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ICA-105665

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ICA-105665 is a novel opener of neuronal KCNQ potassium channels currently in Phase II clinical trials for the treatment of epilepsy. ICA-105665 has broad-spectrum activity in a variety of animal models of anticonvulsant and pain activity. To date, 126 healthy volunteers and 27 patients have received one or more doses of ICA-105665 in single (up to 600 mg) and multiple ascending dose (up to 300 mg BID for 7 days) Phase 1 trials. In these Phase 1 studies, all adverse events were mild to moderate and a maximum tolerated dose was not achieved. Headache, somnolence and dizziness were the most common AEs at the highest doses; only dizziness appeared to be dose-related.

Thirteen patients with photo-induced paroxysmal responses were administered ICA-105665 in a Phase 2 pharmacodynamic study. One of 4 subjects at 100 mg, 2 of 4 subjects at 400 mg and 4 of 6 subjects at 500 mg ICA-105665 exhibited suppression of the photosensitive response with the incidence and severity of CNS AEs increasing at the 500 mg dose. Enrollment was stopped in this study following a serious adverse event in the first subject tested in the 600 mg cohort. The FDA has approved the initiation of a Phase 2 randomized, double blind, placebo-controlled 4-week study of approximately 60 partial onset epilepsy patients, who are refractory to current AED therapy. The study, which will be conducted at 10-15 clinical research centers in the US, will have both safety and efficacy endpoints.