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Duration of “Good On” time per dose: Immediate-release carbidopa-levodopa vs. extended-release carbidopa-levodopa (IPX203, CREXONT®)

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Background

- IPX203 (CREXONT®) is a novel extended-release, oral carbidopa-levodopa (CD-LD) formulation that provides fast onset and prolonged duration of “On”
- For Parkinson’s disease (PD) patients with motor fluctuations, the duration of benefit per levodopa dose is a key metric that reflects a patient’s clinical response

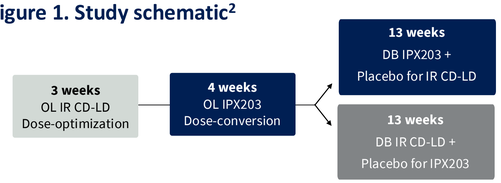
Objective

- Determine the difference in mean durations of “Good On” time per dose of subjects randomized to extended-release CD-LD (IPX203; CREXONT®) vs. immediate-release (IR) CD-LD in the RISE-PD trial

Methods

- RISE-PD was a randomized, double-blind, active-controlled phase 3 study of the safety and efficacy of CREXONT vs IR CD-LD in patients with PD experiencing motor fluctuations[1]
- Patients who successfully completed conversion to IPX203 were randomized to 13 weeks of double-blind treatment with either IR CD-LD or IPX203 at their optimized dosing regimen (plus placebo); double-dummy design (**Figure 1**)[2]

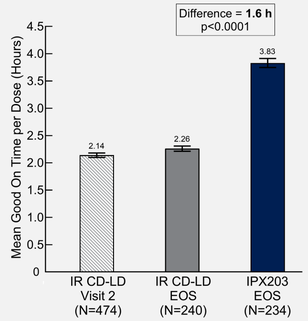
Figure 1. Study schematic[2]



- “Good On” time per dose was assessed at the end of the IR CD-LD dose adjustment phase (Visit 2/Week 3) and compared to End of Study (Visit 7/EOS) between IPX203 and IR CD-LD groups
- Subjects were rank-ordered and divided into quartiles based on initial “Good On” time per dose optimized IR CD-LD values
- Changes in “Good On” time per dose between IPX203 and IR CD-LD groups were then compared for each quartile from Visit 2 to EOS

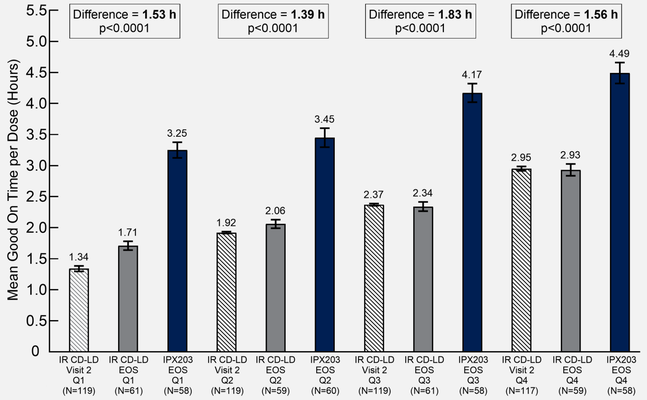
IPX203 provided longer duration of “Good On” time per dose compared with IR CD-LD

Figure 2. “Good On” time per dose at end of IR CD-LD dose-adjustment (Visit 2) and end of study[2]



IPX203 **increased mean “Good On”** time by **1.6 h per dose** than IR CD-LD ($p < 0.0001$)

Figure 3. “Good On” time per dose at end of IR CD-LD dose-adjustment (Visit 2) and end of study by quartile[2]



IR, immediate-release; CD-LD, carbidopa-levodopa; EOS, end of study

Results

- Four hundred and seventy-four (234 IPX203 and 240 IR CD-LD) patients were included in the analysis
- Patients treated with IR CD-LD had an increase in mean “Good On” time per dose from Visit 2 to EOS from 2.15 h to 2.26 h (change = +0.11 h) vs patients treated with IPX203 whose increase in mean “Good On” time per dose from Visit 2 (on IR CD-LD) to EOS (on IPX203) was 2.14 h to 3.83 h (change = +1.69 h) (**Figure 2**)
- IPX203 increased “Good On” time per dose by 1.6 h more than IR CD-LD ($p < 0.0001$) (**Figure 2**)
- Quartile (Q1-Q4) analysis based on “Good On” time per dose at Visit 2 (end of the IR CD-LD dose adjustment phase) yielded the following “Good On” time per dose values at Visit 2 (on IR CD-LD): Q1 = 1.34 h, Q2 = 1.92 h, Q3 = 2.37 h, Q4 = 2.95 h (**Figure 3**)
- For patients treated with IR CD-LD, EOS mean “Good On” time per dose by quartiles was 1.71, 2.06, 2.34, and 2.93 h
- For patients treated with IPX203, the EOS mean “Good On” time per dose by quartiles was 3.25, 3.45, 4.17, and 4.49 h
- The mean differences in “Good On” time per dose between IPX203 and IR CD-LD at EOS were 1.53 h for quartile one, 1.39 h for quartile two, 1.83 h for quartile three, and 1.56 h for quartile four ($p < 0.0001$) (**Figure 3**)

Conclusions

- IPX203 significantly increased “Good On” time per dose regardless of the duration of “Good On” time per dose observed with IR CD-LD
- This data offers clinicians valuable insights for conversion strategies, leading to more predictable patient outcomes and better daily activity planning for patients with PD

REFERENCE

1. Hauser RA, et al. *JAMA Neurol*. 2023;80(10):1062-1069.
2. Hauser RA, et al. *Parkinsonism Relat Disord*. 2025;131:107239.

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