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**FDA APPROVES THE FIRST 3D PRINTED DRUG PRODUCT**

***Aprecia Introduces its First Product Using the ZipDose® Formulation Platform  
for the Treatment of Epilepsy***

**BLUE ASH, Ohio, August 3, 2015** – Aprecia Pharmaceuticals Company today announced that the U.S. Food and Drug Administration (FDA) has approved SPRITAM® levetiracetam for oral use as a prescription adjunctive therapy in the treatment of partial onset seizures, myoclonic seizures and primary generalized tonic-clonic seizures in adults and children with epilepsy.<sup>1</sup> SPRITAM utilizes Aprecia’s proprietary ZipDose® Technology platform, a groundbreaking advance that uses three-dimensional printing (3DP) to produce a porous formulation that rapidly disintegrates with a sip of liquid.<sup>1</sup> While 3DP has been used previously to manufacture medical devices, this approval marks the first time a drug product manufactured with this technology has been approved by the FDA.

“By combining 3DP technology with a highly-prescribed epilepsy treatment,<sup>2</sup> SPRITAM is designed to fill a need for patients who struggle with their current medication experience,” said Don Wetherhold, Chief Executive Officer of Aprecia. “This is the first in a line of central nervous system products Aprecia plans to introduce as part of our commitment to transform the way patients experience taking medication.”

ZipDose Technology enables the delivery of a high drug load, up to 1,000 mg in a single dose.<sup>2</sup> As a result, SPRITAM enhances the patient experience - administration of even the largest strengths of levetiracetam with just a sip of liquid. In addition, with SPRITAM there is no measuring required as each dose is individually packaged, making it easy to carry this treatment on the go. SPRITAM is expected to be available in the first quarter of 2016.

“In my experience, patients and caregivers often have difficulty following a treatment regimen. Whether they are dealing with a swallowing disorder or the daily struggle of getting a child to take his or her medication, adherence can be a challenge,” said Marvin H. Rorick III, M.D., neurologist at Riverhills Neuroscience in Cincinnati, Ohio. “Especially for children and seniors, having an option for patients to take their medication as prescribed is important to managing this disease.”

Nearly three million people in the United States have been diagnosed with active epilepsy, with an estimated 460,000 of those cases occurring in children.<sup>3</sup> Additionally, in a recent survey of people age 65 and older living in an independent living facility, 15 percent reported difficulty swallowing.<sup>4</sup> Other chronic conditions can impair the ability to swallow, further exacerbating the problem.<sup>5</sup>

While there are many reasons, including swallowing difficulties, for which patients may not take their medication as prescribed, missed doses of medication can undermine

treatment outcomes for conditions like epilepsy.<sup>6,7</sup> Patients with poor adherence to epilepsy drugs are more likely to have a breakthrough seizure.<sup>6</sup> In one survey completed by patients, 71 percent acknowledged having forgotten, missed or skipped a dose of seizure medication at some time, and almost half reported having had a seizure after a missed dose at some time during treatment.<sup>8</sup>

### **About ZipDose<sup>®</sup> Technology**

ZipDose Technology combines formulation science with the unique manufacturing capabilities of 3DP. Aprecia developed its ZipDose Technology platform using the 3DP technology that originated at Massachusetts Institute of Technology (M.I.T.). Using 3DP as a catalyst, Aprecia is developing formulations of medicines that rapidly disintegrate with a sip of liquid, even at high dose loads.<sup>2</sup> The company intends to manufacture them on Aprecia's proprietary equipment. Aprecia holds an exclusive, worldwide license for pharmaceutical applications of this 3DP technology.

### **About SPRITAM**

#### **INDICATIONS FOR USE**

SPRITAM (levetiracetam) is a prescription medicine taken by mouth that is used with other medicines to treat primary generalized tonic-clonic seizures in people 6 years of age and older with certain types of generalized epilepsy, myoclonic seizures in people 12 years of age and older with juvenile myoclonic epilepsy, and partial onset seizures in people 4 years of age and older with epilepsy. Administer whole SPRITAM along with a sip of liquid. SPRITAM is recommended for use in patients weighing 20 kg (44 lbs) or more.

