Sunovion Announces Results of Health Outcomes Analyses Supporting the Use of Aptiom® (eslicarbazepine acetate) in People with Partial-Onset Seizures at the 68th American Academy of Neurology (AAN) Annual Meeting

Survey data compares antiepileptic drug preferences for neurologists and people with epilepsy

A systematic review and network meta-analysis among monotherapy AEDs found that Aptiom had the lowest odds of study exit due to meeting pre-specified criteria indicating worsening of seizure control, and the lowest odds of study discontinuation for all other reasons, compared to all evaluated AEDs.

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In a pooled analysis of two historical-controlled APTIOM Phase 3 studies (093-045 and 093-046), patients treated with APTIOM monotherapy, who either completed the trial or responded to treatment, experienced significant improvements in their health-related quality of life, with many experiencing clinically meaningful improvement.

A post-hoc analysis of the Phase 3, randomized, double-blind APTIOM study 093-304 found that patients treated with APTIOM as adjunctive therapy for partial-onset seizures had significantly less seizure severity and bother compared to patients in the placebo group as assessed by the Seizure Severity Questionnaire (SSQ).

A national survey found that people with epilepsy had similar AED preferences to neurologists. The results of this survey also provided additional insights into what AED attributes matter to people with epilepsy, further reinforcing the importance of the neurologist/patient relationship when making AED treatment decisions.
About APTIOM® (eslicarbazepine acetate)

APTIOM® is the latest member of the dibenzazepine carbamimide family of antiepileptic drugs (AEDs), an established class of medicines. APTIOM® is the only exclusively once-daily, non-extended release AED FDA-approved for use as monotherapy or adjunctive therapy for partial-onset seizures. The precise mechanism(s) by which eslicarbazepine acetate acts is unknown but is thought to involve inhibition of voltage-gated sodium channels. APTIOM can be taken whole or crushed, with or without food. APTIOM® is not classified as a controlled substance by the FDA.

The initial research and development of eslicarbazepine acetate was performed by BIAL-Portela & C.a. S.A. (BIAL), a privately held Portuguese research-based pharmaceutical company. Subsequently, Sunovion acquired the rights under an exclusive license to further develop and commercialize eslicarbazepine acetate in the United States and Canada markets from BIAL. BIAL gained approval for eslicarbazepine acetate from the European Commission on April 21, 2009 as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization. In Europe, the product is marketed under the trade name Zebinix®. APTIOM® is approved in Canada for use as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy who are not satisfactorily controlled with conventional therapies.

About Epilepsy and Partial-Onset Seizures

Epilepsy is the fourth most common neurological condition, and one in 26 people in the U.S. will develop epilepsy in his or her lifetime.1 Epilepsy manifests as unprovoked seizures, which are caused by abnormal firing of impulses from nerve cells in the brain.2 Partial-onset seizures, the most common type of seizure, are characterized by bursts of electrical activity that is specifically located in certain areas of the brain and may become more widespread, with symptoms varying according to the affected areas.3 The unpredictable nature of seizures may have a significant impact on those with epilepsy. Reducing the frequency of seizures may lessen the burden of epilepsy.4 With approximately one-third of people living with epilepsy still unable to control seizures, there continues to be a need for new therapies. Up to 40 percent of people living with epilepsy do not respond to the first or second monotherapy,4 and approximately 36 percent fail to achieve adequate control of seizures despite the use of two or more antiepileptic medications.5

Please see Important Safety Information below.

Indication:

APTIOM® (eslicarbazepine acetate) is a prescription medicine used alone or with other medicines to treat partial-onset seizures.

Important Safety Information:

Do not take APTIOM® if you are allergic to eslicarbazepine acetate, any of the other ingredients in APTIOM® or oxcarbazepine.

Suicidal behavior and ideation: Antiepileptic drugs, including APTIOM®, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your doctor right away if you have any of the following symptoms, especially if they are new, worse or worry you thoughts about suicide or dying; attempting to commit suicide; new or worse depression, anxiety, or irritability; feeling agitated or restless; panic attacks; trouble sleeping (insomnia); acting aggressive; being angry or violent; acting on dangerous impulses; an extreme increase in activity and talking (mania); or other unusual changes in behavior or mood.

Allergic reactions: APTIOM® may cause serious skin rash or other serious allergic reactions that may affect organs or other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions. Call your doctor right away if you experience any of the following symptoms: swelling of the face, eyes, lips, or tongue; trouble swallowing or breathing; hives; fever, swollen glands, or sore throat that do not go away or come and go; painful sores in the mouth or around your eyes; yellowing of the skin or eyes; unusual bruising or bleeding; severe fatigue or weakness; severe muscle pain; or frequent infections or infections that do not go away.

Low salt (sodium) levels in the blood: APTIOM® may cause the level of sodium in your blood to be low. Symptoms may include nausea, tiredness, lack of energy, irritability, confusion, muscle weakness or muscle spasms, or more frequent or more severe seizures. Some medicines can also cause low sodium in your blood. Be sure to tell your health care provider about all the other medicines that you are taking.

Nervous system problems: APTIOM® may cause problems that can affect your nervous system, including dizziness, sleepiness, vision problems, trouble concentrating, and difficulties with coordination and balance. APTIOM® may slow your thinking or motor skills. Do not drive or operate heavy machinery until you know how APTIOM® affects you.

Liver problems: APTIOM® may cause problems that can affect your liver. Symptoms of liver problems include yellowing of your skin or the whites of your eyes, nausea or vomiting, loss of appetite, stomach pain, or dark urine.

Most common adverse reactions: The most common side effects in patients taking APTIOM® include dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision, and shakiness.

Drug interactions: Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking APTIOM® with certain other medicines may cause side effects or affect how well they work. Do not start or stop other medicines without first talking to your health care provider. Especially tell your health care provider if you take oxcarbazepine, carbamazepine, phenobarbital, phenytoin, primidone, clobazam, omeprazole, simvastatin, rosuvastatin, or birth control medicine.

Discontinuation: Do not stop taking APTIOM® without first talking to your health care provider. Stopping APTIOM® suddenly can cause serious problems.

Pregnancy and lactation: APTIOM® may cause your birth control medicine to be less effective. Talk to your health care provider about the best birth control method to use. APTIOM® may harm your unborn baby. APTIOM® passes into breast milk. Tell your health care provider if you are pregnant or plan to become pregnant, or are breast-feeding or plan to breastfeed. You and your health care provider will decide if you should continue APTIOM®. If you become pregnant while taking APTIOM®, talk to your health care provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.

Get medical help right away if you have any of the symptoms listed above.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see the APTIOM Medication Guide and Full Prescribing Information.

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion’s spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. The Company has created new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological, and respiratory conditions. Sunovion’s track record of discovery, development and commercialization of important therapies has included Brovana® (afornotrol tartrate), Latuda® (lurasidone HCI), and most recently APTIOM® (eslicarbazepine acetate).


About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

Brovana® is a registered trademark of Sunovion Pharmaceuticals Inc.

Latuda® is a registered trademark of Sumitomo Dainippon Pharma Co., Ltd.

APTIOM® is under license from BIAL.

[1] DCE found that much of the treatment preference for variables: seizure control (45 percent of overall influence and 32 percent, respectively) and number of AED pills taken daily (18 percent and 17 percent, respectively). Patients also added the risk of developing psychiatric issues (depression, anxiety, or irritability) as a third important treatment attribute influencing their decision-making (20 percent influence).

[2] Additional information about APTIOM is under license from BIAL.
References


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