

# Explore ELEVATE-PD Phase 4 interim results

Interim results (n=111) from an ongoing open-label Phase 4 clinical trial are consistent with FDA-approved labeling and showed that patients who switched to CREXONT from other oral LD therapies\* experienced **3.3 more hours of “Good On” time per day<sup>†</sup>** at 6 weeks<sup>1</sup>

New FDA class warning: Evaluate vitamin B6 levels before and during treatment with carbidopa/levodopa therapies due to reported seizures associated with vitamin B6 deficiency. See page 8 for more information.

\*Other oral LD therapies included IR CD/LD (with or without a bedtime dose of CR CD/LD),

IR CD/LD plus a COMT inhibitor, or RYTARY<sup>®</sup> (carbidopa and levodopa) extended-release capsules.<sup>1</sup>

<sup>†</sup>“Good On” time was defined as “On” time without troublesome dyskinesia. The mean difference from baseline was 3.3 more hours of “Good On” time per day.<sup>1,2</sup>

CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; CR=controlled-release; IR=immediate-release; LD=levodopa.

## IMPORTANT SAFETY INFORMATION

### Indications and Usage

CREXONT<sup>®</sup> (carbidopa and levodopa) extended-release capsules for oral use is indicated for the treatment of Parkinson’s disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults.

Please see full Important Safety Information throughout and full Prescribing Information for CREXONT at [CREXONThcp.com](http://CREXONThcp.com).

The RISE-PD head-to-head study evaluated the efficacy of CREXONT vs optimized IR CD/LD<sup>2,3</sup>

### PHASE 3 STUDY DESIGN

 CREXONT was compared to optimized IR CD/LD in a Phase 3, randomized, double-blind study<sup>2,3</sup>


- Efficacy for CREXONT was assessed after patients were optimized on IR CD/LD and then re-optimized on CREXONT, at which point randomization occurred (N=506) and efficacy assessments began, lasting 13 weeks\*

### PHASE 3 EFFICACY RESULTS

 More “Good On” time with less frequent dosing<sup>2,3</sup>

- Patients taking CREXONT experienced a statistically significant improvement in “Good On” time (0.5 hours per day;  $P=0.019^*$ ) while taking CREXONT an average of 3 times per day, compared with optimized IR CD/LD taken an average of 5 times per day

### PHASE 3 SAFETY PROFILE

 CREXONT demonstrated a well-tolerated safety profile in the RISE-PD study<sup>2,3</sup>

- Adverse reactions occurring at a higher rate in the CREXONT group than the IR CD/LD group during the double-blind maintenance period (CREXONT vs optimized IR CD/LD) were nausea (4% vs 1%), anxiety (3% vs 0%), dizziness (2% vs 1%), dyskinesia (2% vs 0.4%), constipation (2% vs 0.4%), headache (1% vs 0%), vomiting (1% vs 0%), and insomnia (1% vs 0.4%)

\*The dosing of IR CD/LD and CREXONT was optimized for all patients during two sequential open-label periods: Weeks 1–3 for optimization of IR CD/LD, followed by Weeks 4–7 for conversion to CREXONT. Baseline and 1:1 randomization (N=506) began at the end of Week 7 for the 13-week, double-blind maintenance period. The primary endpoint was the mean change in “Good On” time per day from baseline through end of study (Week 20) or early termination. “Good On” time was defined as “On” time without troublesome dyskinesia.<sup>2</sup>

<sup>3</sup>0.5 hours per day is the LS mean difference.  $P$  value based on change from end of Week 7 (baseline) to Week 20 (end of study or early termination), as assessed by the patient’s PD diary.<sup>2,3</sup>  
CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; IR=immediate-release; LD=levodopa; PD=Parkinson’s disease.


### IMPORTANT SAFETY INFORMATION (cont’d)

#### Dosage and Administration

- Evaluate vitamin B6 levels before and during treatment with carbidopa/levodopa therapies
- Levodopa-naïve patients: Starting dose is 35 mg carbidopa/140 mg levodopa taken orally twice daily for the first three days; thereafter, dosage may be increased gradually as needed
- For patients converting to CREXONT from immediate-release carbidopa/levodopa, dosages are **not** substitutable on a 1:1 basis. See full prescribing information Section 2.2 for instructions


An interim analysis from the ELEVATE-PD study evaluated real-world efficacy after switching to CREXONT<sup>1</sup>

### PHASE 4 STUDY DESIGN

 CREXONT is being evaluated in a Phase 4, open-label trial assessing real-world efficacy and safety in patients switching from IR CD/LD, IR CD/LD + COMT inhibitor, or RYTARY<sup>1\*</sup>


