Newron Pharmaceuticals S.p.A.

Investor and analyst call

Safinamide phase III results

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Add-on to levodopa in mid-to-late stage PD Study 016 – **EXECUTIVE SUMMARY**

- First Phase III study of safinamide as add-on to levodopa demonstrates statistically significant and clinically relevant efficacy of both 50 mg/day and 100 mg/day of safinamide
  - Primary efficacy endpoint met: safinamide significantly improved motor symptoms by increasing “ON” time
  - Secondary efficacy endpoints analyzed to date met:
    - Decrease in daily “OFF” time
    - Decrease in mean “OFF” time following first morning dose of levodopa
    - Mean change from baseline UPDRS Section III (motor) score during “ON” time
    - Mean change in Clinical Global Impression of severity of disease
    - Change in Clinical Global Impression from baseline
- Study had high completion rate (approx 89%)
  - Incidence of dropouts, serious adverse events or clinically notable events comparable among the three groups of the study
  - High rate (over 90%) of roll-over into extension study
- Full study results will be submitted for presentation at upcoming scientific meetings after completion of ongoing analyses

Safinamide background

- 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

Parkinson's disease treatment strategies: potential options with safinamide as add-on

Current PD treatment paradigm

Dopamine agonist

- Efficacy decreases over time, significant side-effects

Levodopa + adjunct

