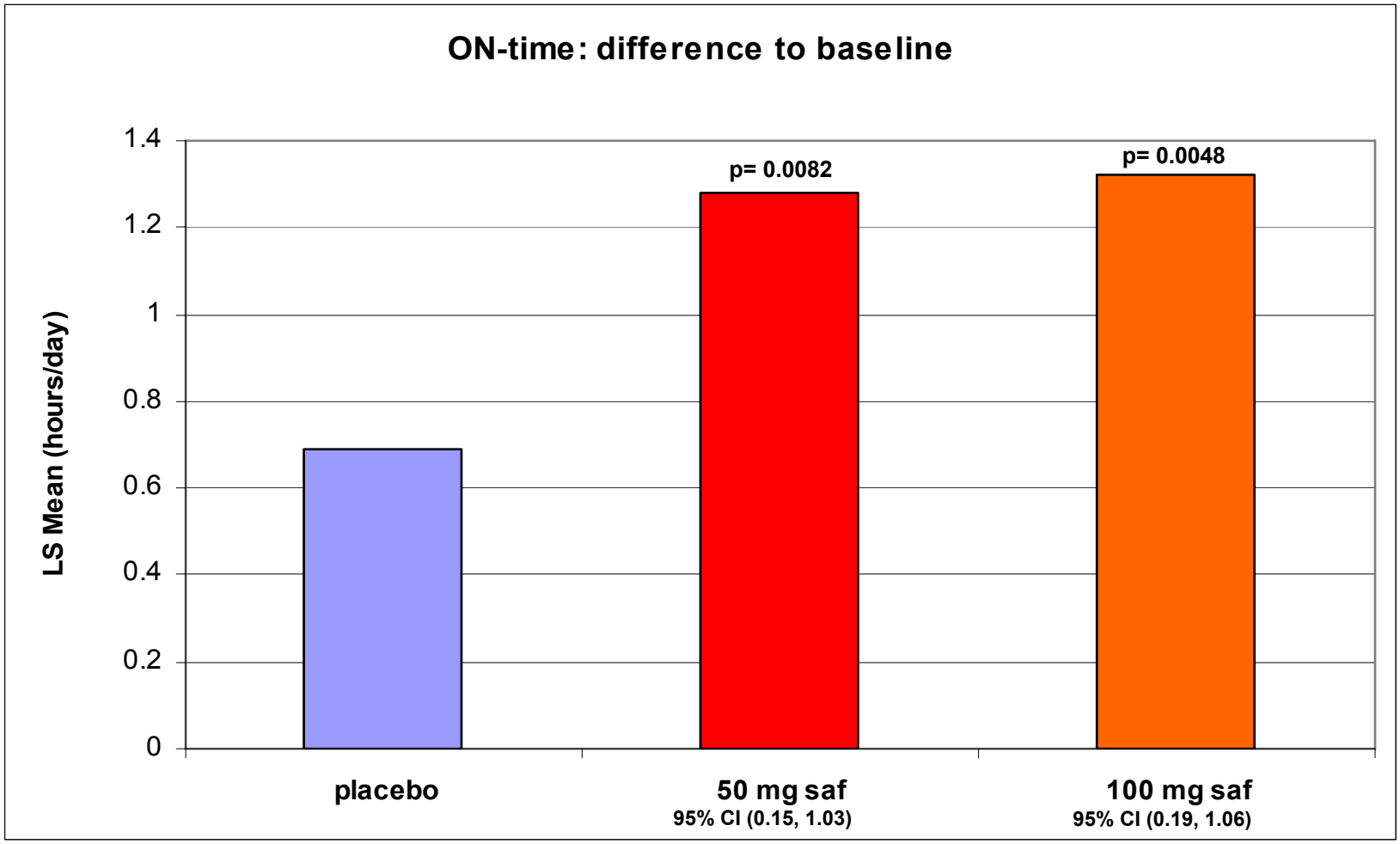
	Placebo (n=222)	Safinamide 50 mg/day (n=223)	Safinamide 100 mg/day (n=224)
Mean age (years) (SD)	59.4 (9.41)	60.1 (9.67)	60.1 (9.19)
Gender Male (%)	72.1%	70.4%	72.8%
Race Asian White	 180 (81.1%) 42 (18.9%)	 180 (80.7%) 43 (19.3%)	 179 (79.9%) 45 (20.1%)
At least one concomitant medical condition/illness	165 (74.3%)	178 (79.8%)	175 (78.1%)