- The dosing of CREXONT is individualized for all patients (N=220) in ELEVATE-PD during a 5-week titration period, followed by a 1-week stable dosing period, and then continued open-label treatment for up to 12 months

### PHASE 4 INTERIM EFFICACY RESULTS (n=111) AFTER 6 WEEKS OF CREXONT

 Patients experienced an average of 3.3 more hours of “Good On” time per day after switching to CREXONT from other oral LD therapies<sup>1\*</sup>

- CREXONT was taken an average of 3 times per day after switching
- Subgroup analyses from other oral LD therapies included patients switching from IR CD/LD (n=78) or RYTARY (n=24)<sup>†</sup>

### PHASE 4 INTERIM SAFETY PROFILE (n=111)

 CREXONT safety profile in ELEVATE-PD interim results<sup>1</sup>

- Adverse reactions occurring in at least 3.0% of patients treated with CREXONT were dizziness (9%; n=10), nausea (7%; n=8), fall (7%; n=8), dyskinesia (5%; n=5), headache (4%; n=4), and hallucination (4%; n=4)

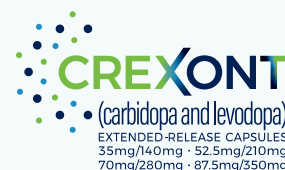
The data presented are an interim analysis of an ongoing open-label study and should be considered within the context of the broader Phase 3 data available. Medical or therapeutic decisions should rely on established evidence, clinical guidelines, and the judgment of qualified healthcare professionals.

\*CREXONT is being evaluated in the Phase 4 open-label, single-arm ELEVATE-PD study over the course of 6 weeks in patients switching from IR CD/LD (with or without a bedtime dose of CR CD/LD), IR CD/LD and a COMT inhibitor, or RYTARY. The dosing of CREXONT is adjusted during the first 5 weeks of treatment, followed by a 1-week stable dosing period and a 12-month extension period. The primary endpoint of the study is the mean change in “Good On” time per day from baseline to Week 6. The number of patients available for this pre-planned interim analysis was 111. “Good On” time was defined as “On” time without troublesome dyskinesia.<sup>1,2</sup>

<sup>†</sup>Predefined subgroup analyses included patients switching from IR CD/LD (with or without bedtime dose of CR CD/LD; n=78), IR CD/LD plus a COMT inhibitor (n=9), or RYTARY (n=24). Considering the small number of patients in the IR CD/LD plus COMT inhibitor group, the results of this patient subgroup switching to CREXONT are not presented here.<sup>1</sup>

CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; CR=controlled-release; IR=immediate-release; LD=levodopa.

Please see full Important Safety Information throughout and full Prescribing Information for CREXONT at [CREXONThcp.com](http://CREXONThcp.com).



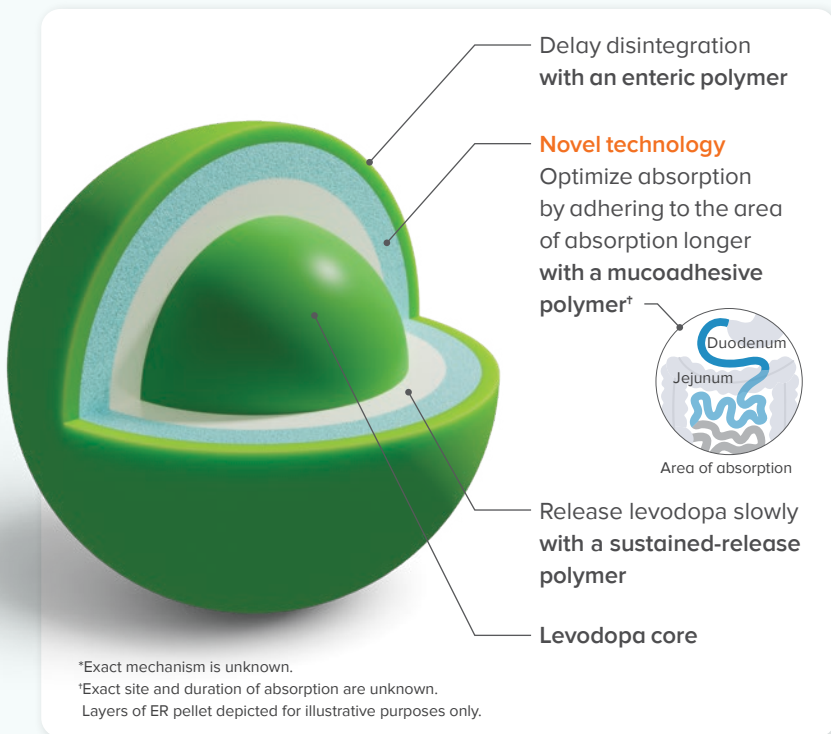
## CREXONT features a novel ER technology<sup>2</sup>

CREXONT contains a mucoadhesive polymer that no other oral CD/LD treatment provides<sup>2,4,5</sup>

	IR CD/LD	RYTARY	CREXONT <sup>®</sup>
Immediate-release (IR) component	✓	✓	✓
Extended-release (ER) component		✓	✓
Mucoadhesive polymer technology			✓

CREXONT combines IR granules (CD/LD) that work rapidly and ER pellets (LD) that sustain LD plasma levels.<sup>2,3</sup>

The ER technology is designed to<sup>2\*</sup>:



CD/LD=carbidopa/levodopa; LD=levodopa.

