WHAT IS THE TITLE OF THE STUDY?
A Phase 3, 12-week, Double-Blind, Placebo-Controlled, Randomized, Multicenter Study to Evaluate the Efficacy of Oral Istradefylline 20 and 40 mg/day as Treatment for Subjects with Moderate to Severe Parkinson's Disease.

WHAT IS THE PURPOSE OF THE STUDY?
The purpose of this study is to test the safety and effect of an investigational study drug, istradefylline, in patients who have been optimally or maximally treated with levodopa/carbidopa therapy. KW-6002 (istradefylline) is an investigational drug which means that it is not approved for use in the United States of America (USA) by the Food and Drug Administration (FDA) and therefore has not been marketed in the U.S. This study will test the safety and effectiveness of istradefylline to determine if it can reduce OFF time for Parkinson’s disease patients with motor fluctuations and a history of dyskinesia (involuntary jerking/twisting). We want to find out what effects, good and/or bad, it has on you and your Parkinson’s disease.

WHO IS NEEDED?
To pre-qualify for this study, the participant must:

- Be 30 years old or older
- Be diagnosed with idiopathic Parkinson’s disease
- Be taking levodopa for at least 1 year
- Be experiencing wearing OFF of your PD medications
- Have no history of Deep Brain Stimulation (DBS)
- Smoke fewer than 5 cigarettes per day (if smoke at all)

Additional criteria apply

WHAT IS INVOLVED IF I PARTICIPATE?
Duration: There are up to 7 office visits over a period of approximately 18 weeks.
Tests/procedures: Physical and Neurological exams, an ECG test to trace heart rhythm, questionnaires, blood draws, urine test, and daily input into a diary. The study drug is administered in a tablet form, which you swallow, and may be taken with food or drink.
Risks: Risks will be discussed with volunteers as part of the informed consent process.
Benefits: Participation might help future patients with PD.
Compensation: Compensation is provided.

WHO IS THE PRINCIPAL INVESTIGATOR (DOCTOR)?
Susan Criswell, MD

WHERE WILL THE STUDY TAKE PLACE?
Washington University School of Medicine
Coordinator Name: Karen McDonell 314-747-0514 or mcdonellk@neuro.wustl.edu