#### **IMPORTANT SAFETY INFORMATION**

SPRITAM may not be for everyone. Ask your healthcare provider if SPRITAM is right for you.

#### **Warnings and Precautions**

Antiepileptic drugs, including SPRITAM, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your healthcare provider right away if you have new or worsening symptoms of depression, any unusual changes in mood or behavior, or suicidal thoughts, behavior, or thoughts about self-harm that you have never had before or may be worse than before.

SPRITAM may cause extreme sleepiness, tiredness, and weakness, and problems with muscle coordination. You should not drive, operate machinery or do other dangerous activities until you know how SPRITAM affects you. Call your healthcare provider right away if you have a skin rash. Serious skin rashes can happen after you start taking SPRITAM. There is no way to tell if a mild rash will become a serious reaction.

Do not stop taking SPRITAM unless instructed by your healthcare provider. Stopping a seizure medication all at once can cause seizures that will not stop, a very serious problem.

## Common Adverse Reactions

In clinical trials, the most common side effects (incidence  $\geq 5\%$  more than placebo) seen in people who take SPRITAM include sleepiness, weakness, dizziness, and infection. In addition to those previously listed, the most common side effects seen in children who take SPRITAM include tiredness, acting aggressive, nasal congestion, decreased appetite, and irritability.

Talk to your healthcare provider about other possible side effects with SPRITAM. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

For additional safety information, please see U.S. [Full Prescribing Information](#) and [Medication Guide](#) at [www.SPRITAM.com](http://www.SPRITAM.com). This information does not take the place of talking with your healthcare provider about your condition or your treatment.

SPRITAM<sup>®</sup> is a registered trademark of Aprecia Pharmaceuticals Company.

## About Aprecia

Aprecia is an emerging pharmaceutical company that uses proprietary ZipDose Technology to transform the way people take medicine. Aprecia is the first and only company in the world to utilize three-dimensional printing (3DP) technology to develop and manufacture pharmaceutical products at commercial scale. Aprecia plans to introduce multiple new products utilizing ZipDose Technology in the coming years, focusing first on the central nervous system therapeutic area, where there is a need for medicines that are easy to take. The company is privately owned, with Prasco Laboratories and its parent company, Scion Companies, holding controlling interest. For more information visit [www.aprecia.com](http://www.aprecia.com).

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<sup>1</sup> SPRITAM [package insert]. East Windsor, N.J. Aprecia Pharmaceuticals Company; 2015.

<sup>2</sup> Data on file. Aprecia Pharmaceuticals Company.

<sup>3</sup> Centers for Disease Control and Prevention. *Epilepsy Fast Facts. March 12, 2015. Available: <http://www.cdc.gov/epilepsy/basics/fast-facts.htm>. Accessed July 29, 2015.*

<sup>4</sup> Chen PH, et al. Prevalence of Perceived Dysphagia and Quality-of-Life Impairment in a Geriatric Population. *Dysphagia*. 2009;24(1):1-6.

<sup>5</sup> Ekberg O. et al. Social and psychological burden of dysphagia; its impact on diagnosis and treatment. *Dysphagia*. 2002;17:139-146.

<sup>6</sup> Davis KL, Candrilli SD, Edin HM. Prevalence and Cost of Nonadherence with Antiepileptic Drugs in an Adult Managed Care Population. *Epilepsia*. 2008. 49.

<sup>7</sup> Stegemann S, Gosch M, Breitreutz J. Swallowing dysfunction and dysphagia is an unrecognized challenge for oral drug therapy. *International Journal of Pharmaceutics*. 430 (2012) 197-206.

<sup>8</sup> Cramer JA, Glassman M, Rienzi V. The relationship between poor medication compliance and seizures. *Epilepsy and Behavior*. 08/2002; 3(4):338-342.