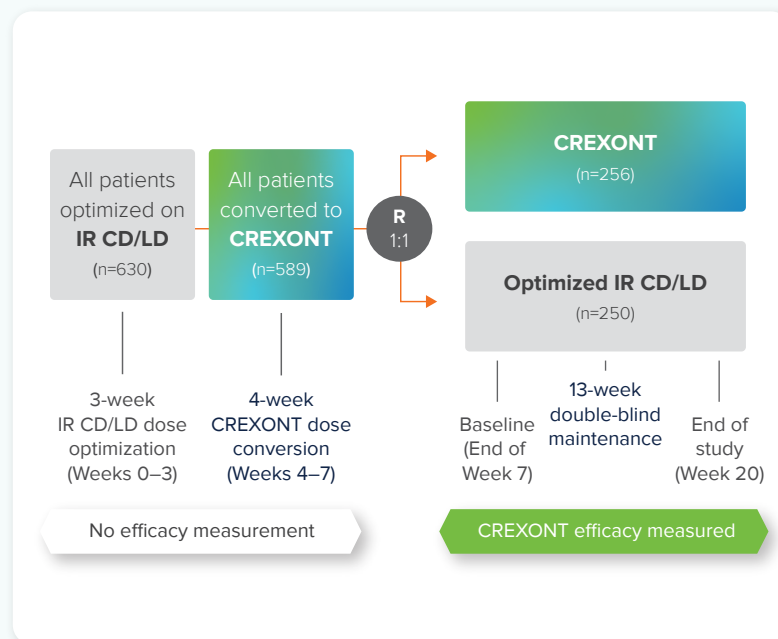
### IMPORTANT SAFETY INFORMATION (cont'd)

#### Dosage and Administration (cont'd)

- For patients converting from Rytary<sup>®</sup> (carbidopa and levodopa) extended-release capsules, initiate CREXONT on an approximately 1:1 mg basis using the levodopa component for conversion
- CREXONT may be taken up to four times daily. The maximum recommended daily dosage is 525 mg carbidopa/2100 mg levodopa

The RISE-PD head-to-head study evaluated the efficacy of CREXONT vs optimized IR CD/LD<sup>2,3</sup>

In a Phase 3, randomized, double-blind study with patients switching to CREXONT from IR CD/LD<sup>2,3\*†</sup>



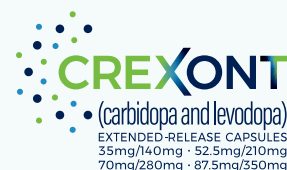
The dose of IR CD/LD could be adjusted during a 3-week, open-label optimization period to achieve optimal balance of efficacy and tolerability. In a subsequent 4-week, open-label period, patients converted from IR CD/LD to CREXONT, followed by a 13-week, double-blind, double-dummy maintenance period. Randomization and baseline began at the end of Week 7.<sup>2†</sup>

\*Patients were permitted to be on a COMT inhibitor up to 4 weeks prior to study entry. CR CD/LD was permitted only in patients who were receiving a single bedtime dose at study entry; this dose was discontinued and initially replaced with an equivalent 1:1 mg dose of IR CD/LD.<sup>1</sup>

†Select inclusion criteria: Stage I–IV per Hoehn and Yahr Scale; 3-day average in “Off” time lasting ≥2.5 hours per day with ≥1.5 hours of cumulative waking “Off” time per day; a stable regimen of CD/LD for ≥4 weeks; CD/LD dose frequency of 4–9 times per day.<sup>1</sup>

<sup>2</sup>Dosing was based on the regimen established at the end of Week 7 for CREXONT and at the end of Week 3 for IR CD/LD. No new dose adjustments could be made during the double-blind maintenance period.<sup>2</sup> CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; CR=controlled-release; IR=immediate-release; R=randomization.

Please see full Important Safety Information throughout and full Prescribing Information for CREXONT at [CREXONThcp.com](http://CREXONThcp.com).



