Clinical study summary (CSS)

CT registry ID#: NCT00139880
Study no.: SP867

These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert.

Proprietary drug name	**INN**	**Therapeutic area and indication(s)**
PARCOPA®	Carbidopa/levodopa	Parkinson's disease

Name of Sponsor/company: UCB

Title of study:
A single center, randomized, double-blind, crossover pilot trial comparing the onset of action of Parcopa® with Sinemet® in subjects with stable Parkinson's disease.

Investigator(s) (number only): 1

Study center(s) (number only): 1

Length of study:
Date first patient enrolled: 27 Jun 2005
Date last patient completed: 12 Aug 2005

Phase of development: Phase 4

Abstract:
The objective of this pilot trial was to compare the onset of action of Parcopa (carbidopa-levodopa orally disintegrating tablet [ODT]) with Sinemet immediate-release tablet using the Unified Parkinson's Disease Rating Scale (UPDRS) Motor Exam (Part III).

All Visits occurred within 1 to 7 days of the previous Visit. Subjects were screened for eligibility at Visit 1. Subjects with a pre- to post-dose difference >5 points in UPDRS Motor Exam scores following a single dose of Sinemet at Baseline (Visit 2), were eligible for randomization at Visit 3. Timing and dose of trial medication were as for the subjects' pretrial medication, and Visits were scheduled to occur within 1 hour of the same time on the respective days. At Visit 3, subjects were randomized to receive either Sinemet at Visit 3 and Parcopa at Visit 4, or Parcopa at Visit 3 and Sinemet at Visit 4. The UPDRS Motor Exam was administered predose and every 10 minutes from 15 to 65 minutes postdose by a blinded rater at Visit 3 and Visit 4.

Safety assessments included adverse event (AE) reporting, vital sign assessment (predose at Visit 2, Visit 3 and Visit 4), physical examination (Screening Visit only) and urine pregnancy testing (Screening Visit only).

Number of subjects:	**Overall**
Planned, N:	1 0
Enrolled, N:	10
Completed, n (%):	10 (100.0)
Number of subjects withdrawn, n (%):	0
Withdrawn due to adverse events, n (%):	0
Withdrawn for other reasons, n (%):	0
Demography:	**Overall**
Gender (Females/males):	7 female/3 male
Age (years), mean (range):	63 (range: 44-71). [[50% over 50]]
Race, n (%):	Caucasian (100%)

CT registry ID#: NCT00139880
Study no.: SP867

Safety outcomes:
- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:

Among the 10 subjects, only 1 AE was reported (urinary tract infection). The AE was mild and judged by the investigator as non-serious and not related to trial medication. No deaths or pregnancies were reported during this trial, and no subjects discontinued prematurely for any reason.

During the trial, mean changes in vital sign measurements (heart rate, systolic blood pressure, and diastolic blood pressure) were small and not clinically important.

Treatment-emergent AEs (TEAE)	
Subjects with at least one TEAE, n (%):	**1 (10.0)**
Subjects with TEAEs (by Primary System Organ Class)	***n (%) [n considered drug-related by the Investigator]***
Urinary tract infection	*1 (10.0) [0]*
Deaths and other SAEs:	
Death, n (%):	**0**
Subjects with SAEs, n (%):	**0**

Primary & secondary outcomes:

Following administration of identical doses of Sinemet and Parcopa in the same individuals on different days, the onset times for a decrease ≥30% in the UPDRS Motor Exam totals score were similar (43 minutes vs 47 minutes, respectively).

Publication reference(s) based on the study: none

Date of report: 19 Nov 2008