BouNDless: An active-controlled randomized, double-blind double-dummy study of continuous ND0612 infusion in patients with fluctuating Parkinson’s disease

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Study medication

In the IR LD/CD Regimen Optimization Period, patients’ current oral levodopa formulations (including COMT inhibitors) are converted to supplied IR LD/CD followed by dose adjustment to minimize motor complications.

In the ND0612 Regimen Optimization Period, all patients are converted to ND0612 and doses of oral IR LD/CD, if necessary, adjusted to minimize motor complications.

- ND0612 is administered using a pump system (2 infusion sites) over 24 hours to a total LD/CD dose of 720/90 mg/day.
- Immediate release LD/CD and its placebo counterparts are overencapsulated for an identical appearance.

During the double-blind maintenance phase, patients receive either the ND0612 and placebo IR LD/CD regimen, or the placebo infusion and active IR LD/CD regimen. ND0612 and placebo infusion are supplied in identical vials and packaging, and are similar in color and appearance, thereby enabling double-blind conditions.

Changes to other antiparkinsonian medications are not permitted during the study.

All patients entering the optional open-label extension receive active ND0612 for a further 12 months. The switch of patients receiving placebo infusion to active ND0612 treatment is performed via interactive web response system (iWRS) kit allocation to avoid unblinding of the main part of the study.

Endpoints

- Efficacy is assessed as the change from Baseline to the end of the double-blind assessment period.
- Clinical assessments are assessed by a blinded rater.

Methods

BouNDless is a multicenter, randomized, active-controlled, double-blind, double-dummy, parallel group clinical trial.

Inclusion/exclusion criteria

Key inclusion criteria

- Male and female patients, aged ≥30 years
- PD diagnosis consistent with the UK Brain Bank Criteria2
- Modified Hoehn & Yahr score ≤3 during ON
- Average of ≥2.5 hours of OFF time (≥2 hours OFF every day) during waking hours as confirmed by patient diary over 3 days
- Taking ≥4 levodopa doses/day (≥3 doses/day/Raty at a total daily dose of 4000mg

Key exclusion criteria

- Atypical or secondary parkinsonism.
- Severe disabling dyskinesias.
- Previous neurosurgery for PD.
- Use of duodenal levodopa infusion (LCLG) or apomorphine infusion.
- Use of rescue medication (subcutaneous apomorphine injections, sublingual apomorphine, or intranasal levodopa) within 4 weeks.
- Previous participation in ND0612 studies.
- History of significant skin conditions or disorders

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Conclusions

BouNDless is the first Phase III randomized, active-controlled trial designed to assess the efficacy and safety of treatment with continuous subcutaneous ND0612 in comparison to oral immediate-release LD/CD in patients with PD experiencing motor fluctuations.

References


Disclosures

Neither the authors nor any of the present authors have a relationship with any company or entity with a financial interest in the subject matter of this presentation. B. Oren, T. Yardeni, L. Adar reported ownership of NeuroDerm. No author received funding or payments from any third party for any work associated with this study. C. W. Olanow, F. Stocchi disclosed ownership of ND0612, manufactured by NeuroDerm. No author received funding from a third party for the preparation of this manuscript. Assistance for this paper provided by A. Miller and A. Shlomo (NeuroDerm).