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Simplified Twice-Daily CREXONT (IPX203, ER CD/LD) Regimen Delivers Significant Gain in "Good On" Time in Parkinson's Patients With Lower Levodopa Needs

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Background

- CREXONT® (IPX203), a novel extended-release carbidopa-levodopa formulation containing a mucoadhesive polymer, is designed to improve levodopa delivery and absorption, enhancing therapeutic benefit.
- In RISE-PD, conversion to CREXONT from IR CD/LD was associated with significant gains in daily "Good On" time.[1]
- When converting from IR CD/LD, the total daily levodopa dose (TDD-LD) dictates CREXONT's recommended starting frequency.
  - TDD-LD < 500mg initiate BID
  - TDD-LD ≥ 500mg initiate TID

Objective

- To assess daily "Good On" time in patients treated with CREXONT BID and compare it to other dosing frequencies.

Methods

- **RISE-PD** was a 20-week **phase 3** study with a 3-week open-label IR CD/LD dose-optimization period, 4-week open-label dose-conversion to CREXONT, and a 13-week randomized, double-blind, double-dummy maintenance phase with two arms: **IR CD/LD** and **CREXONT (Figure 1)**.
- Patients on CREXONT BID were isolated at each timepoint.
  - Dose frequency increases during the CREXONT conversion period were quantified.
  - Daily "Good On" time values in BID patients were compared to higher dosing frequencies (CREXONT only).
- Differences in end of study values (EOS) were tested by t-test.

Twice-daily CREXONT treatment provides more daily "Good On" time compared to higher dosing frequencies in the RISE-PD trial

Figure 1. RISE-PD Trial Design

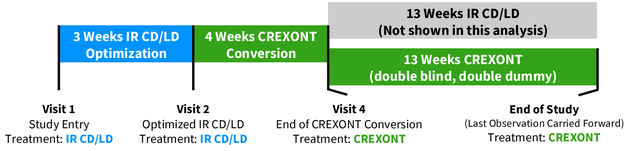
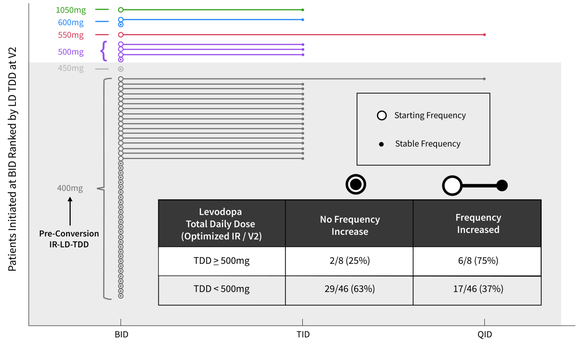


Figure 2. CREXONT Dose-Frequency Adjustments in Patients Initiated at BID



Levodopa Total Daily Dose (Optimized IR / V2)	No Frequency Increase	Frequency Increased
TDD ≥ 500mg	2/8 (25%)	6/8 (75%)
TDD < 500mg	29/46 (63%)	17/46 (37%)

Figure 3. Daily "Good On" Time in BID patients Compared to Higher Dosing Frequencies

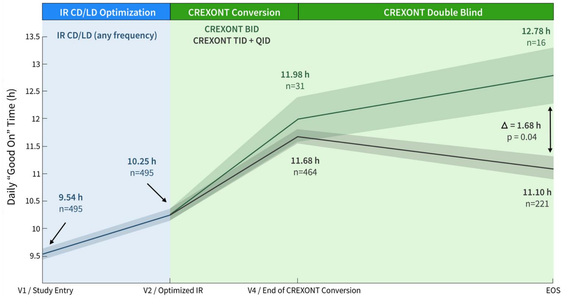
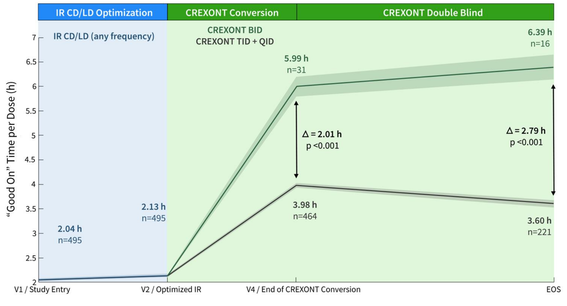


Figure 4. "Good On" Time per Dose in BID Patients Compared to Higher Dosing Frequencies



IR, immediate-release; CD, carbidopa; LD, levodopa; TDD, total daily dose.

Results

- All RISE-PD patients who had at least 1 post-randomization datapoint were included in this analysis, n=495.
- **54 patients** were **initiated at BID** during the conversion period.
  - 8/54 were converted against guidance, having IR-LD-TDD ≥ 500mg.
- **37% of patients** with **pre-conversion IR-LD-TDD < 500mg needed a frequency increase** during the conversion period (Figure 2).
- 75% of patients with pre-conversion IR-LD-TDD ≥ 500mg needed a frequency increase during the conversion period (Figure 2).
- During the conversion period, patients who stabilized on **CREXONT BID** treatment **outperformed** patients who stabilized at **higher dosing frequencies,** with
  - **significantly more daily good on time** at the end of study (12.78 h vs 11.10 h, p=0.04) (Figure 3, shaded area represents standard error)
  - **significantly higher "Good On" time per dose** both at the end of open-label CREXONT conversion (5.99 h vs 3.98 h, p<0.001) and at the end of study (6.39 h vs 3.60 h, p<0.001) (Figure 4, shaded area represents standard error)

Conclusions

- A twice-daily CREXONT treatment provided more daily "Good On" time compared to higher dosing frequencies.
- Patients experiencing "Off" time on less than 500mg of IR CD/LD should be considered for conversion to CREXONT.

Disclosures

Simon Allard and **Stanley Fisher**: Employees, Amneal. **Laxman Bahroo:** Speakers Bureau—AbbVie, Acorda, Amneal, Kyowa Kirin, Lundbeck, Merz, Neurocrinem Sunovion, and Supernus, Neurocrine; Consultant—AbbVie, Acorda, Acadia, Amneal, Ipsen, Merz, Neurocrine, Revance, Supernus, and Teva.

References

1. Hauser RA, et al. IPX203 vs Immediate-Release Carbidopa-Levodopa for the Treatment of Motor Fluctuations in Parkinson Disease: The RISE-PD Randomized Clinical Trial. *JAMA Neurol*. 2023 Oct 1;80(10):1062-1069. doi: 10.1001/jamaneurol.2023.2679.

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