Vertical Pharmaceuticals, LLC, an Osmotica Company, Announces Acceptance of New Drug Application by FDA for RVL-1201 (Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%) for Acquired Blepharoptosis (Droopy Eyelid)

November 20, 2019

--PDUFA date of July 16, 2020--

BRIDGEWATER, N.J., Nov. 20, 2019 (GLOBE NEWSWIRE) -- Vertical Pharmaceuticals, LLC (a subsidiary of Osmotica Pharmaceuticals plc (Nasdaq: OSMT) ("Osmotica" or the "Company"), a fully integrated biopharmaceutical company) today announced that the Company received notification that the New Drug Application ("NDA") for RVL-1201 ("RVL") for Acquired Blepharoptosis (droopy eyelid or ptosis) has been filed by the U.S. Food and Drug Administration ("FDA") with a Prescription Drug User Fee Act (PDUFA) goal date of July 16, 2020.

"We are delighted that our NDA has been accepted for filing. Today, there are no pharmacologic options approved for treatment of droopy eyelid. If approved, RVL would offer physicians and patients a therapeutic option for the treatment of ptosis supported by compelling safety and efficacy data from three well-controlled pivotal studies. With the simplicity of using a once-daily eye drop, RVL has the potential to transform the clinical treatment of acquired blepharoptosis," said Brian Markison, Osmotica's Chief Executive Officer.

"We look forward to continuing to engage with key opinion leaders and the medical community to build awareness of this novel therapeutic option for the treatment of droopy eyelid. As we build out our commercial and educational strategy for RVL, we are focused on messaging and pre-launch preparation activities that target both ophthalmologists and optometrists," concluded Markison.

About Acquired Blepharoptosis

Acquired blepharoptosis is a unilateral or bilateral drooping of the upper eyelid that usually occurs from a partial or complete dysfunction of the muscles that elevate the upper eyelid. It can generally be classified as congenital or acquired, with the most common type being age-related aponeurotic ptosis. The current standard of care is surgery, which is often reserved only for severe cases and may carry an increased risk of adverse events such as infection, bleeding, and asymmetry.

About RVL-1201
RVL-1201 is a novel, once-daily ophthalmic formulation of oxymetazoline, a direct-acting α-adrenergic receptor agonist, which when administered to the eye is believed to selectively target Müller's muscle and elevate the upper eyelid. If approved, RVL-1201 will be the first pharmacologic treatment option for the wide range of patients suffering from droopy eyelid.

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, 2018 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