Study 016 – Parkinson's disease 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)
% of patients with Troublesome Dyskinesia (≥ 30 mins)	32.8 %	32.3 %	29.5 %
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%)

Study 016 primary endpoint met : ON Time

Study qualified pivotal study



p-values were calculated using a mixed linear model based on the change from baseline with baseline as covariate

Study 018 objective:

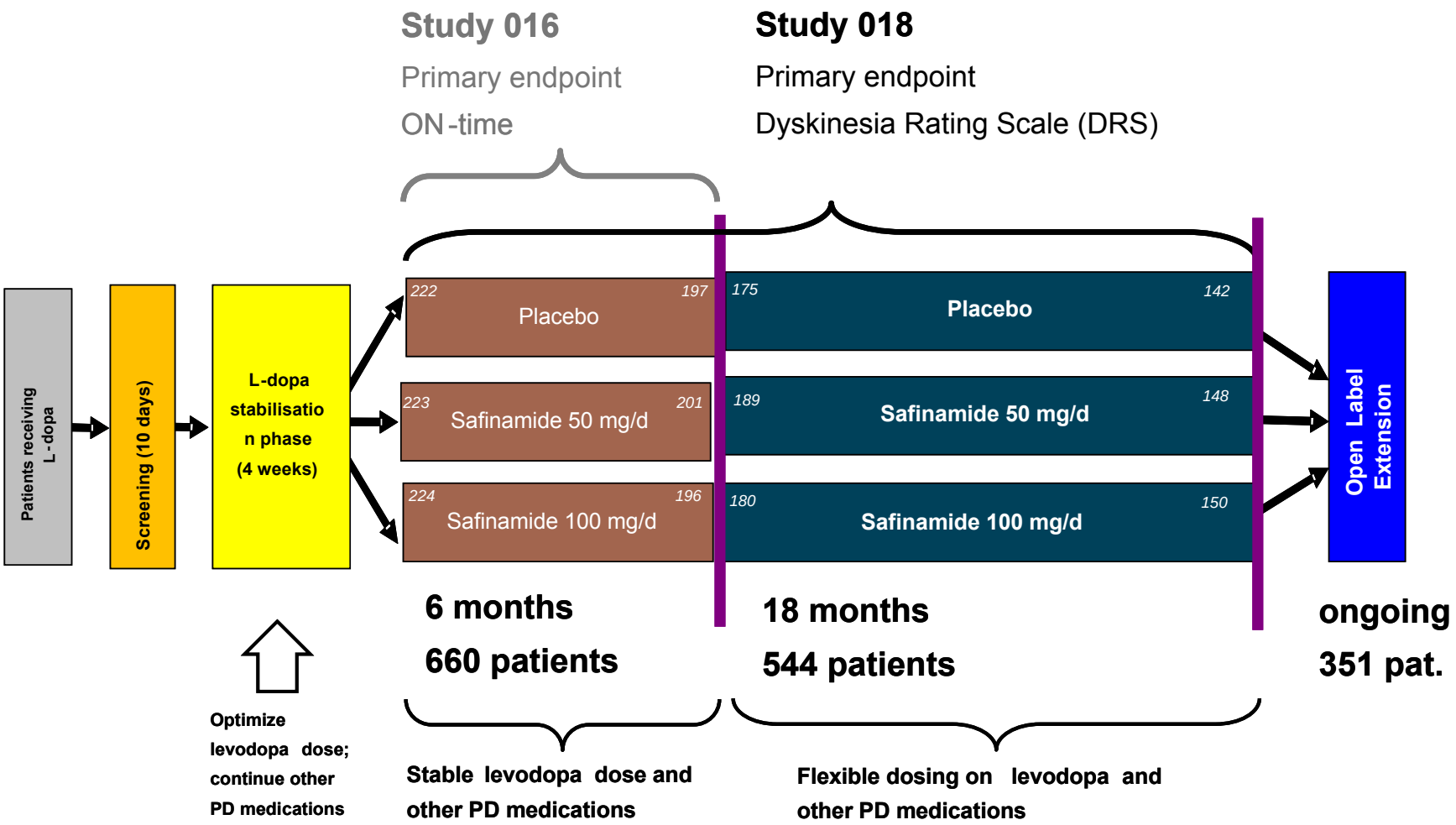
Long-term safety and efficacy for mid-to-late stage Parkinson's disease

