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Switching to CREXONT® (ER CD/LD, IPX203) Substantially Improves "Good On" Time and Reduces Motor Fluctuations in Parkinson's Disease: Interim Results From the Real-World ELEVATE-PD Phase 4 Study

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Background

- CREXONT® (IPX203), a novel extended-release carbidopa-levodopa (ER CD/LD) formulation containing a mucoadhesive polymer, is designed to improve levodopa delivery and absorption, and increase duration of benefit.
- ELEVATE-PD evaluates its safety and efficacy under real-world conditions.

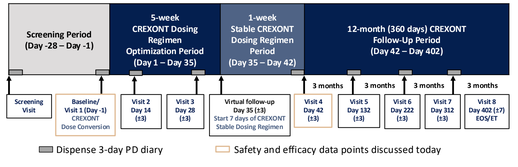
Objective

- To evaluate interim outcomes from the real-world study of CREXONT, assessing its impact to extend "Good On" time and reduce "Off" time in Parkinson's Disease (PD) patients after switching from other levodopa-based treatment regimens.

Methods

- ELEVATE-PD is an ongoing multicenter, open-label phase 4 trial. After screening, patients are converted from their current therapy (IR CD/LD, IR + COMT inhibitors, or Rytary®) to CREXONT and undergo a 5-week dose-optimization period (Visit 1-Day 35), followed by a 1-week stable dosing period (Day 35-42) and a 12-month follow-up **(Figure 1)**.
- Eligible participants are required to have ≥2.5 hours of daily "Off" time.
- The primary endpoint is change in daily "Good On" time from baseline (Visit 1) to Day 42/Visit 4, assessed by the PD diary; the secondary endpoint is the change in daily "Off" time.
- This interim analysis includes the first 111 patients completing Week 6 (Day 42/Visit 4).
- Treatment differences were estimated using all available data; missing post-baseline values were not imputed.

Figure 1. ELEVATE-PD Study Design



Disclosures

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CREXONT substantially increased "Good On" time, reduced "Off" time, increased duration of continuous "Good On" intervals, and improved motor function in a real-world study

Figure 2. Increased "Good On" Time per Day With CREXONT

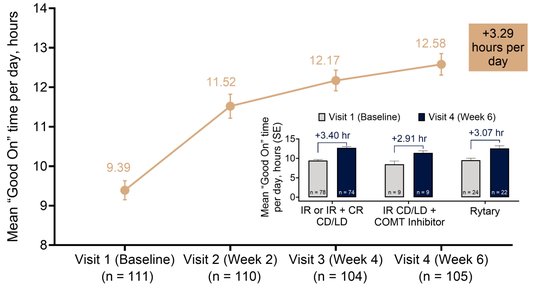


Figure 3. Reduced "Off" Time per Day With CREXONT

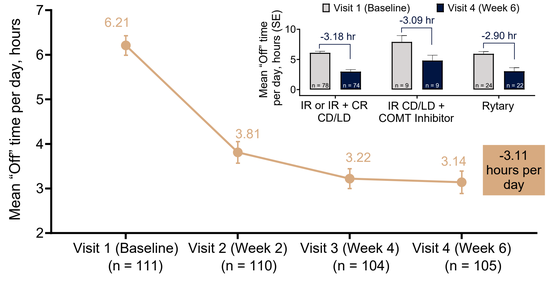
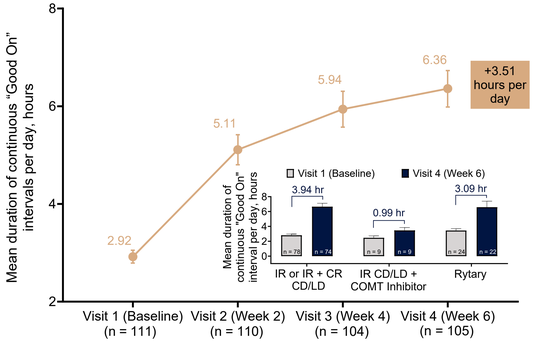


Figure 4. Increased Continuous "Good On" Intervals With CREXONT



IR, immediate-release; CD, carbidopa; COMT, catechol-O-methyltransferase; COMTi, COMT Inhibitor; CR, controlled-release; LD, levodopa; SE, standard error.