## More “Good On” time with less frequent dosing<sup>2,3</sup>

Average dose frequency of 3 times per day with CREXONT vs an average of 5 times per day with optimized IR CD/LD<sup>2,3</sup>

### Phase 3 primary endpoint results



- Patients taking CREXONT experienced a **statistically significant improvement in “Good On” time (0.5 hours per day)** vs optimized IR CD/LD ( $P=0.019$ )<sup>2,3\*\*</sup>

### Phase 3 secondary endpoint results

- Significantly less “Off” time (0.5 hours per day) with less frequent dosing** with CREXONT vs optimized IR CD/LD ( $P=0.025$ )<sup>2,3†</sup>
  - Change in “Off” time from baseline to end of study or early termination (hours) for CREXONT: 4.0–4.2 (LS mean difference: 0.4) vs optimized IR CD/LD: 4.0–4.8 (LS mean difference: 0.9)<sup>1,3</sup>

\*0.5 hours per day was the LS mean difference.<sup>2</sup>

†P value based on change from end of Week 7 (baseline) to Week 20 (end of study or early termination), as assessed by the patient’s PD diary.<sup>2,3</sup>

CD/LD=carbidopa/levodopa; IR=immediate-release; LD=levodopa; LS=least squares; PD=Parkinson’s disease.

### IMPORTANT SAFETY INFORMATION (cont’d)

#### Dosing and Administration (cont’d)

- CREXONT may be taken with or without food. Capsules should not be chewed, divided or crushed
- CREXONT should not be taken with alcohol

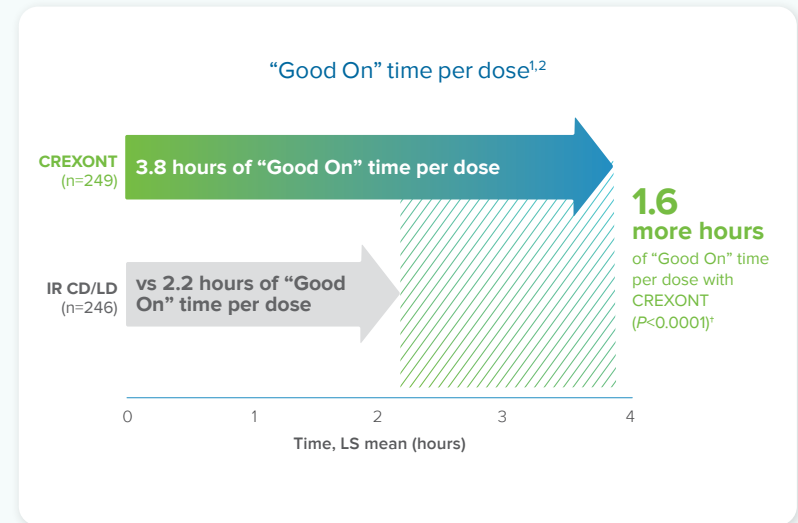
#### Contraindications

Nonselective MAO inhibitors.

## Significantly longer “Good On” time per dose<sup>2\*</sup>

1.6 more hours of “Good On” time per dose with CREXONT

### Phase 3 post hoc analysis of the primary endpoint



\*\*“Good On” time per dose was defined as daily “Good On” time (hours) divided by the daily dose frequency in the subject’s stable dose regimen, as determined at the end of the dose adjustment period for subjects randomized to the IR CD/LD group and at the end of the dose conversion period for subjects randomized to the CREXONT group. Measured at the final study visit.<sup>2</sup>

†1.6 more hours of “Good On” time per dose was the LS mean difference.<sup>2</sup>

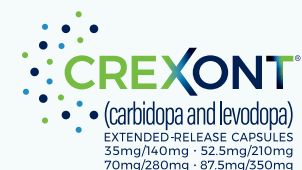
CD/LD=carbidopa/levodopa; IR=immediate-release; LS=least squares.

### IMPORTANT SAFETY INFORMATION (cont’d)

#### Warnings and Precautions

- CREXONT may cause falling asleep during activities of daily living, somnolence or dizziness. Patients should avoid activities that require alertness such as driving and operating machinery until they know how CREXONT affects them
- It is important to avoid sudden discontinuation or rapid dose reduction to reduce the risk of withdrawal symptoms such as high fever or confusion. Patients who are discontinuing CREXONT should taper off with healthcare provider guidance

Please see full Important Safety Information throughout and full Prescribing Information for CREXONT at [CREXONThcp.com](http://CREXONThcp.com).



