

**Pharmacokinetic and safety characterisation of  
levodopa/carbidopa subcutaneous infusion (ND0612):  
Phase I studies in healthy volunteers and  
patients with fluctuating Parkinson's disease**

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# ND0612 Introduction

## Background

- Continuous LD/CD administration is considered the optimal delivery route for treating PD patients with motor fluctuations because it avoids the fluctuations in levodopa levels that are associated with oral delivery
- ND0612 is a proprietary drug-device combination delivering *liquid LD/CD* via *continuous subcutaneous* infusion

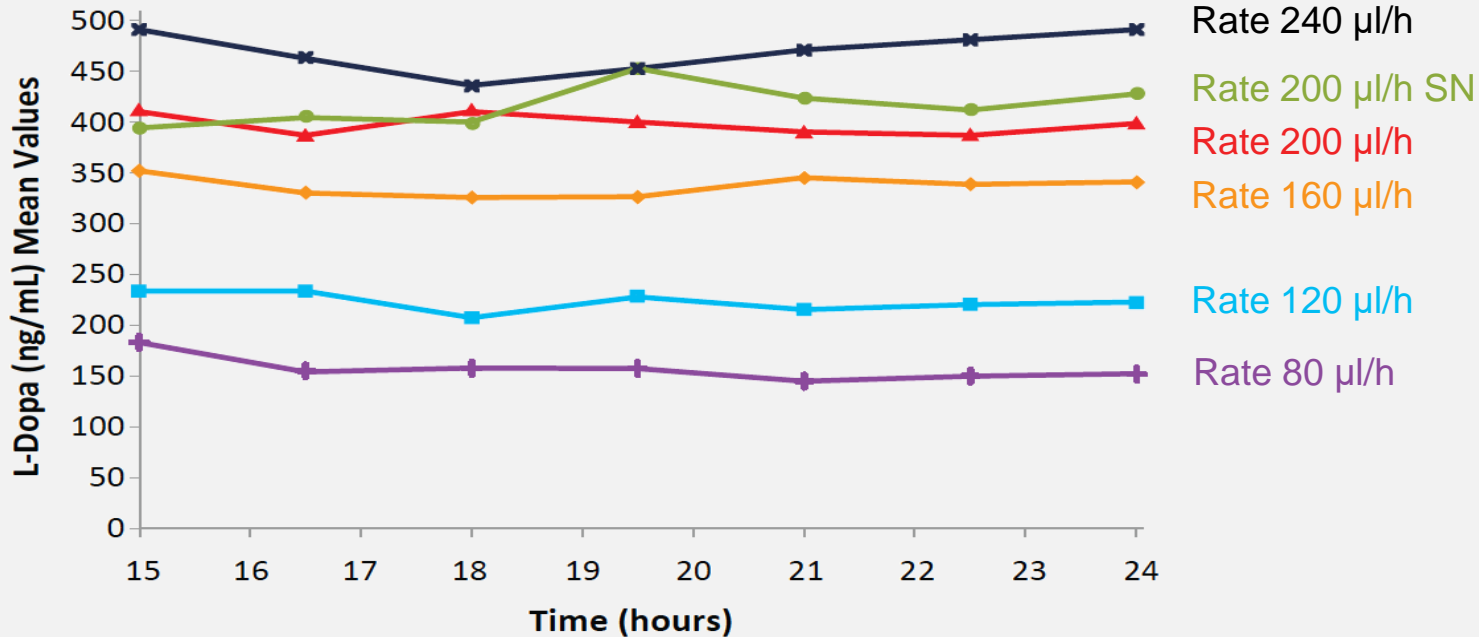


## *Phase I studies*

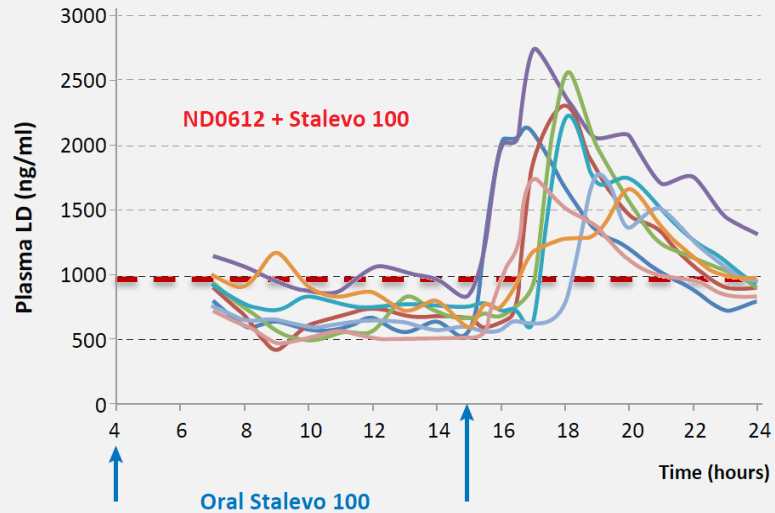
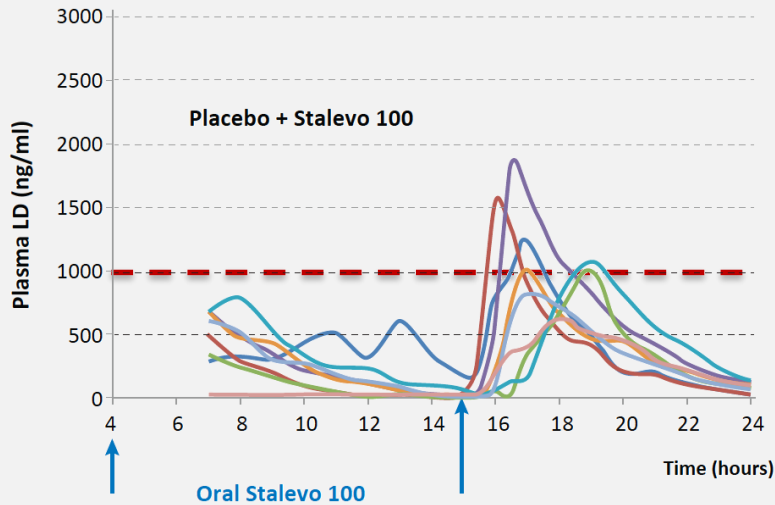
- **Study 001:** Healthy volunteers (N=54), escalating doses
- **Study 002:** PD patients with motor fluctuations (N=8), given as add on to Stalevo 100 (BID)
- Both studies assessed steady state plasma concentrations of LD and CD following continuous subcutaneous delivery of ND0612 (low doses)
- Systemic and local skin safety was evaluated

