The BeyoND study: Design and baseline characteristics of an international, multicentre study evaluating the long-term safety of ND0612 for Parkinson's disease

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Speaker disclosures

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ND0612 infusion in Parkinson's disease patients with motor fluctuations

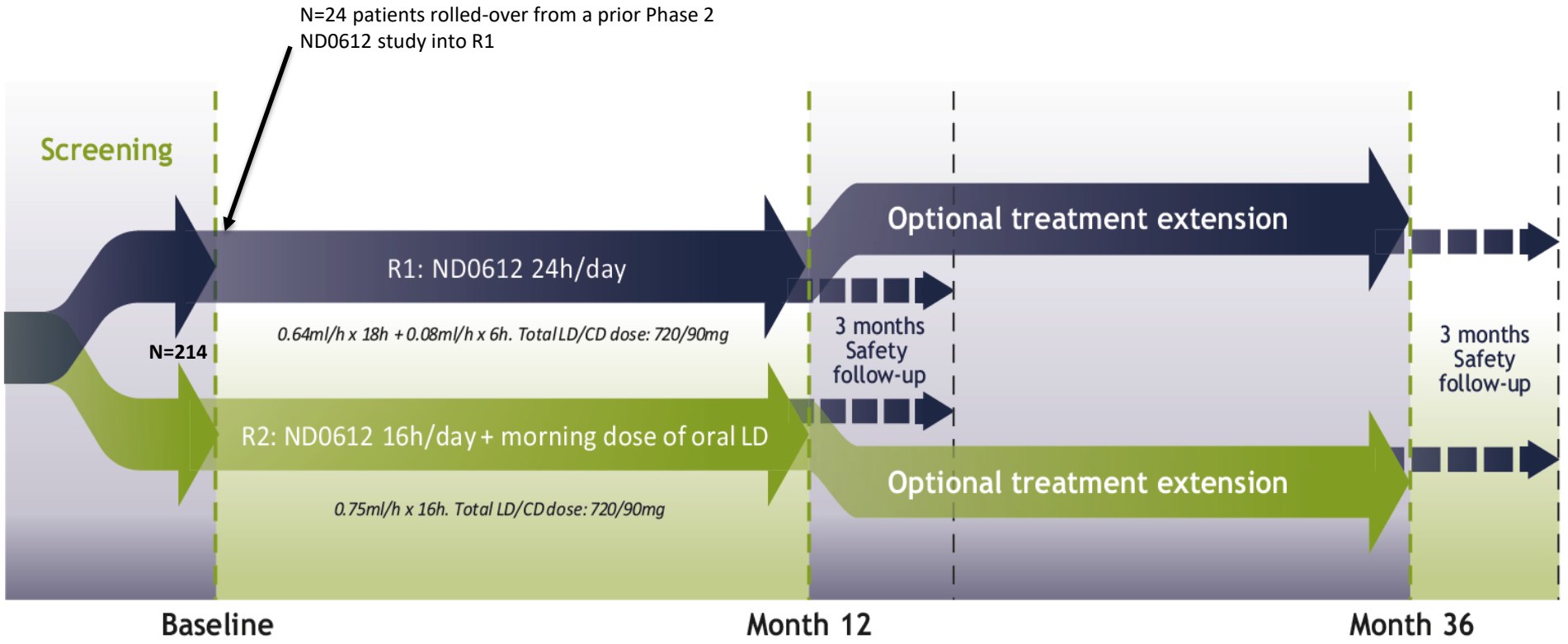
Background

- Continuous LD/CD infusion is considered the optimal delivery route for treating advanced motor fluctuations because it avoids the peaks and troughs associated with oral dosing
  - Utility of infusion strategies has thus far been limited by the need for invasive surgery
- ND0612 is a drug-device combination that ***continuously*** delivers ***liquid LD/CD subcutaneously*** through a pump system
- Phase II clinical studies in PD patients with motor fluctuations have shown a ***clinically meaningful and statistically significant reduction in OFF time*** without an increase in troublesome dyskinesia

The aim of this Phase 2b/3 study is to assess the long-term safety (systemic and local) and tolerability of continuous subcutaneous infusion of ND0612

Olanow et al. 2017 Late-breaking poster at MDS, Hauser et al. 2014 doi: 10.1155/2014/467131

ND0612 BeyoND Study: *Design*



ND0612 BeyoND Study: *Inclusion/exclusion criteria**

Key inclusion criteria	Key exclusion criteria
PD patients aged 30-85 years old	Previously unable to tolerate ND0612, regardless of the dosing regimen administered (previously treated patients only)
Modified Hoehn & Yahr scale ≤3 during ON	Atypical or secondary parkinsonism.
≥2 hours of OFF time per day with predictable early morning OFF periods	Acute psychosis or hallucinations in past 6 months
Taking ≥4 levodopa doses/day (≥3 doses/day of Rytary)	Any relevant medical, surgical, or psychiatric condition
Taking, or have attempted to take, ≥1 other PD treatment for ≥30 days in the previous year	Prior neurosurgical procedure for PD or LCIG treatment
	Clinically significant ECG rhythm abnormalities

**Rollover patients met these criteria at the start of the prior ND0612 study*

ND0612 BeyoND Study*: Assessments*

Safety and tolerability	Efficacy (exploratory outcomes)
AE reporting	Daily OFF time based on home diaries
Local skin safety at infusion site	Good ON time (no or non-troublesome dyskinesia)
Tolerability: - % patients completing 12 months of treatment - % patients discontinuing from the 12-month treatment period due to an AE	Total daily dose of oral levodopa therapy
	UPDRS ADL and motor scores
	PDQ-39
	CGI for severity and improvement
Vital signs, physical and neurological examination	Parkinson's disease sleep scale (PDSS)

ND0612 BeyoND Study: *Baseline characteristics*

Characteristic	(N=209)
Percent male	66%
Age (years); mean ±SD	64. 1 ± 8.76
Time from diagnosis (years); mean ±SD	9.02 ± 4.70
Time with motor fluctuations (years); mean ±SD	5.23 ± 4.20
Duration of daily OFF time (hours); mean ±SD	5.47 ± 2.72
UPDRS motor score; mean ±SD	27.4± 12.5
MMSE score; mean ±SD	28.8 ± 1.2
Levodopa dose (mg); mean ±SD	1060 ± 665
N (%) patients taking ≥900mg LD/day	109 (52.2%)
Use of COMT inhibitor; N (%)	54 (25.8)

ND0612 BeyoND Study: *Take Home Messages*

- The BeyoND Study is the first study to evaluate the long-term safety of high dose ND0612
- The demographics in the study are typical to those with Parkinson's disease experiencing motor fluctuations despite optimal use of oral therapies
- Recruitment is complete and the trial is ongoing. Twelve-month data are expected by December 2019.
- A phase 3 double-blind, double-dummy pivotal efficacy trial (BouNDless) is currently being initiated to evaluate ND0612 in a similar population