## CREXONT demonstrated a well-tolerated safety profile vs optimized IR CD/LD<sup>2,3</sup>

Adverse reactions occurring in at least 2% of patients treated with CREXONT while converting from IR CD/LD and at a higher rate than IR CD/LD in the double-blind maintenance period<sup>2,3</sup>:

ADVERSE REACTION	Dose conversion period		Double-blind period
	CREXONT (n=589)	CREXONT (n=256)	IR CD/LD (n=250)
Nausea	5%	4%	1%
Anxiety	2%	3%	0%
Dizziness	3%	2%	1%
Dyskinesia	7%	2%	0.4%
Constipation	2%	2%	0.4%
Headache	2%	1%	0%
Vomiting	2%	1%	0%
Insomnia	2%	1%	0.4%

- During the 4-week dose conversion period to CREXONT, 6% of patients discontinued treatment due to adverse reactions<sup>3</sup>
- Common adverse reactions leading to drug discontinuation during the dose conversion period were dyskinesia, dizziness, and nausea<sup>3</sup>

CD/LD=carbidopa/levodopa; IR=immediate-release.

### New FDA class warning:

- Evaluate vitamin B6 levels before and during treatment with carbidopa/levodopa therapies, and supplement as needed. Patients may start and continue CREXONT while taking vitamin B6 supplements
- Treatment with carbidopa/levodopa, including CREXONT, may reduce vitamin B6 levels; higher doses may further increase the risk of deficiency, which has been associated with seizures that did not respond to traditional anti-seizure medications and resolved only after vitamin B6 administration

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Warnings and Precautions (cont'd)

- Consider dose reductions or stopping CREXONT in patients with hallucinations or impulse control disorders (e.g., gambling, sexual urges, or uncontrolled spending)
- Consider dose reduction in patients with dyskinesia

## Expanding clinical understanding to reflect real-world practice



Efficacy measured from the start of dose conversion



Response rates of patients switching from RYTARY



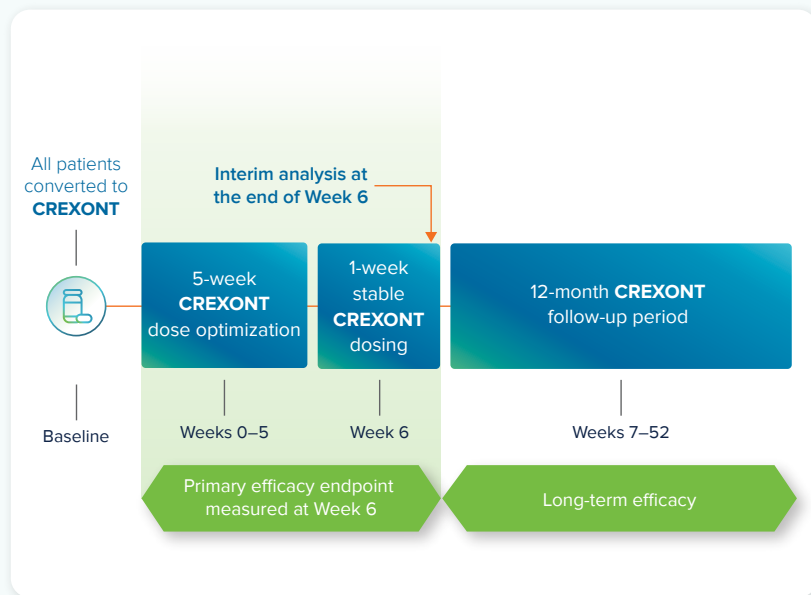
Results from an open-label study designed to mirror real-world use

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**CREXONT**<sup>®</sup>  
(carbidopa and levodopa)  
EXTENDED-RELEASE CAPSULES  
35mg/140mg · 52.5mg/210mg  
70mg/280mg · 87.5mg/350mg

## ELEVATE-PD: An ongoing open-label study designed to evaluate the real-world efficacy and safety of CREXONT<sup>1</sup>

### ELEVATE-PD study design\*



- Baseline efficacy measures were assessed before switching to CREXONT using a PD diary 3 days prior to dose conversion
- Change in efficacy was measured from baseline to Week 6 of treatment with CREXONT
- The study included patients who were **previously treated with IR CD/LD, IR CD/LD plus a COMT inhibitor, or RYTARY<sup>1</sup>**
- **Long-term (12-month) efficacy and safety results** will be evaluated in this study

\*CREXONT was evaluated in the Phase 4 open-label, single arm ELEVATE-PD study over the course of 6 weeks in patients switching from IR CD/LD (with or without a bedtime dose of CR CD/LD), IR CD/LD and a COMT inhibitor, or RYTARY.<sup>1</sup>

CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; CR=controlled-release; IR=immediate-release; LD=levodopa; PD=Parkinson's disease.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Warnings and Precautions (cont'd)

- Treatment with carbidopa/levodopa, including CREXONT, may contribute to reduced vitamin B6 levels. Seizures associated with vitamin B6 deficiency have been reported. Seizures were refractory to traditional anti-seizure medications and were only resolved after vitamin B6 administration. Supplement with vitamin B6 as necessary
- Patients with a major psychotic disorder should not be treated with CREXONT

## Understanding the interim analysis

### Early assessment of interim study results

#### Planned interim analysis:

Predefined interim analysis of an ongoing, open-label Phase 4 study evaluating CREXONT under real-world conditions

#### Patient population:

**111 of the planned ~220 patients**, representing approximately half of the total study population, with outcomes assessed at 6 weeks of treatment. **Baseline demographic characteristics were consistent** with those observed in the RISE-PD study.