- Associated with dyskinesia and other major side effects

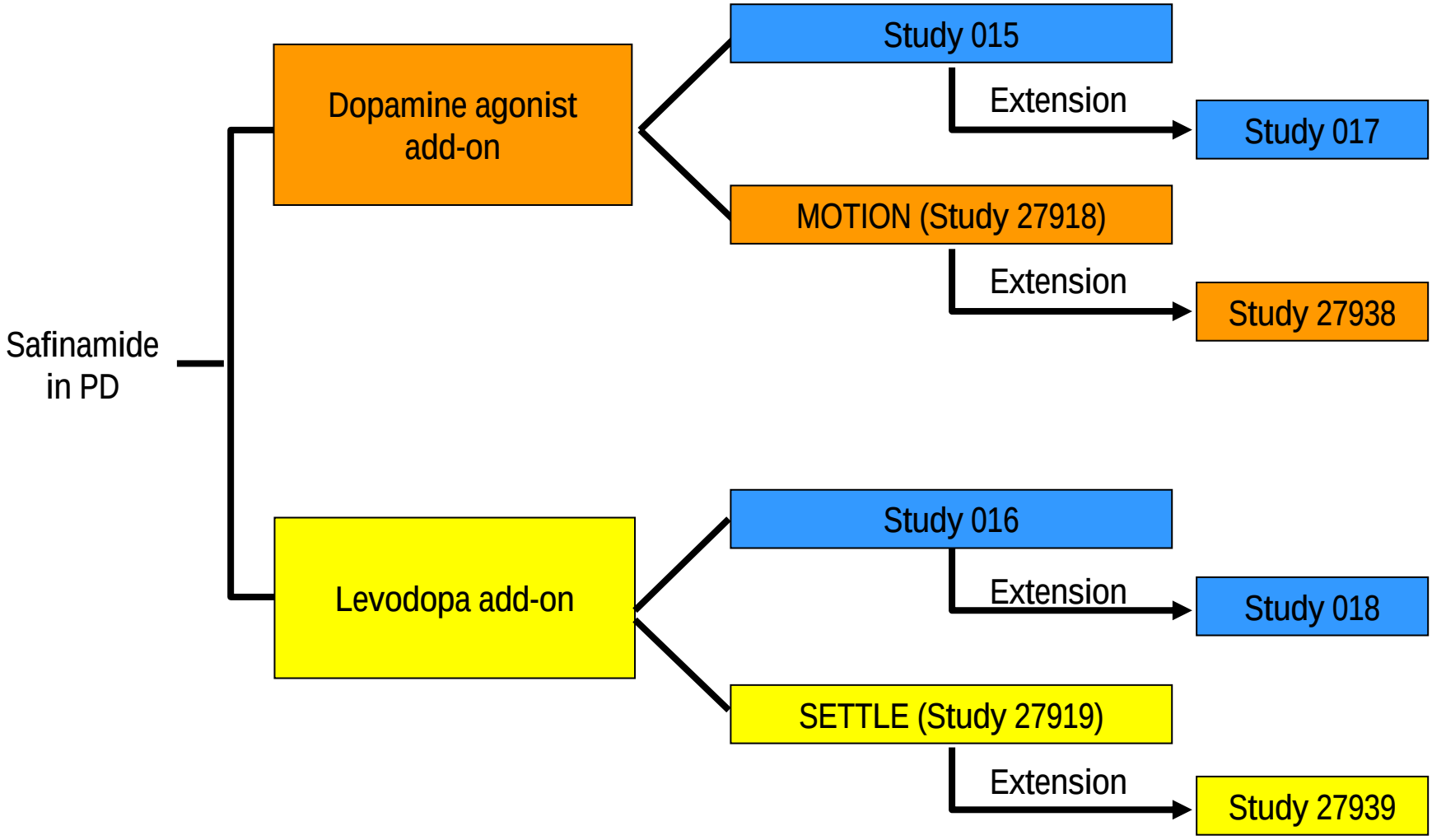
+ safinamide

Potential to enhance existing treatment paradigm

- **Enhances dopamine agonist effects**
- **Improves "ON" time, reduces "OFF" time**
- **Delays levodopa use**
- **Potential to improve cognition**

Safinamide could be the first add-on treatment for both dopamine agonists and levodopa

Safinamide Clinical Development Plan



Previous clinical results

- Phase II placebo-controlled study in early PD patients on DA:
  - Statistically significant and clinically relevant superiority at a daily dose of 1 mg/kg (~85 mg) of safinamide on motor symptoms (UPDRS III)

- First phase III trial (270 patients) confirmed positive phase II results:
  - Safinamide 50 to 100mg/day added to patients who are still benefiting from dopamine agonist treatment showed:

<u>at 6 months</u>

  - Statistically significant, clinically relevant improvement in motor symptoms (UPDRS III)
  - Statistically significant improvement in activities of daily living (UPDRS II) and quality of life (EUROQOL)

<u>at 18 months</u>

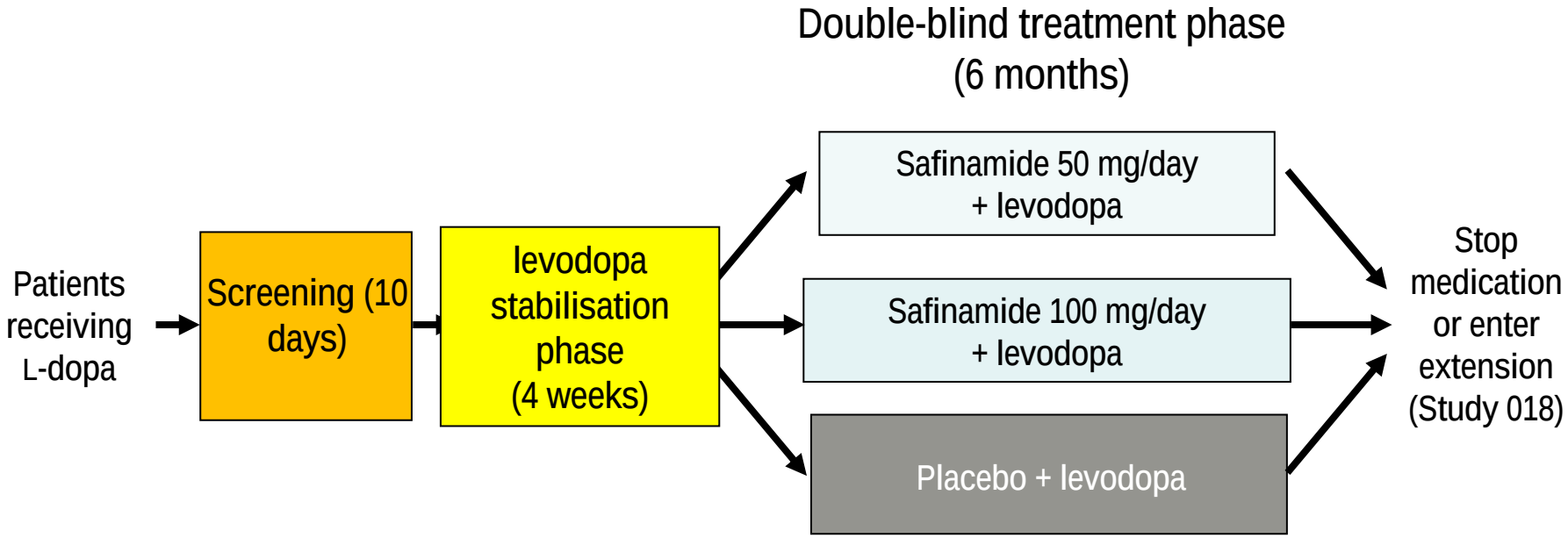
  - Side effects, ECG changes and vital signs abnormalities reported with similar frequency in patients receiving safinamide and in placebo group
  - Statistically significant improvement in motor symptoms (UPDRS III) and quality of life (EUROQOL)
  - Potential to reduce the number of patients experiencing interventions

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).

