Osmotica Pharmaceutical US LLC Announces FDA User Fee Goal Date of December 29, 2020 for Arbaclofen Extended Release Tablets

July 20, 2020

BRIDGEWATER, N.J., July 20, 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 U.S. Food and Drug Administration (FDA) considers the Company's resubmission to its new drug application (NDA) for arbaclofen extended release (ER) tablets a complete, class 2 response to the July 9, 2016, action letter; the user fee goal date is December 29, 2020.

About Arbaclofen ER

Osmotica Pharmaceuticals 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.

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.

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