- A double-blind, placebo controlled 18 months extension study of phase 3 pivotal study 016 (study 018 is not a pivotal study)

- To assess 2 year safety and efficacy of 50 and 100 mg safinamide/day as add-on therapy to stable L-dopa in PD patients with motor fluctuations

Study design 016 and 018

Double-blind, placebo controlled study through 2 years



Study 018 - Secondary endpoints

- Change in “On-time” (ON + ON with minor dyskinesia) from baseline of study 016
- Change in individual diary categories compared to baseline of study 016
  - Improvement in ON time + ON time with minor dyskinesia with no increase in troublesome dyskinesia with respect to the 016 baseline
  - Lack of worsening (≤ 30 mins) in ON time + ON time with minor dyskinesia with no increase in troublesome dyskinesia with respect to the 016 baseline
- Diary responder rate at 12-, 18-, and 24-months on the ITT and mITT, and on those who completed 24 months treatment period)
- UPDRS part IV (total and dyskinesia sub-items 32-35 and 32-24)
- Time to develop troublesome dyskinesia (≥ 30 minutes increase compared to baseline)
- Time to develop any (minor + troublesome) dyskinesia (≥ 30 minutes increase compared to baseline)
- Change in ADLs during ON-time (UPDRS part II) compared to placebo
- Maintenance of effects in UPDRS part II responders (≥ 20% improvement from baseline to 016 endpoint)
- Percentage of change in L-dopa dose
- Percentage of change in any anti-PD dose
- Change in motor symptoms (UPDRS part III)
- CGI – change from baseline – mean score in the course of the study
- CGI – severity of illness – mean change from baseline to endpoint

