

A Study to Investigate the Efficacy and Safety of Bemdaneprocel in Adults Who Have Parkinson's Disease

Status: RECRUITING

Eligibility Criteria

Age: 45 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Diagnosis of clinically established PD as defined by the International Parkinson and Movement Disorders Society * Individual of any sex ≥ 45 to ≤ 75 years of age at informed consent * Robust and clear response to DA therapy as defined by MDS-UPDRS Part III * ≥ 4 and < 12 years from time of PD diagnosis at informed consent * Must demonstrate responsiveness to levodopa therapy * Receiving medical therapy for the treatment of PD symptoms * ≥ 2.5 hours of daily OFF-time * Vaccinated per current national guidelines or local practice for patients with altered immunocompetence

Exclusion Criteria:

* PD presenting with recurrent falls * Diagnosis of primary mitochondrial disorder, epilepsy, stroke, multiple sclerosis, or clinical features suggestive of a neurodegenerative disease other than PD, including multiple system atrophy, progressive supranuclear palsy, corticobasal degeneration, or Lewy body dementia * Any current or relevant previous history of serious, severe, or unstable physical, neurological, or psychiatric illness that may interfere with study participation, participant's safety, or assessment of endpoints per investigator's judgment * History of gene therapy or cell therapy * Prior treatment with intrajejunal or subcutaneous infusion therapies for PD * Prior surgical or radiation therapy to the brain, including deep brain stimulation (DBS) and lesion therapy, or prior history of intradural spinal cord surgery * Contraindication to surgery, general anesthesia, cell therapy, immunosuppression, or other required drugs, or anything that prevents use of PET or MRI * Any active infection (including but not limited to HIV, HCV, HBV, CMV, syphilis, or tuberculosis) or condition that, in the opinion of the investigator could put the participant at significant risk from immunosuppression or impact the participant's ability to perform study assessments * Current or previously active malignant disease within the past 5 years * Chronic immunosuppressive therapy * Receipt of another investigational therapy within 5 half-lives of the active treatment * Pregnancy or breastfeeding

Conditions & Interventions

Interventions:

BIOLOGICAL: bemdaneprocel, PROCEDURE: Sham surgery

Conditions:

Parkinsons Disease (PD)

Keywords:

exPDite-2, Cell Therapy, Cellular Therapy, Dopaminergic Neuronal Cell Therapy, Parkinsons Disease

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT06944522

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