TOZ-PD

A Phase 3, multicenter, randomized, double-blind, placebo controlled study with an open label phase to determine the efficacy and safety of Tozadenant as adjunctive therapy in Levodopa-treated patients with Parkinson's disease experiencing end of dose "wearing off" (TOZ-PD)

Clinical Trial Status:
This study is currently recruiting participants

Clinical Trial Principal Investigator:
Dr. James Boyd

Clinical Trial Protocol Description:
The main objectives of this study are to show the efficacy of Tozadenant as a treatment for end-of-dose "wearing off", to determine the safety and tolerability of Tozadenant, and to assess the effects of Tozadenant on non-motor symptoms, such as behavior and sleep.

Tozadenant works as an A2a receptor antagonist, which is believed to influence the control of voluntary movement in the brain. Tozadenant has been used as investigational product (IP) in two Phase II studies, which showed Tozadenant to be well-tolerated at the doses we will be using, and also to significantly reduce the amount of OFF time.

This study consists of two parts:

- Part A: double-blind, three arm (60mg, 120mg, placebo) phase with 24 weeks of IP treatment; visits at Baseline, weeks 2, 6, 12, 18 and 24

- Part B: open-label phase with 52 weeks of Tozadenant treatment; visits at weeks 26, 30, 36, 48, 60, 76 and week 80 for safety follow-up

Both Part A and B will use a series of questionnaires related to PD symptoms, as well as clinical laboratory samples and physiological assessments to evaluate Tozadenant.

Clinical Trial Eligibility Criteria:
In order to participate, you must meet the following criteria:

- Have a clinical diagnosis of idiopathic PD according to the UK PD brain bank criteria
- Are 30-80 years of age
- Are currently taking Levodopa treatment and at least one other anti-PD medication
- Are experiencing end-of-dose "wearing-off"
- Have a Hoehn and Yahr stage 2-4 when in OFF state and ≤ 3 in ON state

You will not be eligible to participate if any of the following criteria apply to you:

- Have participated in any study with Tozadenant
- Have any form of secondary of atypical parkinsonism
- Have had neurosurgical intervention for PD
- Have a history of malignant melanoma
- Are currently taking antipsychotic drugs, or have taken any for more than 1 month in the last 2 years

- Are taking apomorphine, budipine, istradefylline, tolcapone, or DUOPA
- Have uncontrolled hyperthyroidism or hypothyroidism
- Have orthostatic hypotension
- Have significant depression or suicidal ideation
- Have an impulse control disorder (ICD)

Note: this is a partial list of the inclusion and exclusion criteria

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