Study 016/018 – Parkinson's disease 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)
% of patients with Troublesome Dyskinesia (≥ 30 mins)	32.8 %	32.3 %	29.5 %
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Levodopa	222 (100.0%)	223 (100.0%)	224 (100.0%)
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Stalevo	33 (14.9%)	30 (13.5%)	36 (16.1%)
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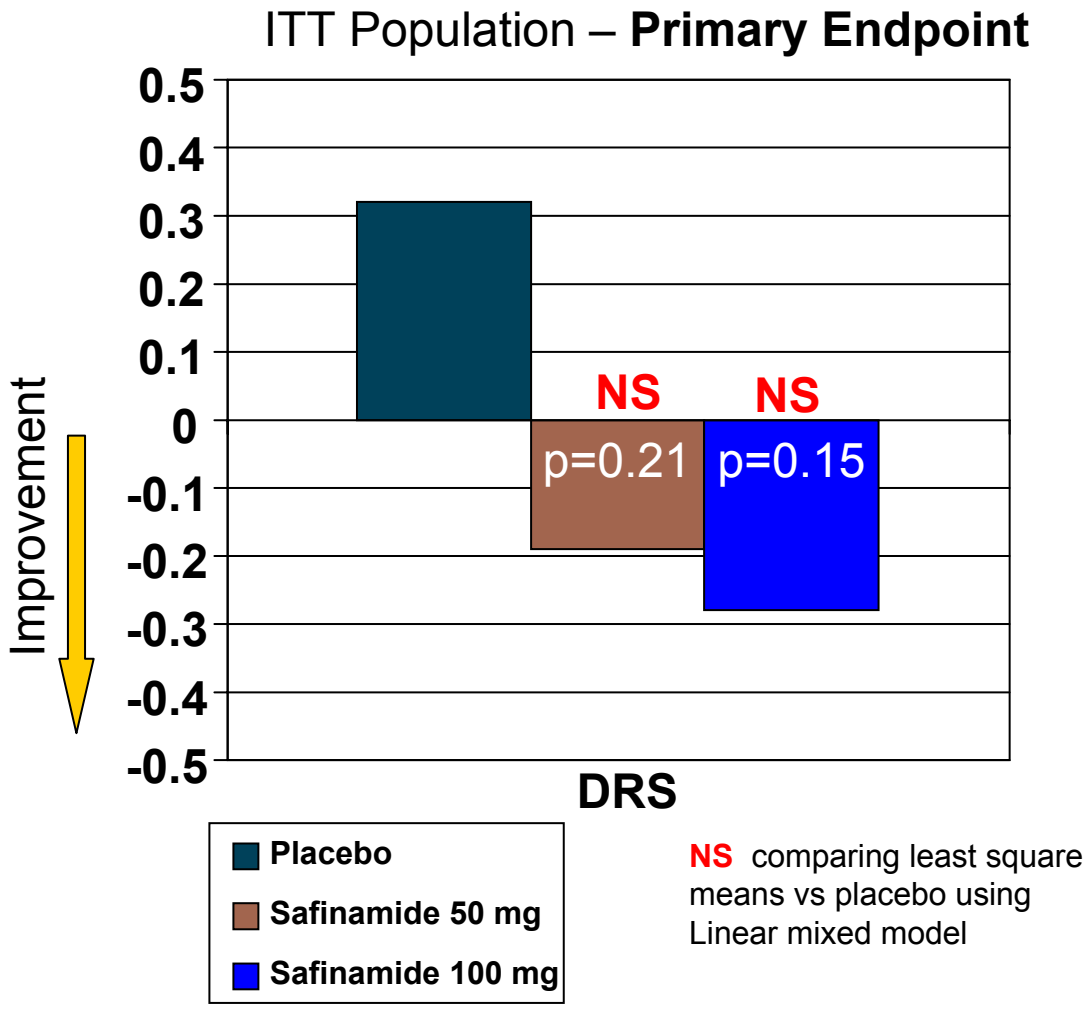
Source reference: Tables 30.1 - 33 -25.3 - 12.2

Dyskinesia Rating Scale (DRS)

Primary endpoint not met - Sub-sequential pre-specified endpoints considered as exploratory

