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Switching to CREXONT® Significantly 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

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

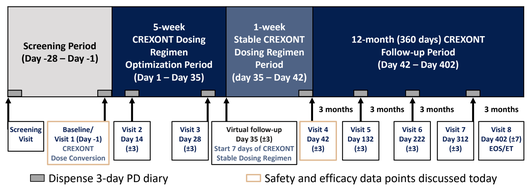
Objective

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

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 55 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



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

Figure 2. Increased "Good On" Time Per Day with CREXONT

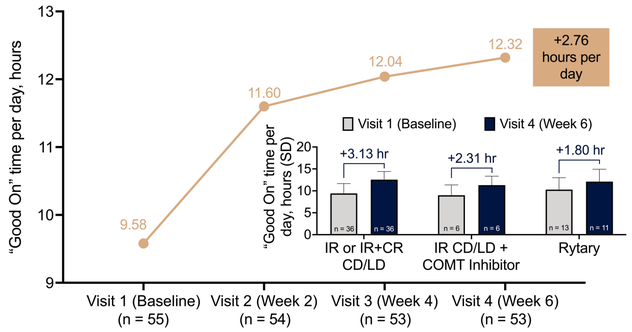


Figure 3. Reduced "Off" Time Per Day with CREXONT

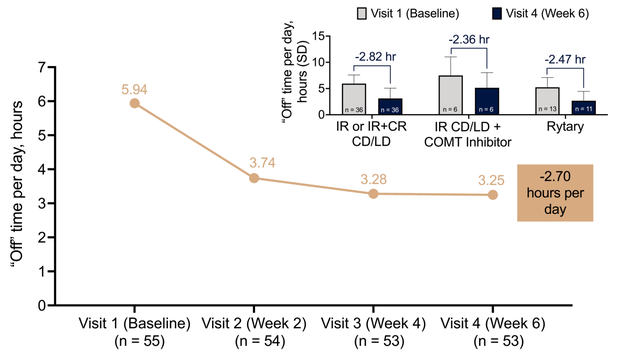


Figure 4. Increased "Good On" Time Per Dose with CREXONT

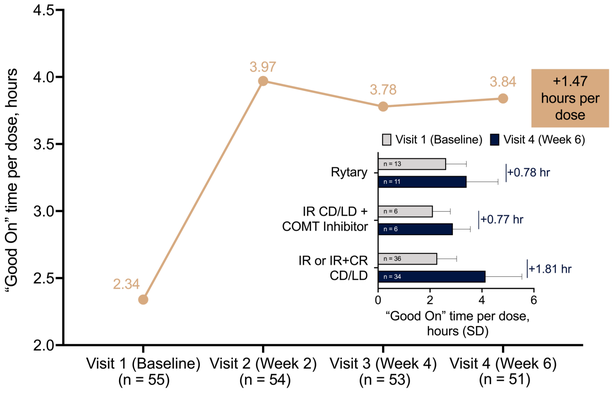


Table 1. Improved MDS-UPDRS Scores with CREXONT[a]

Score	Treatment Group	Visit 1 (Baseline) (n =55)	Visit 4 (Week 6) (n = 54)	Change from Baseline
MDS-UPDRS Total Score[b]	Total	57.8	44.8	-12.3
	IR or IR+CR CD/LD	57.1	42.9	-14.1
	IR CD/LD + COMT	57.3	53.2	-4.2
	Rytary	60	46.1	-10.8
MDS-UPDRS Part III	Total	29.4	19.2	-9.8
	IR or IR+CR CD/LD	30	20.1	-9.8
	IR CD/LD + COMT	28.3	18.5	-9.8
	Rytary	28.2	16.6	-9.7

[a]MDS-UPDRS evaluation was performed in the "On" state

[b]Sum of all item scores across Parts I-IV

IR, immediate-release; CD, carbidopa; COMT, catechol-O-methyltransferase; CR, controlled-release; LD, levodopa; TEAE, treatment-emergent adverse event.

Results

- Fifty-five patients (mean age 66.4±8.95 years) were analyzed. At baseline, mean daily "Good On" time was 9.58±2.36 hours, "Off" time was 5.94±2.02 hours:
  - CREXONT treatment increased daily "Good On" time: +3.13 hours for patients switching from IR CD-LD (n=36), +2.31 hours from IR CD-LD+COMT inhibitor (n=6), +1.80 hours from Rytary (n=11-13) **(Figure 2)**.
  - Corresponding reductions in "Off" time were –2.82, –2.36, –2.47 hours, respectively **(Figure 3)**.
  - CREXONT increased "Good On" time per dose by 1.81, 0.77, 0.78 hours, respectively **(Figure 4)**.
  - CREXONT also improved MDS-UPDRS total scores: –14.1, –4.2, –10.8 points, respectively **(Table 1)**.
  - CREXONT improved MDS-UPDRS part III scores: -9.8, -9.8, and -9.7 points, respectively **(Table 1)**.
  - TEAEs were mild to moderate; most common (≥3%) were nausea (5.5%), falls (3.6%), dizziness (3.6%), urinary tract infection (3.6%).
    - 6 TEAEs were mild, 3 were moderate, and none were severe.
    - 5 TEAEs were considered not related to the drug, while 4 were considered related.

Conclusions

- CREXONT substantially increased "Good On" time, reduced "Off" time, and improved motor function in PD patients across all therapy groups.
- Switching patients from other levodopa-based therapies to CREXONT offers meaningful improvements in symptom control through the day.

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Data from Amneal Pharmaceuticals LLC

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