Health related quality of life in LCIG patients and LICG eligible patients continuing oral therapy. A multicenter Post Marketing Observational Study for LCIG in Germany and Switzerland – BALANCE

Principal Investigator:	PD Dr. med. Georg Kägi
Status:	active, not recruiting
Project Start:	17/04/2015
Project End:	end of 2019
Trial Design/Class:	prospective, multicounty, multi-centre, observational, parallel-group study / Class: A
Number of Patient:	266 patients
Centers:	approximately 45 sites in Germany and 5 sites in Switzerland (Luzerner Kantonsspital, Klinik Bethesda, Rehaklinik Zihlschlacht, University Hospital Zurich, Kantonsspital St. Gallen), Hospitals and office based physicians specialized in Parkinson Disease with experience in LCIG therapy
Sponsor/Partner:	AbbVie AG, Baar, Switzerland
Funding:	AbbVie AG, Baar, Switzerland

Summary:

Parkinson's disease (PD) is the second most common neurodegenerative disorder in the world. However, as Parkinson's disease is progressive in its nature, over time, the duration of the treatment effect becomes shorter and medication effects become challenging. Frequent complications seen in patients receiving long-term oral levodopa treatment are fluctuations in clinical response, including dyskinesia.

The quality of life is relentlessly deteriorating with longer disease duration once the complications of conservative oral therapy develop.

Continuous dopaminergic stimulation using Levodopa/Carbidopa Intestinal Gel (LCIG) improves the motor complications of the Parkinson's disease and preliminary data suggest that also the quality of life is improved.

Objectives:

Primary Objective

Primary Objective is to assess the effect of LCIG on Health Related Quality of Life (HRQL) of patients according to selection criteria from German guidelines and compare improvement in HRQL between patients continuing to LCIG treatment and patients staying on oral treatment, despite being eligible according to these guidelines.

Secondary Objectives

The secondary objectives will be to assess the changes in HRQL, motor symptoms, non-motor symptoms, Healthcare Resource Utilization, Caregiver Burden, reason for transition to LCIG (or continuing oral therapy).