- **Select inclusion criteria** include a stable regimen of oral CD/LD,  $\geq 20$  MDS-UPDRS Part III score ("Off" state), and an average of  $\geq 2.5$  cumulative hours per day of waking "Off" time
- **At baseline**, patients experienced approximately 6 hours of "Off" time and approximately 9 hours of "Good On" time per day. 91% of patients were stage II-IV PD per the Hoehn and Yahr scale, with a combined MDS-UPDRS Parts II and III ("On") mean score of approximately 43 across treatment groups

#### Future analyses:

Analyses of additional patients and long-term follow-up will continue as planned throughout the 12-month study period

CD/LD=carbidopa/levodopa; MDS-UPDRS=Movement Disorder Society-Unified Parkinson's Disease Rating Scale; PD=Parkinson's disease.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Warnings and Precautions (cont'd)

- Monitor patients with a history of cardiovascular disease for cardiac function
- Monitor patients with a history of peptic ulcer for upper GI hemorrhage
- Monitor patients with glaucoma for increased intraocular pressure

#### Adverse Reactions

The most common adverse reactions (incidence  $\geq 3\%$  and greater than immediate-release CD/LD) are nausea and anxiety.

#### Drug Interactions

Iron salts and dopamine D2 antagonists, including metoclopramide, may reduce the effectiveness of CREXONT.

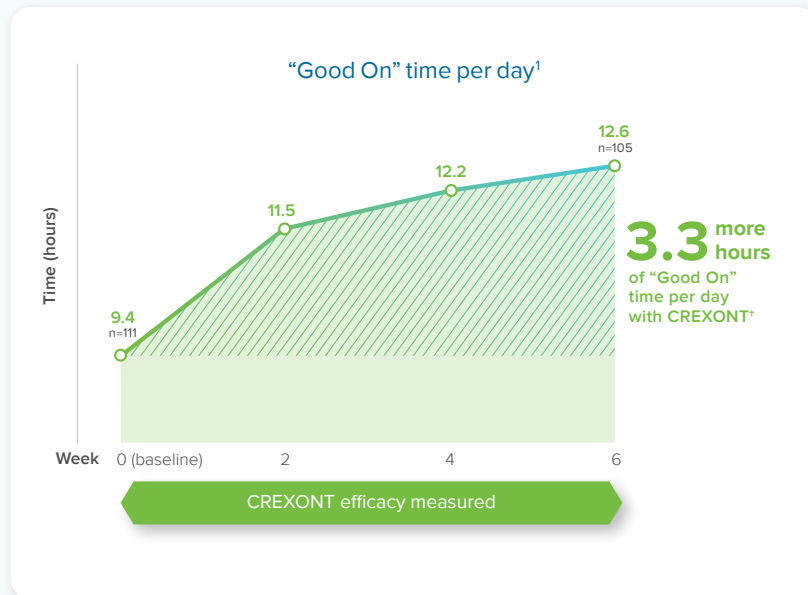
Please see full Important Safety Information throughout and full Prescribing Information for CREXONT at [CREXONThcp.com](http://CREXONThcp.com).



## CREXONT increased “Good On” time per day by 3.3 hours after switching from other oral LD therapies<sup>1\*†</sup>

Results from an ongoing open-label Phase 4 study of patients with PD who switched to CREXONT and continued treatment for 6 weeks<sup>1</sup>

### Primary endpoint results<sup>1</sup>



- Patients who switched to CREXONT from other oral LD therapies\* experienced an **improvement in “Good On” time of 3.3 hours per day** (from 9.4 hours to 12.6 hours), on average
- **Secondary endpoint results:** Patients who switched to CREXONT from other oral LD therapies\* experienced a decrease in “Off” time of 3.1 hours per day (from 6.2 hours to 3.1 hours), on average
- Average CREXONT dose frequency was 3 times per day at Week 6

The data presented are an interim analysis of an ongoing open-label study and should be considered within the context of the broader Phase 3 data available. Medical or therapeutic decisions should rely on established evidence, clinical guidelines, and the judgment of qualified healthcare professionals.

