

erecurrent

Monthly newsletter from the **epilepsy** RESOURCE CONNECTION

UCB's Vimpat™ Recommended For Approval In Europe



The pharmaceutical company UCB announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending that the European Commission grants a marketing authorization for lacosamide, proposed trade name Vimpat™, for the adjunctive treatment of partial onset seizures with or without secondary generalization in patients with epilepsy, aged 16 years and older.

The recommendation has been granted for the oral tablet, oral syrup and intravenous formulations.

"The European positive opinion for approval of Vimpat™ marks a major achievement for patients with epilepsy whose seizures are not well controlled by current antiepileptic drugs, and for UCB, strengthening our leadership in treatments for this severe disease," said Roch Doliveux, CEO, UCB.

The CHMP decision is supported by data from three multicenter, double blind, placebo controlled clinical trials that evaluated the efficacy, safety and tolerability of lacosamide (200, 400 and 600 mg/day given in two divided doses) in a total of over 1,300 adults with uncontrolled partial onset seizures. Patients in these trials were taking at least one to three antiepileptic drugs (AEDs) and many of the patients had previously tried at least seven AEDs.

Across these studies significantly greater than 50% responder rates and reductions in median seizure frequency were seen versus placebo. Lacosamide was also generally well tolerated with the most common adverse events (>=10% and greater than placebo) reported in these trials including dizziness, nausea, diplopia and headache.

"With as many as 30% of epilepsy patients continuing to have seizures despite treatment with antiepileptic drugs, there is a need for new, efficacious and well tolerated treatment options," said Professor Elinor Ben-Menachem, Department of Clinical Neuroscience, Goteborg University, Sweden. "These clinical studies suggest that adjunctive lacosamide may be a useful pharmacological treatment option for patients with partial onset seizures."

Regulatory filings for Vimpat™ oral tablet, oral solution and intravenous formulation are currently also under review by the FDA for use as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy in the U.S. AMERICAN ACADEMY OF NEUROLOGY

Failure To Take Seizure Drugs Linked To Increased Risk Of Death

Not taking medication to control seizures could be deadly. People with epilepsy who fail to take their seizure medication regularly could be as much as three times more likely to die, according to a study published in the June 18, 2008, online issue of *Neurology*.

For the study, researchers looked at insurance records from three state Medicaid programs over eight and a half years. The study included 33,658 people with epilepsy who filled at least two epilepsy drug prescriptions.



The study found that people who took their epilepsy medication less than 80% of the time over the course of three months appeared to be three times more likely to die compared to people who took their medication regularly in a three-month period.

In addition, the study showed that hospital visits went up by 86% and emergency room visits increased by 50% during the time when people didn't take their medication regularly.

There also appeared to be a significantly higher incidence of car accidents and bone breaks. Only head injuries were less common during periods of non-compliance with epilepsy drugs.

"These results are concerning since some studies show about 30 to 50% of people with epilepsy do not take their medication regularly," said study author Edward Faught, MD, Director of the University of Alabama Epilepsy Center in Birmingham and Fellow of the American Academy of Neurology.

"There are many reasons epileptic patients fail to take their seizure medications, including cost, side effects and pregnancy. But this study suggests that none of those reasons overshadow the threat of death or other problems related to uncontrolled seizures. Patients need to stay on their medications and physicians need to recognize and treat issues related to people failing to take epilepsy drugs," said Faught.

AMERICAN ACADEMY OF NEUROLOGY

ADA Restoration Act Passes House

The ADA Amendments Act of 2008 passed the House by an overwhelming margin, 402-17, marking a historic move toward securing the promise of the original ADA, signed into law in 1990.

In a show of bipartisan unity, congressional leaders and key members of the disability and employer communities held a press conference in support of the bill shortly before it went to the House floor for a vote.

The bill clarifies for the courts that people with disabilities should not lose civil rights protections because their condition is treatable with medication or can be addressed with the help of assistive technology. The bill also clarifies the definition of disability to include all individuals whose impairment substantially limits a major life activity.

The bill now moves to the Senate. The public is urged to contact their senators and help ensure the bill's passage in order to secure the promise of the ADA, as it was originally envisioned.

EPILEPSY FOUNDATION

Adult Epilepsy Support Group

Group Meets Second Tuesday of the month.
LOCATION: 2919 W. Second Street (Wichita) • TIME: 5:00 PM

July 8: Dealing with Medication Side Effects
August 12: Dealing with Epilepsy Confusion



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Sedgwick County...
 working for you

erc Family Camp Day

Sunday, August 3, 2008 • 12:30 - 5:30 PM
 Camp Hiawatha • 1605 W. 51st N. Street N.