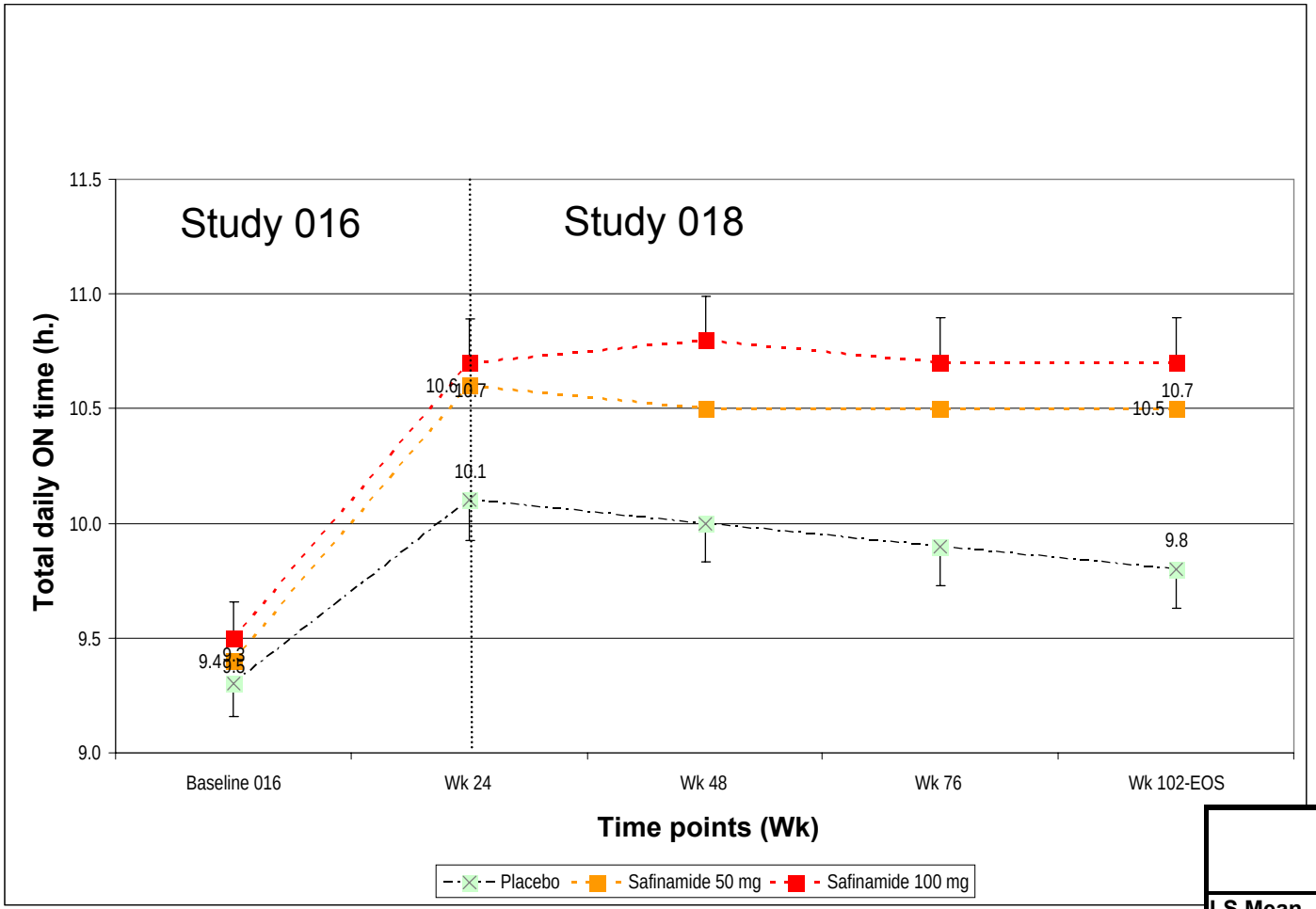
After 24 months, non-statistically significant mean improvements of 0.19 and 0.28 in the DRS score were observed in patients who received safinamide 50 mg and 100 mg respectively, versus a worsening of 0.32 for the placebo group (respectively p=0.21 and p=0.15 versus placebo)



Main secondary endpoint: ON time

(primary endpoint 016)

Maintained clinical effect over 2 years (exploratory analysis)



	Safinamide 50 mg/day	Safinamide 100 mg/day
LS Mean	1.01	1.18
LS Diff vs Placebo	0.67	0.83
95% CI of LS Diff	(0.23,1.11)	(0.39,1.27)
p-value vs Placebo	0.0031	0.0002

Additional secondary endpoints

- Significant benefit of the 100 mg/day dose on:
  - Activities of daily living (UPDRS II)
  - Motor symptoms (UPDRS III)
  - Complications of dopaminergic treatment (UPDRS IV)
  - Symptoms of depression (GRID HAMD)
  - Quality of life (PDQ-39)

  at the two year-endpoint

➢ Full study results will be submitted for presentation at upcoming scientific meetings

Study 018 supports safety profile of safinamide on long-term

Adverse Events

- Serious adverse events, clinically notable events among both treatment groups in the study (50 mg and 100 mg/d) were comparable with those in the placebo group

Drop Outs

- There were approx. 80% completers across the 3 groups

Prospect

- These long-term treatment results are encouraging because they support the safety profile of safinamide and results of an exploratory analysis of its effect on motor function were consistent with the effect observed in the six-month study in this advanced Parkinson's disease population
- These results may offer new hope to patients with Parkinson's disease as they need to take medications for long periods of time
- The effect of safinamide on dyskinesia will be further explored in an ongoing dedicated pilot study