Exposure-Efficacy/Safety Analyses to Support Trigeminal Neuralgia Phase 3 Study Dosing Regimen for Vixotrigine (BIIB074)

Problem or Challenge

Support phase 3 dosing regimen for Vixotrigine

Solution or Achievement

Establish exposure (Caverage) - efficacy/safety (pain score or incidence of dizziness) relationship for vixotrigine based upon data from completed Phase 2 POC efficacy study in patients with trigeminal neuralgia and safety data from completed 7 phase 1/2 studies.

Use exponential effect model to characterize concentration-effect (pain score) relationship and time to first event (dizziness) model to characterize concentration-safety relationship for vixotrigine.

Perform simulations using developed models with various dosing regimen to establish therapeutic window and support starting dose for vixotrigine.

Impact on R&D

Based upon simulations 150 mg TID dose and up titration to 250 mg TID dose of vixotrigine will provide optimum efficacy and expected to have dizziness events similar to that of placebo.

Analyses supported starting dose of 150 mg TID of vixotrigine in the phase 3 studies for trigeminal neuralgia.

Next Steps

Analyses will be used to support starting phase 3 dose of vixotrigine in discussions with FDA.

Biogen