Reviewer's report

Title: Novel design for a Phase IIa Placebo-Controlled, Double-Blind Randomized Withdrawal Study to Evaluate the Safety and Efficacy of CNV1014802 in Patients with Trigeminal Neuralgia

Version: 2  Date: 22 October 2013

Reviewer: Wilhelm J Schulte-Mattler

Reviewer's report:

After review of the above mentioned manuscript, I feel it describes an innovative study design on a clinically important topic. It fully meets the requirements for a publication in Trials.

The study design is well chosen, especially with respect to the nature of the disease to be treated. Hypothesis, rationale and methodology are sensible, appropriate, and clearly described. The answer to each the 4 questions below is "yes", with one minor point: I'd prefer to see an explicit statement on how the primary outcome measure, namely "the number of treatment failures on CNV1014802 vs. number of treatment failures on placebo throughout the double-blind treatment period" will be judged statistically.