Error bars represent standard errors.

Table 1. Reduced Number of Daily Motor Fluctuations With CREXONT

Score	Treatment Group	Visit 1 (Baseline)	Visit 4 (Week 6)	Change From Baseline
Average Number of Daily Motor Fluctuations	**Total**	**5.86 (n=111)**	**3.11 (n=105)**	**-2.79 (47.61%)**
	IR or IR + CR CD/LD	**6.15 (n=78)**	**2.96 (n=74)**	**-3.25 (52.85%)**
	IR CD/LD + COMTi	**6.26 (n=9)**	**5.15 (n=9)**	**-1.11 (17.73%)**
	Rytary	**4.75 (n=24)**	**2.79 (n=22)**	**-1.92 (40.42%)**

Table 2. Improved MDS-UPDRS Scores With CREXONT[a]

Outcome	Treatment Group	Visit 1 (Baseline) (n=111)	Visit 4 (Week 6) (n=107)	Change From Baseline
MDS-UPDRS Total Score[b]	**Total**	**59.9**	**45.7**	**-13.8**
	IR or IR + CR CD/LD	**62.0**	**46.7**	**-15.3**
	IR CD/LD + COMTi	**60.8**	**50.8**	**-10.0**
	Rytary	**52.6**	**40.4**	**-10.3**
MDS-UPDRS Part III	**Total**	**29.2**	**20.6**	**-8.4**
	IR or IR + CR CD/LD	**31.3**	**22.4**	**-9.0**
	IR CD/LD + COMTi	**30.0**	**21.7**	**-8.3**
	Rytary	**22.0**	**14.1**	**-6.6**

[a]MDS-UPDRS evaluation was performed in the "On" state; [b]Sum of all item scores across Parts I-IV

Results

This interim analysis includes the first 111 patients (mean age 67.3±9.58 years) that completed Week 6. At baseline, mean daily "Good On" time was 9.39±0.24 hours, "Off" time was 6.21±0.22 hours. After switching to CREXONT from other levodopa-based therapies, patients experienced:

- +3.29 hours increase in "Good On" time per day **(Figure 2)**
  - Subgroup results: +3.40, +2.91, +3.07 hours for patients switching from IR CD/LD (n=74), IR CD/LD + COMT inhibitor (n=9), and Rytary (n=22), respectively
- -3.11 hours of reduction in "Off" time per day **(Figure 3)**
  - Subgroup results: -3.18, -3.09, -2.90 hours, respectively
- 6.36 hours of continuous "Good On" intervals per day (+3.51 hours increase) **(Figure 4)**
  - Subgroup results: 6.65 (+3.94 hours increase), 3.46 (+0.99 hours increase), 6.58 (+3.09 hours increase), respectively
- -2.79 (47.61%) reduction in the average number of daily motor fluctuations **(Table 1)**
  - Subgroup results: -3.25 (52.85%), -1.11 (17.73%), -1.92 (40.42%), respectively
- -13.8 points improvement in MDS-UPDRS total scores **(Table 2)**
  - Subgroup results: -15.3, -10.0, -10.3 points, respectively
- -8.4 points improvement in MDS-UPDRS Part III score **(Table 2)**
  - Subgroup results: -9.0, -8.3, -6.6 points, respectively
- Majority of treatment-emergent adverse events were mild-to-moderate; most common (≥3%) were dizziness (9.0%), nausea (7.2%), fall (7.2%), dyskinesia (4.5%), hallucination (3.6%), and headache (3.6%)

Conclusions

- CREXONT substantially increased "Good On" time, reduced "Off" time, and improved motor function in patients with PD across all therapy subgroups, including patients switching from Rytary.
- The longer duration of continuous "Good On" intervals and reduced daily motor fluctuations after switching to CREXONT provides patients with PD greater uninterrupted time and predictability to perform their daily activities.
- Overall, switching patients with motor fluctuations from other levodopa-based therapies to CREXONT offers meaningful improvements in symptom control through the day.

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