European multicenter retrospective-prospective cohort study to observe Safinamide safety profile and pattern of use in clinical practice during the first post-commercialization phase– Study Z7219N02

Principal Investigator**:**	PD Dr. med. Georg Kägi
Status:	completed
Project Start:	2016
Project End:	2019
Trial Design/Class:	Multi-country multicentre retrospective-prospective cohort observational study / Class: A
Number of Patient:	13 in St. Gallen (1600 patients worldwide)
Centers:	about 140 neurology sites in Belgium, France, Germany, Italy, Spain, Switzerland, United Kingdom
Sponsor/Partner:	Zambon S.p.A., Bresso (MI), Italy
Funding:	Zambon S.p.A., Bresso (MI), Italy

Summary:

During the initial marketing authorization procedure, at day 180 the European Medicines Agency (EMA) recommended to the Applicant to provide additional real world data on Safinamide given the uncertainties regarding categories of patients not well represented in clinical trials, namely patients aged > 75 years and those with concomitant psychiatric conditions such as psychosis, cognitive dysfunction and depression.

Following this request, a Drug Utilization Study (DUS) aimed at investigating how Safinamide is prescribed and used in routine clinical practice was designed, including also Parkinson's disease (PD) patients with relevant concomitant diseases. It will allow to evaluate not only the extent of these categories of patients, but also safety data (in terms of occurrence of adverse events) will be provided. With this approach the opportunity of collecting and disseminating relevant data concerning the use of Safinamide in a real life setting was seized.

In order to improve the knowledge about the product beyond the findings of clinical trials, the study will provide data on drug safety profile and on Safinamide treatment patterns.

Objectives:

Primary Objective:
Primary objective is to describe the occurrence of adverse events in patients treated with Safinamide in real-life conditions during 1 year in the first post-commercialization phase as reported by the Investigators. The analysis will be conducted overall and in some subgroups of interest, namely in patients aged >75 years and those with relevant concomitant conditions.

Secondary Objectives:
To describe characteristics of patients treated with Safinamide according to clinical practice (demographics, disease duration, disease severity, previous treatment for PD, concomitant relevant conditions with particular focus on psychiatric ones and related treatments).

To describe Safinamide treatment patterns in real-life setting (treatment duration, dose adjustments and interruptions, dose discontinuation and reason, changes in concomitant PD therapies, treatments for PD administered after Safinamide).