Camp Day welcomes persons of all ages with epilepsy & their families. Camp is an opportunity to meet others facing similar challenges living with epilepsy.

ACTIVITIES INCLUDE:

Swimming (bring your suit)
 Horseback Riding
 Inflatibles to bounce in
 Games & Crafts
 BBQ Dinner @ 5:00 PM
 (air conditioned shelter is used)

☛ Please use registration form enclosed

Registration before July 28:

Family \$15 • Individual \$5

(after July 25:

\$10 Individual; \$20 Family)

For more info
 or to register
 call 943-2453

New Approach To Epilepsy Treatment Takes Its First Steps

The most prestigious funding body in the world for epilepsy has financially backed Australian research into new approaches to treat the condition.

The Epilepsy Therapy Project will provide almost \$300,000 over the next two years to a group of researchers from leading Australian institutions including the University of Newcastle.

The group will further develop new ways to treat the one-third of epilepsy patients for whom current treatments do not control their seizures.

Associate Professor Adam McCluskey from the University's School of Environmental and Life Sciences said the new funding would build on recent discoveries involving brain cell communication in sufferers of epilepsy.

"We have already found that compounds designed to block the action of a protein called dynamin are effective against laboratory models of epilepsy - in these models they appear to block progression of key elements associated with epileptic seizures," McCluskey said.

"Four classes of drugs have been tested and two of these show real potential in stopping epileptic seizures, which is promising news for the one-third of people who don't respond to current treatments."

Approximately one in 120 people have epilepsy, while up to 5% of the world's population will have a seizure at some time in their lives.

"The funding will allow us to continue clinical development of the new drugs and move towards commercialization. If all goes to plan a new treatment for epilepsy could be entering clinical trials within the next three to five years," said McCluskey.



↳ RESEARCH AUSTRALIA

Brain Pathway That Shuts Down Seizures Identified

Researchers at the University of Iowa and the Veterans Affairs Iowa City Health Care System have uncovered a brain pathway that shuts down seizures.

The multidisciplinary team of scientists pieced together information from clinical observations made in the first half of the 20th century with knowledge from modern genetics and molecular biology to show that an acid-activated ion channel in the brain reacts to a drop in pH (increased acid) in a way that shuts down seizure activity.

The link between low pH in the brain and seizure termination was first hinted at nearly 80 years ago when clinical experiments showed that breathing carbon dioxide, which makes brain tissue more acidic, helps stop epileptic seizures. Subsequent studies in the 1950s found that seizures themselves reduce brain pH. However, it was the modern discovery of an acid-activated ion channel (ASIC1a) in the brain that provided the key to the UI discovery, which is reported in *Nature Neuroscience Advance* Online Publication.

"We found that ASIC1a does not seem to play a role in how a seizure starts, but as the seizure continues and the pH is reduced, ASIC1a appears to play a role in stopping additional seizure activity," said Adam Ziemann, a student in the Medical Scientist Training Program at the UI and co-lead author of the study.

Specifically, the study shows that mice without the ASIC1a gene have more severe and longer seizures than mice with the gene. In addition, chemically blocking ASIC1a increases the severity and duration of seizures in mice with the gene. Conversely, increasing the expression of ASIC1a in mice protects the animals from severe seizures.

The team also showed that reducing the pH in slices of brain tissue expressing ASIC1a reduced seizure activity, but acid had no effect on seizures in tissue without the protein.

When the team measured pH in mouse brains, they showed that seizures lower the pH to levels that can activate ASIC1a channels. They also found that breathing carbon dioxide causes an additional rapid drop in brain pH, and that breathing 10 percent carbon dioxide was sufficient to protect mice with the ASIC1a protein from lethal seizures.

"In seizures, ASIC1a appears to be activating inhibitory neurons," explained John Wemmie, M.D., Ph.D., senior study author and assistant professor of psychiatry in the UI Carver College of Medicine, and a staff physician and researcher at the VA Iowa City Health Care System. "This is the first study to show that ASIC1a activation can have an inhibitory effect."

"One of the most exciting aspects of the work is that it highlights the potent anti-epileptic effects of acid in the brain -- effects that have been recognized for nearly 100 years but until recently have been poorly understood -- and it identifies ASIC1a as a key player in mediating the anti-epileptic effect of low pH," Ziemann said. ↳ UNIVERSITY OF IOWA