DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

Summary of the Neurological Devices Panel Meeting
February 22, 2013

Introduction

The Neurological Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on February 22, 2013, to discuss, make recommendations, and vote on information related to the premarket approval (PMA) application, P100026, sponsored by NeuroPace, Inc. for the NeuroPace RNS System.

The NeuroPace RNS System neurostimulator is surgically implanted subcutaneously in the cranium. The neurostimulator senses and records electrocorticographic (ECoG) patterns from intracranial electrodes and delivers short trains of current pulses to the brain that are intended to interrupt the ECoG ictal discharge. The detection and stimulation parameters can be adjusted non-invasively.

Proposed Indications for Use

The NeuroPace RNS System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures from no more than two foci that are refractory to two or more antiepileptic medications.

Panel Deliberations/FDA Questions:

The Sponsor presented a multi-center, prospective, randomized, double-blinded, sham-stimulation controlled pivotal study designed to assess the safety and effectiveness of the NeuroPace RNS System.

The pivotal study met the primary safety endpoints, which compared the rates of serious adverse events in the acute period (surgical period and the following 4 weeks) and in the short-term

chronic period (surgical periods and the following 12 weeks) to similar surgical procedures. The panel discussed these findings and concluded that the risks of the device were reasonable.

The panel discussed multiple effectiveness endpoints. The revised primary effectiveness endpoint utilized a generalized estimating equation (GEE) model, which indicated that the mean seizures per month, adjusted for covariates, fell by 37.9% (95% confidence interval 27.7%, 46.7%) in the treatment arm and 17.3% (95% CI 2.3%, 29.9%) in the sham arm (p=0.012). The responder rates indicated that 29% of patients in the treatment group had their numbers of seizures reduced by 50% or more; 27% of patients in the sham group showed this response (p=0.727). The numbers of mean seizures per month dropped by 11.5 in the treatment group and 5.0 in the sham group (p=0.238). The number of days each month with seizures dropped by 18.9% in the treatment group and 18.3% in the control group. The percentage of patients with increases of 5 points or more in the quality of life in epilepsy score (QOLIE-89) was 36.6% in the treatment group and 39.1% in the control group (p=0.760). The panel concluded that these results represented a clinically significant treatment effect.

Panel members suggested it would be beneficial to identify which patients were most likely to benefit from this device. They indicated a preference for some restrictions on which doctors or centers utilized the device. Most panelists felt that a post-approval study duration of 2-3 years would be appropriate.

Panel Vote

On voting question 1, the panel voted 13-0-0 (yes, no, abstain) that the data show that there is reasonable assurance that the NeuroPace RNS System is safe for use in patients who meet the criteria specified in the proposed indication.

On voting question 2, the panel voted 12-0-1 (yes, no, abstain) that there is reasonable assurance that the NeuroPace RNS System is effective for patients who meet the criteria specified in the proposed indication.

On voting question 3, the panel voted 11-0-2 (yes, no, abstain) that the benefits of the NeuroPace RNS System do outweigh the risks for use in patients who meet the criteria specified in the proposed indication.

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