Add-on to L-dopa in mid-to-late stage PD
Study 016 – Efficacy variables

Primary efficacy variable

- Increase in mean daily “ON” time (“ON” time without dyskinesia plus “ON” time with minor dyskinesia)

Secondary efficacy variables analyzed to date

- Decrease in total daily “OFF” time
- Decrease in mean “OFF” time following first morning dose of levodopa
- UPDRS Section III during “on” phase
- CGI - Severity of illness
- CGI - Change from baseline

Full study results (incl. further secondary and tertiary endpoints) will be submitted for presentation at upcoming scientific meetings after completion of ongoing analyses

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

Full study results will be submitted for presentation at upcoming scientific meetings after completion of ongoing analyses

Add-on to L-dopa in mid-to-late stage PD Study 016 – Inclusion criteria

Patients met the following criteria:

- Male or female, aged 30-80 years
- Diagnosis of idiopathic PD of > 3 yrs, based on medical history and neurological examination
- 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 (CR, IR or CR/IR combination) 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 hrs “OFF” time during day
- Ability to maintain diary (18-hr) with help of caregiver
- Willing and able to provide informed consent in writing

Add-on to L-dopa in mid-to-late stage PD
Study 016 – Exclusion criteria

Related to Parkinson's disease:

- Forms of Parkinsonism other than idiopathic Parkinson's disease
- Late stage PD with severe, disabling peak-dose or biphasic dyskinesias or wide/unpredictable fluctuations
- Stereotactic surgery to treat PD
- Treatment of PD symptoms with a MAO inhibitor

  COMT inhibitors DA agonists and/or anticholinergics, amantadine will be permitted if at a stable dose at Screening
- History of allergic response to anticonvulsants, levodopa, or other anti-Parkinsonian agents

Cardiovascular:

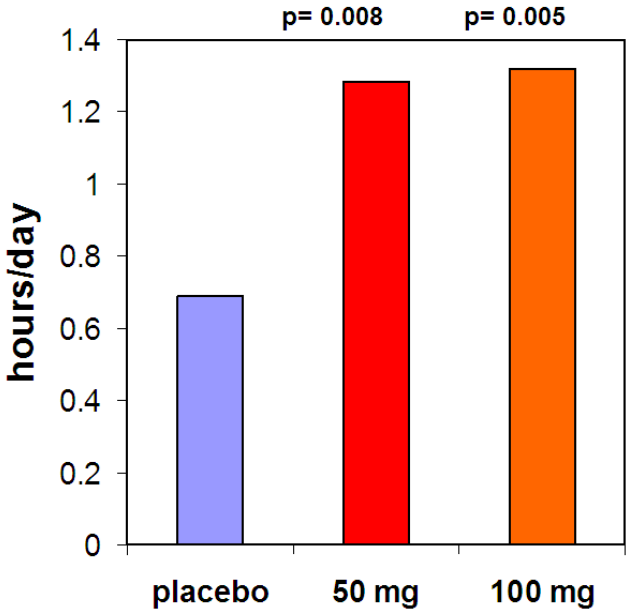
- II/III degree AV block, sick-sinus syndrome, uncontrolled atrial fibrillation, severe/unstable angina, congestive heart failure, myocardial infarction within 3 months, or significant ECG abnormality
- QTc interval ≥ 450 msec (males) or ≥ 470 msec (females), using Bazett's formula
- Severe dizziness or fainting on standing due to postural hypotension

Add-on to L-dopa in mid-to-late stage PD
Study 016 – Topline Results

Add-on to L-dopa in mid-to-late stage PD
Study 016 – Efficacy endpoints

Primary endpoint met

Total Daily "ON" Time
- Average increase vs baseline



Secondary efficacy endpoints analyzed to date also met (statistically significant improvement compared to placebo)

- Total Daily "OFF" Time
- OFF Time After Morning Dose of Levodopa
- UPDRS Part III (motor) "ON"
- Clinical Global Impression – Severity
- Clinical Global Impression – Change

Full study results will be submitted for presentation at upcoming scientific meetings after completion of ongoing analyses

Add-on to L-dopa in mid-to-late stage PD
Study 016 – Safety

- High completion rate
  - 89% of patients treated with safinamide completed the study
    - 91% in the 50 mg dose group
    - 87% in the 100 mg dose group
  - 89% of patients who received placebo completed the study

- Incidence of dropouts, serious adverse events or clinically notable events comparable among the three groups of the study

Add-on to L-dopa in mid-to-late stage PD
Study 016 – Topline results - Conclusions

- First Phase III study of safinamide as add-on to levodopa demonstrates statistically significant and clinically relevant efficacy of both 50 mg/day and 100 mg/day of safinamide
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  - High rate (over 90%) of roll-over into extension study
- Full study results will be submitted for presentation at upcoming scientific meetings after completion of ongoing analyses
- Newron and Merck Serono are completing the development program towards the registration of safinamide in PD