A Study of CREXONT (Carbidopa and Levodopa) Extended-Release Capsules in Participants With Parkinson's Disease

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Participants with PD consistent with the United Kingdom Parkinson's Disease Society Brain Bank Diagnostic Criteria and who are being treated with stable regimens of oral CD-LD. 2. Participants with a score of at least 20 units at Screening on the Movement Disorder Society

•Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III total score in the "Off" state. 3. Participants with predictable "Off" periods at Screening defined by a score of 1 or 2 (Complexity of Motor Fluctuations) of the MDS-UPDRS Part IV B (Motor Fluctuations). 4. By history, for the 4 weeks (28 days) prior to Screening, the participant experiences. 1. Daily predictable "wearing-off" episodes with periods of worsening motor symptoms. 2. An average of at least 2.5 cumulative hours per day of "Off" time, during the hours the participant awake. 5. At Screening, the participant is able to differentiate "On" state from "Off" state as determined by at least 75 percentage (%) concordance with a trained rater (that is, investigator or qualified and certified site staff) in "On/Off" ratings for 8 ratings over a 4-hour training period. The concordance must include at least one "On" and one "Off" rating in this 4-hour training period. 1. If the concordance is less than 75%, or if it does not include at least one "On" and one "Off" rating within the first 4-hour training period, a second 4-hour training period should be conducted with the participant before being considered for inclusion in the study. 2. If during the second 4-hour training-period a concordance of at least 75% is also not achieved, or if it does not include at least one "On" and one "Off" rating, the participant cannot be included in the study. 6. At baseline (Visit 1), review of the 3-day PD diaries confirms the following: 1. The participant is able to properly complete the PD diaries with valid entries. Inability to properly complete the diaries is indicated when more than 1 day of a diary is not returned or if more than 1 day of the diary is not valid (that is, more than 2 hours \[4 half-hour periods\] of the 24-hour diary day are missing); and 2. The participant has an average of at least 2.5 hours per day of "Off" time, during the hours the participant is awake, over the 3 PD diary days; and 3. The participant has at least 1.5 hours of cumulative "Off" time, during the hours the participant is awake, on each of the 3 PD diary days. 7. Participant is responsive to CD-LD therapy and currently being treated on a stable regimen of oral CD-LD for at least 4 weeks (greater than equal to \[\>=\] 28 days) prior to baseline (Visit 1) and meets the following criteria: a. Daily Dose Requirements: i. All participants should be taking at least 100 mg of immediate-release (IR) CD-LD or 195 mg of Rytary for the first morning dose. ii. For participants taking IR CD-LD (with or without a bedtime dose of CR CD-LD): * Require a total daily dose of at least 300 mg of LD and a maximum total daily dose of less than equal to \[\<=\]1200 mg LD (from IR CD-LD alone or from IR CD-LD in combination with a single daily bedtime dose of CR CD-LD). * The maximum individual dose allowed is 250 mg of LD. * The minimum individual dose should be at least 100 mg of LD. iii. For participants using a catechol-O-methyltransferase (COMT) inhibitor: * Require a total daily dose of at least 300 mg of LD and a maximum total daily dose of less than \[\<\]1000 mg LD. * The maximum individual dose is 200 mg of LD. iv. For participants using Rytary: * Require a total daily dose of at least 585 mg of LD and a maximum total daily dose of \<2100 mg LD. * The maximum individual dose is 685 mg of LD. b. Dose Frequency Requirement: i. If a participant is using IR/CR CD-LD alone or in combination with a COMT inhibitor, then the dosing frequency must be 3 to 6 times daily. ii. If a participant is using Rytary, then the dosing frequency must be 3 to 4 times daily. 8. Participant is able and willing to provide written informed consent prior to the conduct of any study-specific procedures. 9. Participant is able and willing to comply with the protocol, including completion of PD diaries, questionnaires, and available for all study visits and telephone calls. 10. Participants who have participated in prior CREXONT clinical studies are allowed to be enrolled in this Phase 4 study.

Exclusion Criteria:

1. Participant who, in the opinion of the clinical investigator, should not participate in the study based on the CREXONT Prescribing Information. 2. Participant had a prior neurosurgical treatment for PD (example, deep brain stimulation \[DBS\] surgery or neurosurgical ablation treatment procedures) or if such procedure is planned or anticipated prior to Visit 4 (Day 42) of the study. 3. Participant received the following within 4 weeks (\<=28 days) prior to baseline (Visit 1) 1. Any doses of a CR CD-LD apart from a single daily bedtime dose. 2. Duopa. 3. Nonselective monoamine oxidase inhibitor (MAOI). 4. Rescue medication used to treat "off" episodes for example: apomorphine or inhaled LD (Inbrija®). 5. Received any investigational drugs within 30 days or 5 times the half-life, whichever is longer, prior to baseline (Visit 1). 4. Participant who, in the opinion of the clinical investigator, should not participate in the study (example, based on clinical assessment, participant does not adequately comprehend the terminology needed to complete the PD diary and participant -reported outcomes, or any other reason). 5. Employees or family members of the investigator, or study site staff, or Sponsor.

Conditions & Interventions

Interventions:
DRUG: CREXONT ER
Conditions:
Parkinson Disease

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE4
IRB
Number:
System ID: NCT06765668
