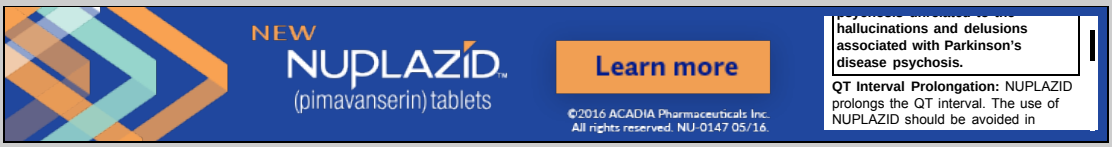


April 29, 2014
- Poster Session III
  - Epilepsy and Clinical Neurophysiology: AED

Lacosamide for Uncontrolled Primary Generalized Tonic-Clonic Seizures: An Open-label Extension Study (P3.276)

Stephen Yates[2], **Robert Wechsler**[1] **and Cynthia Beller**[2]

+ SHOW AFFILIATIONS

Published online before print April 8, 2015,
Neurology April 8, 2014 vol. 82 no. 10 Supplement P3.276

Abstract

ABSTRACT

OBJECTIVE: This open-label extension (OLE) study (SP0962 [NCT01118962]) assessed long-term (>12-months) safety of adjunctive lacosamide in patients (16-65y) with idiopathic-generalized epilepsy (IGE) and uncontrolled primary generalized tonic-clonic seizures (PGTCS). **BACKGROUND:** Safety of adjunctive lacosamide for uncontrolled PGTCS in IGE was reported in a 13-week, Phase 2, open-label, pilot study (SP0961 [NCT01118949]). Patients completing SP0961 could enroll in SP0962. **DESIGN/METHODS:** Initial lacosamide dose for SP0962 was that received at end of SP0961 (300 or 400mg/day), and could be increased (up to 800mg/day) or decreased throughout SP0962 56-week Treatment Period. New AEDs approved for PGTCS could be introduced, as needed. Primary variables were treatment-emergent adverse-events (TEAEs) and withdrawals due to TEAEs. Secondary variables included: percentage-change in PGTCS frequency/28days from Baseline (SP0961 4-week Prospective or 16-week Combined [12-week Historical+4-week Prospective]); change from Prospective-Baseline in absence or myoclonic seizure days/28days; continuous 6-months or 1-year freedom from PGTCS. **RESULTS:** 39/40 patients who completed SP0961 enrolled in SP0962 (30.3y; 72% female). All had history of PGTCS within 12-weeks of enrollment, 67% of absence, and 54% of myoclonic-seizures. 79% were taking 1-2 concomitant AEDs. 29/39 patients (74%) completed OLE. 32/39 (82%) had >12 months lacosamide exposure. Mean modal lacosamide dose was 428.2mg/day. 37/39 patients (95%) reported 蠅1 TEAE. Most frequent were: dizziness (26%), upper respiratory tract infection (26%), headache (18%), tremor (15%). Two patients discontinued prematurely due to TEAEs (abnormal behavior; confusional state). One patient each experienced TEAE increased absence-seizures and increased myoclonic-seizures. Mean±SD reduction from Prospective-Baseline in absence and myoclonic seizure days/28 days was -2.4±5.5 and -2.8±6.4 [Prospective-Baseline: absence 4.9±9.1; myoclonic 4.3±7.7]. Median percentage-change in PGTCS frequency/28 days was -89.3% (from Prospective-Baseline) and -72.3% (from

Related Content

Articles Cited by this Article via CrossRef

WriteClick Responses to This Article

Be the first to respond to this article

Respond

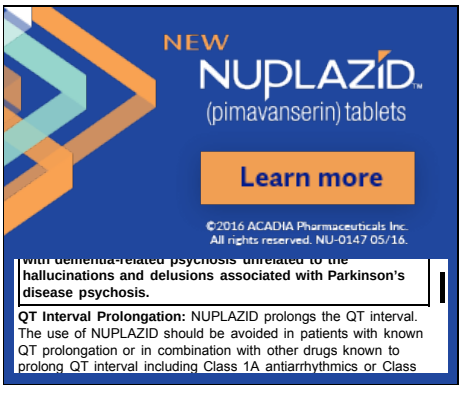
Article Metrics

Related Articles

View related articles»

Find similar articles in Google Scholar >

ADVERTISEMENT



DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

CONCLUSIONS: No new safety signals were identified following >12-months adjunctive lacosamide treatment in patients with IGE. Lacosamide reduced PGTCS frequency, and generally reduced days with absence and myoclonic seizures. Results support further evaluation of lacosamide for PGTCS. **Study Supported by:** UCB Pharma

Disclosure: Dr. Yates has received personal compensation for activities with UCB Pharma. Dr. Yates holds stock and/or stock options in UCB Pharma. Dr. Wechsler has received personal compensation for activities with USB Pharma, GlaxoSmithKline Inc., Lundbeck, Cyberonics, Eisai Inc., Gerson Lehrman Group, Jazz Pharmaceuticals, Upsher-Smith Laboratories Inc. Dr. Wechsler has received research support from UCB Pharma, Lundbeck, Eisai Inc., Vertex, Icagen, King Pharmaceuticals, Sunovion Pharmaceuticals, Upsher-Smith Laboratories Inc., Pfizer Inc., and GlaxoSmithKline Inc. Cynthia Beller has received personal compensation for activities with UCB BioSciences, Inc. as an employee.,

Tuesday, April 29 2014, 3:00 pm-6:30 pm

Copyright © 2014 by AAN Enterprises, Inc.

RSS Feeds ▼ Mobile Neurology FOLLOW NEUROLOGY:

Neurology®
Print ISSN: 0028-3878
Online ISSN: 1526-632X

AMERICAN ACADEMY OF NEUROLOGY. aan.com
HighWire
Wolters Kluwer

WriteClick is a trademark of the AAN, registered in the U.S.
© 2016 American Academy of Neurology | Help | Feedback | Advertise

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.