# ND0612 Study 001: Results

***Stable levels and dose proportionality of LD were demonstrated***



# ND0612 Study 002: Results



- With the addition of a single dose of oral Stalevo 100 to ND0612 infusion, relevant LD plasma concentrations of  $\geq 1000$  ng/mL are achievable for a clinically meaningful period of time
- Stable, clinically relevant LD levels, for longer duration

Treatment	Peak to trough ratio
Stalevo 100 <sup>®</sup>	22
ND0612	1.1
Stalevo 100 <sup>®</sup> + ND0612	2.3

x10

## ND0612 Studies 001 & 002: *Safety Results*

### **Both studies:**

- No significant systemic AE
- No clinically relevant effects on lab measurements or vital signs
- Small, transient nodules could be felt in some subjects following deep palpation of infusion sites

## ND0612 studies 001 & 002: *Take Home Messages*

- Continuous, subcutaneous delivery of ND0612 is a practical way for maintaining therapeutic LD plasma concentrations, with less fluctuations in LD plasma concentrations
  - Relevant LD plasma concentrations were achievable for a clinically meaningful period of time with addition of oral Stalevo 100 to ND0612 low dose infusion
  - ND0612 was generally well-tolerated
- ND0612 has now entered Phase III development for PD patients with motor fluctuations