



## **FDA Approves Osmotica Pharmaceutical's Once-Daily OSMOLEX ER™ (amantadine) extended-release tablets for the treatment of Parkinson's Disease and Drug-Induced Extrapyrimal Reactions in Adults**

**Bridgewater, NJ – February 19, 2018** – Osmotica Pharmaceutical US LLC ("Osmotica" or the "Company"), a privately-held specialty pharmaceutical company developing novel central nervous system (CNS) treatments utilizing its proprietary osmotic drug delivery platform, announced today that the U.S. Food and Drug Administration (FDA) has approved OSMOLEX ER™, an amantadine extended release tablet, for the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients. Extrapyrimal symptoms are known side effects of many common medications.

"The FDA's approval of OSMOLEX ER provides a new treatment option for those patients suffering from Parkinson's disease and adults who have extrapyramidal reactions, or movement disorders, that are caused by certain medicines. We are eager to make OSMOLEX ER available to physicians and patients in the U.S.," stated Brian Markison, Chief Executive Officer of Osmotica.

"We are currently finalizing our plans to commercialize the product and ensure patients and providers have access as soon as possible. We believe that the approved indications and compelling value proposition will be important factors in physician adoption and marketing of OSMOLEX ER," added Markison.

OSMOLEX ER tablets, a proprietary drug formulation containing a combination of immediate release and extended release amantadine utilizing Osmotica's patented Osmodex® technology, represents a new once-a-day approach to the treatment of Parkinson's disease and drug-induced involuntary movements in adults. The OSMOLEX ER tablet is taken once-daily in the morning, releasing amantadine throughout the day. Physicians have three dosage options with 129 mg, 193 mg and 258 mg tablets, with a maximum daily dose of 322 mg, providing them with dosing flexibility for each patient.

OSMOLEX ER is protected by three formulation patents with protection extending through March 2030, with additional patent applications pending.

### **About OSMOLEX ER**

OSMOLEX ER tablets, a proprietary drug formulation containing a combination of immediate release and extended release amantadine utilizing Osmotica's patented Osmodex® technology, represents a new once-a-day approach to the treatment of Parkinson's and drug-induced extrapyramidal reactions in

adults. The OSMOLEX ER tablet is taken once-daily in the morning, releasing amantadine throughout the day. Tablet strength options include 129 mg, 193 mg, and 258 mg with a maximum daily dose of 322 mg.

For more information about OSMOLEX ER, including the full Prescribing Information, please visit [www.OSMOLEX.com](http://www.OSMOLEX.com) or call 1-877-482-3788.

## Indications

OSMOLEX ER is indicated for the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients.

## Important Safety Information

### INDICATIONS AND USAGE

OSMOLEX ER is indicated for the treatment of Parkinson's disease and for the treatment of drug induced extrapyramidal reactions in adult patients.

### CONTRAINDICATIONS

OSMOLEX ER (amantadine) extended-release tablets, is contraindicated in patients with creatinine clearance below 15 mL/min/1.73 m<sup>2</sup>.

### WARNINGS AND PRECAUTIONS

**Falling Asleep During Activities of Daily Living and Somnolence:** Patients treated with amantadine have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes has resulted in accidents. Patients may not perceive warning signs, such as excessive drowsiness, or they may report feeling alert immediately prior to the event. If a patient develops daytime sleepiness or episodes of falling asleep during activities that require full attention (e.g., driving a motor vehicle, conversations, eating), OSMOLEX ER should ordinarily be discontinued. If a decision is made to continue OSMOLEX ER, advise patients not to drive and to avoid other potentially dangerous activities that might result in harm if they become somnolent.

**Suicidality and Depression:** Suicide, suicide attempts, and suicidal ideation have been reported in patients with and without prior history of psychiatric illness while treated with amantadine. Monitor patients for depression, including suicidal ideation or behavior. Prescribers should consider whether the benefits outweigh the risks of treatment with OSMOLEX ER in patients with a history of suicidality or depression.

**Hallucinations/Psychotic Behavior:** Patients with a major psychotic disorder should ordinarily not be treated with OSMOLEX ER because of the risk of exacerbating psychosis. Monitor patients for hallucinations throughout treatment but especially after initiation and after the dose of OSMOLEX ER is increased or decreased.

**Dizziness and Orthostatic Hypotension:** Patients should be monitored for these adverse reactions, especially after starting OSMOLEX ER or increasing the dose.

Withdrawal-Emergent Hyperpyrexia and Confusion: Abrupt discontinuation of OSMOLEX ER may cause an increase in the symptoms of Parkinson's disease or cause delirium, agitation, delusions, hallucinations, paranoid reaction, stupor, anxiety, depression, or slurred speech. It is recommended to avoid sudden discontinuation of OSMOLEX ER.

Impulse Control/Compulsive Behaviors: Patients can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge eating, and/or other intense urges, and the inability to control these urges while taking one or more of the medications that increase central dopaminergic tone, including OSMOLEX ER. It is important for prescribers to specifically ask patients or their caregivers about the development of new or increased urges while being treated with OSMOLEX ER. Consider dose reduction or stopping the medication if a patient develops such urges while taking OSMOLEX ER.

#### ADVERSE REACTIONS

The most common adverse reactions reported in  $\geq 5\%$  of patients at the recommended dosage of immediate-release amantadine were nausea, dizziness/lightheadedness, and insomnia.

#### DRUG INTERACTIONS

Other Anticholinergic Drugs: The dose of anticholinergic drugs or of OSMOLEX ER should be reduced if atropine-like effects appear when these drugs are used concurrently

Drugs Affecting Urinary pH: The pH of the urine has been reported to influence the excretion rate of amantadine. Alterations of urine pH towards the alkaline condition may lead to an accumulation of the drug with a possible increase in adverse reactions. Monitor for efficacy or adverse reactions under conditions that alter the urine pH to more acidic or alkaline, respectively.

Live Attenuated Influenza Vaccines: Amantadine may interfere with the efficacy of live attenuated influenza vaccines. Therefore, live vaccines are not recommended during treatment with OSMOLEX ER. Inactivated influenza vaccines may be used, as appropriate.

Alcohol: Concomitant use with alcohol is not recommended, as it may increase the potential for central nervous system effects such as somnolence, dizziness, confusion, lightheadedness, and orthostatic hypotension.

#### **About Osmotica Pharmaceutical**

Osmotica Pharmaceutical US LLC is a privately-held fully-integrated specialty pharmaceutical company utilizing its proprietary osmotic technology platform, Osmodex<sup>®</sup>, to develop high-quality branded and generic pharmaceutical products. The Osmotica portfolio includes multiple products currently on the market, and a pipeline of therapeutic drug candidates in various stages of development, addressing central nervous system and neurological movement disorders.

Osmotica has a track record of developing products with successful commercialization strategies around the world and through its U.S. affiliates Vertical Pharmaceuticals, LLC and Trigen Laboratories, LLC. Osmotica Pharmaceutical has principal operations located in the United States, Argentina, and Hungary. For more information, please visit the Company's website at [www.osmotica.com](http://www.osmotica.com).

**Investor and Media Relations for Osmotica Pharmaceutical:**

Lisa M. Wilson

In-Site Communications, Inc.

T: 212-452-2793

E: [lwilson@insitecony.com](mailto:lwilson@insitecony.com)