Osmotica Pharmaceuticals US LLC Submits Amended NDA for Arbaclofen Extended Release Tablets to U.S. Food and Drug Administration

June 30, 2020

-- Submission based on world's largest database of patients treated for spasticity associated with Multiple Sclerosis --

-- Demonstrated efficacy, tolerability and one-year safety results on 80 mg/day --

BRIDGEWATER, N.J., June 30, 2020 (GLOBE NEWSWIRE) -- Osmotica Pharmaceuticals plc (Nasdaq: OSMT) through its subsidiary Osmotica Pharmaceutical US LLC ("Osmotica" or the "Company"), a fully integrated biopharmaceutical company, announced today that the Company has resubmitted its New Drug Application ("NDA") for arbaclofen extended release ("ER") tablets for the alleviation of spasticity in Multiple Sclerosis ("MS") patients to the U.S. Food and Drug Administration ("FDA").

"We are excited to have resubmitted our NDA for arbaclofen ER, our novel treatment, using the Osmodex technology, for MS spasticity. With the recent completion of our 12-month open-label study – assessing the long-term safety and tolerability of arbaclofen ER 80 mg/day - this resubmission also includes the full results of our second Phase 3 efficacy study ("OS440-3004"). The safety and efficacy results from these studies, together with the entire data package from our clinical development program, supports the clinical significance of arbaclofen ER as a potential treatment for MS spasticity. We look forward to working with the FDA during the course of its review," stated Brian Markison, Chief Executive Officer of Osmotica Pharmaceuticals plc.

The arbaclofen ER clinical development program represents one of the largest clinical databases of placebo-controlled and open-label studies conducted in MS spasticity patients. The key primary efficacy assessment of spasticity for the pivotal studies was the generally accepted gold standard measure, Total Numeric modified Ashworth Scale TNmAS most affected limb ("TNmAS-MAL"). In addition, a co-primary measure, the Clinician Global Assessment of Change ("CGIC") was examined to provide an assessment of patient's general well-being. The compelling evidence provided by these studies clearly demonstrated clinically improved MS spasticity in patients administered arbaclofen ER in two, large three-month, placebo-controlled studies, and in two one-year, open-label safety studies.

Results of Study OS440-3004 revealed a statistically significant improvement from baseline to Day 84 in TNmAS-MAL scores in the arbaclofen ER tablet target dose of 40 mg/day (20 mg given twice a day) group compared to the placebo group. Subjects dosed with 80 mg/day (40 mg given twice a day) also derived significant clinical benefit. Though the mean Clinical Global Impression of Change score for arbaclofen ER was not significantly better than placebo, subjects treated with arbaclofen ER tablets did not show a mean worsening of CGIC scores after treatment.

The long-term open-label study OS440-3005 dosed subjects for up to one year on arbaclofen ER. The majority of subjects enrolled completed the study on the arbaclofen 80 mg/day dose. Of particular note, subjects dosed with arbaclofen ER up to 80 mg daily showed an overall improvement from baseline scores in the TNmAS measure up to one year demonstrating the durability of arbaclofen ERs efficacy. The drug was safe and generally well tolerated throughout the study.

"We are currently unaware of any MS spasticity program that has the breadth and scope in terms of long-term safety and tolerability assessments while demonstrating efficacy," stated David Jacobs, MD MBA VP Clinical Development and Medical Affairs.

Spasticity is one of the more common and disabling symptoms of MS. Spasticity in MS is a result of demyelination along the nerves of the brain and spinal cord that control movement. Certain muscles are continuously contracted, which causes stiffness and tightness of the muscles and/or a wide range of involuntary muscle spasms. The main feature of spasticity is stiffness or increased resistance when attempting to move a limb or joint. Often, spasticity can worsen at night with tight muscles and pain from symptoms making it difficult for patients to sleep. Current anti-spastic treatment options, such as baclofen and tizanidine, as well as others, offer limited clinical benefit due to tolerability concerns.

About Arbaclofen ER

Osmotica Pharmaceutical plc is developing arbaclofen ER tablets for the treatment of spasticity in patients with MS. This program aims to demonstrate the clinical efficacy and safety of arbaclofen ER tablets in patients with spasticity due to MS.

Baclofen is a racemate (rac-baclofen) consisting of an equal mixture of two enantiomers: the l- or R-enantiomer (arbaclofen) and the d- or S-enantiomer. Arbaclofen is the active R-enantiomer of baclofen, and the literature reveals convincing evidence that the efficacy of baclofen is primarily due to the R-enantiomer whereas the S-enantiomer may be inactive and may contribute to adverse events. In a pharmacokinetic/ pharmacodynamic study in healthy volunteers, R-baclofen plasma and cerebral spinal fluid concentrations following administration of immediate-release arbaclofen and baclofen were comparable. The observed increased propensity for drowsiness to occur after baclofen administration was attributed to the S-enantiomer of baclofen.

About Osmotica Pharmaceuticals plc

Osmotica Pharmaceuticals plc is a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. Vertical Pharmaceuticals, LLC represents the Company's diversified branded portfolio and Trigen Laboratories, LLC represents the non-promoted products including complex generic formulations.

Osmotica has operations in the United States, Argentina, and Hungary.

Forward Looking Statements

This press release includes statements that express the Company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." The Company's actual results may

vary significantly from the results anticipated in these forward-looking statements, which can generally be identified by the use of forward-looking terminology, including the terms “believes,” “expects,” “may,” “will,” “should,” “seeks,” “projects,” “approximately,” “intends,” “plans,” “estimates” or “anticipates,” or, in each case, their negatives or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They include statements regarding the Company’s intentions, beliefs or current expectations concerning, among other things, our growth plan, strategies, trends and other events, particularly relating to the development, approval and introduction of new products, FDA and other regulatory applications, approvals and actions. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following: our ability to successfully develop or commercialize new products, or do so on a timely or cost effective basis; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of competition from both brand and generic companies; any interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on for our products; our ability to develop and maintain our sales capabilities; the impact of any litigation related to allegations of infringement of intellectual property; any changes to the coverage and reimbursement levels for our products by governmental authorities and other third-party payors as a result of healthcare reform or otherwise; the impact of any changes in the extensive governmental regulation that we face; manufacturing or quality control issues that we may face; and other risks and uncertainties more fully described in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2019 and other filings that the Company makes with the Securities and Exchange Commission. These forward-looking statements speak only as of the time of this release and we do not undertake to publicly update or revise them, whether as a result of new information, future events or otherwise, except as required by law.

Investor and Media Relations for Osmotica Pharmaceuticals plc
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Source: Osmotica Holdings US LLC