\*Other oral LD therapies included IR CD/LD (with or without a bedtime dose of CR CD/LD), IR CD/LD plus a COMT inhibitor, or RYTARY.<sup>1</sup>

<sup>†</sup>3.3 more hours of “Good On” time per day was the mean difference from baseline.<sup>1</sup>

CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; CR=controlled-release; IR=immediate-release; LD=levodopa; PD=Parkinson’s disease.

### IMPORTANT SAFETY INFORMATION (cont’d)

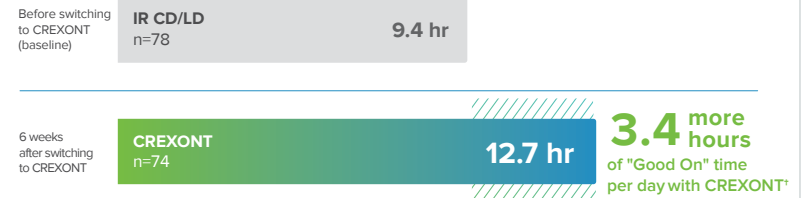
#### Use in Specific Populations

**Pregnancy:** Based on animal data, CREXONT may cause fetal harm. There are no adequate data on the developmental risk associated with the use of CREXONT in pregnant women.

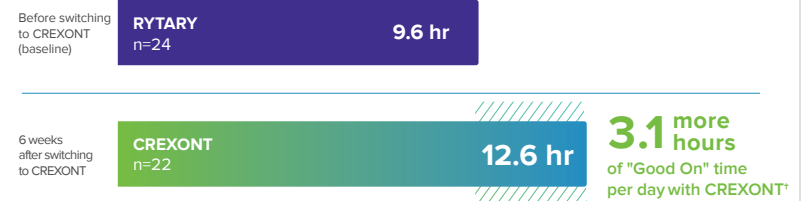
## Subgroup analysis shows increased “Good On” time per day regardless of prior oral LD therapy<sup>1\*†</sup>

### Subgroup analysis of primary endpoint<sup>1</sup>

#### “Good On” time per day before and after switching to CREXONT from IR CD/LD<sup>†</sup>



#### “Good On” time per day before and after switching to CREXONT from RYTARY



The data presented are an interim analysis of an ongoing open-label study and should be considered within the context of the broader Phase 3 data available. Medical or therapeutic decisions should rely on established evidence, clinical guidelines, and the judgment of qualified healthcare professionals.

\*Other oral LD therapies included IR CD/LD (with or without a bedtime dose of CR CD/LD), IR CD/LD plus a COMT inhibitor, or RYTARY.<sup>1</sup>

<sup>†</sup>“Good On” time per day as measured was the mean difference from baseline.<sup>1</sup>

<sup>†</sup>Patients switching from IR CD/LD included patients on IR CD/LD alone or on IR CD/LD with a single bedtime dose of CR CD/LD.<sup>1</sup>

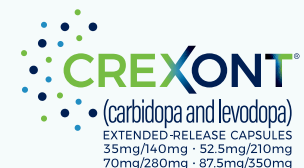
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### IMPORTANT SAFETY INFORMATION (cont’d)

#### Use in Specific Populations (cont’d)

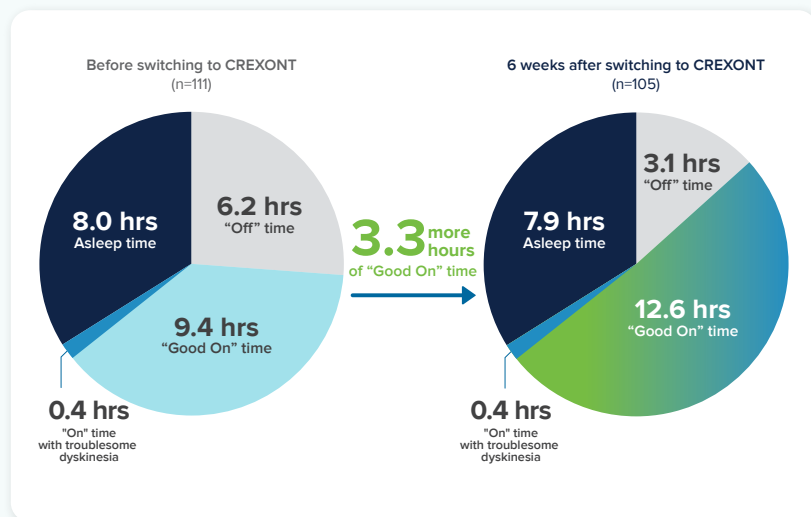
**Breastfeeding:** The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for CREXONT.

