A Study to Assess the Safety, Tolerability, and Effectiveness of NUEDEXTA (Dextromethorphan 20 mg/Quinidine 10 mg) in the Treatment of Pseudobulbar Affect (PBA) [PRISM II]

Rachelle Doody,1 Andrew Cutler,2 Stephen D’Amico,3 Richard Zorowitz,4 David Alexander,4 Flora Hammond,5 William Sauve,6 and Charles Yonan5

1Baylor College of Medicine, Houston, TX; 2Phoenix Clinical Research Center LLC, Bradenton, FL; 3Concordia Medical Group, Fridley, MN; 4John Hopkins Bayview Medical Center, Baltimore, MD; 5Rosedale Neurological Research Center, Los Angeles, CA; 6Oklahoma University School of Medicine, Indianapolis, IN; 7Universal Health Services, King of Prussia, PA; 8Axeon Pharmaceuticals, Inc., Aliso Viejo, CA

Study Objectives

• Pseudobulbar affect (PBA) is a neurological condition characterized by sudden, frequent, and uncontrollable episodes of laughter and/or crying that are excessive or inappropriate to the situation and the underlying cause (e.g., stroke).

—PBA episodes are disruptive, embarrassing, and distressing to patients and others.

—PBA may lead to social isolation and even contribute to living facility/skilled nursing home placement.

—PBA occurs secondary to neurological conditions, including dementia, and is hypothesized to be caused by injury to, or presence of brain lesions in, the neurological pathways that regulate and coordinate affect.

—Prevalence studies estimate 10% to 20% of patients with dementia have PBA symptoms,7,8 however, the condition remains under-recognized and may be missed as depression or other behavioral disturbances.9

—Dextromethorphan 20 mg/quinidine 10 mg (DMQ) is currently the only FDA-approved treatment for PBA.10

—Safety and efficacy studies of DMQ for treatment of PBA were conducted in patients with amyotrophic lateral sclerosis (ALS)11 or multiple sclerosis (MS)12 (e.g., mg/kg dose for ≥2 months).

• This open-label, double-blind (baseline), randomized controlled study (study called PRISM II) of 600 patients (n=170 each) provided additional safety data.13

—A baseline visit score ≥ 13 on the Center for Neurologic Study –Lability Scale (CNS-LS) for Pseudobulbar Affect (PBA)14,15 validated in patients with MS and ALS14,15 (Figure 3).

—The symptoms are not the direct physiological effect of a substance (e.g., drug abuse or medication).

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—Disease-specific functional measures

—Dysphoria, or feeling sad or depressed

—Dysthymia, or feeling sad or depressed

—Vital signs

—Laboratory measures

—Clinical Global Impression-Change of PBA symptoms

—Estimated PBA episode counts

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As of July 1, 2013, 40 patients have enrolled (Figure 4).

Conclusions

• PRISM II will provide a prospective, systematic assessment of DMQ effectiveness and safety as treatment for PBA in patients with dementia, stroke, or TBI.

References


Disclosures

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