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## Increase in "Good On" time and decrease in "Off" time after switching to CREXONT from other oral LD therapies<sup>1\*</sup>

Changes in daily motor control as reported in PD diary data:



- Patients who switched to CREXONT from other oral LD therapies\* experienced an improvement in "Good On" time of 3.3 hours per day (from 9.4 hours to 12.6 hours), on average<sup>1</sup>
- The increase in "Good On" time occurred with a decrease in "Off" time

The data presented are an interim analysis of an ongoing open-label study and should be considered within the context of the broader Phase 3 data available. Medical or therapeutic decisions should rely on established evidence, clinical guidelines, and the judgment of qualified healthcare professionals.

\*Other oral LD therapies included IR CD/LD (with or without a bedtime dose of CR CD/LD), IR CD/LD plus a COMT inhibitor, or RYTARY.<sup>1</sup>

CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; CR=controlled-release; Hrs=hours; IR=immediate-release; LD=levodopa.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Use in Specific Populations (cont'd)

Geriatric patients: There were no differences in safety outcomes between patients less than 65 years of age, 65-75 years of age, or 75 years and older.

**To report SUSPECTED ADVERSE REACTIONS, contact Amneal Specialty, a division of Amneal Pharmaceuticals, LLC at 1-877-835-5472 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## CREXONT safety profile in ELEVATE-PD interim results<sup>1</sup>

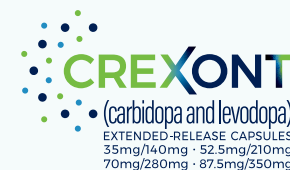
Adverse reactions occurring in at least 3.0% of patients treated with CREXONT<sup>1</sup>:

ADVERSE REACTION	CREXONT (n=111)
Dizziness	9% (n=10)
Nausea	7% (n=8)
Fall	7% (n=8)
Dyskinesia	5% (n=5)
Headache	4% (n=4)
Hallucination	4% (n=4)

The data presented are an interim analysis of an ongoing open-label study and should be considered within the context of the broader Phase 3 data available. Medical or therapeutic decisions should rely on established evidence, clinical guidelines, and the judgment of qualified healthcare professionals.

**References:** 1. Data on file. Amneal Pharmaceuticals LLC. 2. Hauser RA, Espay AJ, Ellenbogen AL, 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;80(10):1062-1069. 3. CREXONT [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; 2024. 4. SINEMET [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2020. 5. Mittur A, Gupta S, Modi NB. Pharmacokinetics of Rytary<sup>®</sup>, an extended-release capsule formulation of carbidopa-levodopa. *Clin Pharmacokinet.* 2017;56(9):999-1014. 6. Hauser RA, Espay AJ, LeWitt P, et al. A phase 3 trial of IPX203 vs IR CD-LD in Parkinson's disease patients with motor fluctuations (RISE-PD). Presented at: American Academy of Neurology Annual Meeting; April 2-7, 2022; Seattle, WA, and virtual. S16.010.

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Interim analysis shows that patients on CREXONT (n=111) achieved more “Good On” time per day after 6 weeks of treatment

After switching to CREXONT from other oral LD therapies,\* patients experienced, on average<sup>1</sup>:

### 3.3 more hours of “Good On” time per day



- Switching from IR CD/LD subgroup: 3.4 more hours of “Good On” time
- Switching from RYTARY subgroup: 3.1 more hours of “Good On” time



### 3.1 less hours of “Off” time per day

### CREXONT safety profile in ELEVATE-PD interim results<sup>1</sup>

Adverse reactions occurring in at least 3.0% of patients treated with CREXONT were dizziness (9%; n=10), nausea (7%; n=8), fall (7%; n=8), dyskinesia (5%; n=5), headache (4%; n=4), and hallucination (4%; n=4).

The data presented are an interim analysis of an ongoing open-label study and should be considered within the context of the broader Phase 3 data available. Medical or therapeutic decisions should rely on established evidence, clinical guidelines, and the judgment of qualified healthcare professionals

\*Other oral LD therapies included IR CD/LD (with or without a bedtime dose of controlled-release CD/LD), IR CD/LD plus a COMT inhibitor, or RYTARY.<sup>1</sup>

CD/LD=carbidopa/levodopa; COMT=catechol-O-methyltransferase; IR=immediate-release; LD=levodopa.

## IMPORTANT SAFETY INFORMATION


### Indications and Usage

CREXONT® (carbidopa and levodopa) extended-release capsules for oral use is indicated for the treatment of Parkinson’s disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults.

Please see full Important Safety Information throughout and full Prescribing Information for CREXONT at [CREXONT.hcp.com](http://CREXONT.hcp.com).

*Amneal*

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 **CREXONT**<sup>®</sup>  
(carbidopa and levodopa)  
EXTENDED-RELEASE CAPSULES  
35mg/140mg · 52.5mg/210mg  
70mg/280mg · 87.5mg/350mg