Vertical Pharmaceuticals LLC, an Osmotica company, Announces Presentation of Phase III RVL-1201 Clinical Trial Data in Patients with Acquired Blepharoptosis (droopy eyelid)

September 18, 2019

Results from Three Pivotal Phase III Efficacy and Safety Trials (Studies RVL-1201-201, 202 and 203) to Be Presented at Multiple Global Conferences

BRIDGEWATER, N.J., Sept. 18, 2019 (GLOBE NEWSWIRE) -- Vertical Pharmaceuticals, LLC (a subsidiary of Osmotica Pharmaceuticals plc ("Osmotica" or the "Company") (Nasdaq: OSMT), a fully integrated biopharmaceutical company) today announced that Phase III clinical trial results for RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) will be presented at multiple global congresses in October and November.

"With the New Drug Application (NDA) now submitted for RVL-1201, we are excited to have the opportunity to present these data and build upon the scientific and medical awareness of RVL-1201 and acquired blepharoptosis," said Brian Markison, Osmotica’s Chief Executive Officer.

Phase III clinical trial data for RVL-1201 will be presented at the following meetings:

- Ophthalmology Innovation Summit (OIS@AAO 2019), October 10, 2019, San Francisco, California
  - Innovation Showcase podium presentation, October 10, 2019

  - Digital presentation, Oct 10-11, 2019

  - Poster presentation, Oct 24, 4:30-6:30 pm
  - Vision Theater (podium) presentation, Oct 25, 11:00-11:30 am

- Academy of Managed Care Pharmacy (AMCP) Nexus 2019, Oct 29-Nov 1, 2019, National Harbor, Maryland
  - Poster presentation, Oct 31, 12:30-2:00 pm

- 16th annual American Academy of Aesthetic Medicine (AAAM) Congress, Nov 8-11, 2019, Las Vegas, Nevada
  - Podium presentation, Nov 9, 5:40-5:55 pm

“We are excited to present results from the Phase III RVL-1201 studies to all of our eye care colleagues this fall. This product has the potential to revolutionize the clinical treatment of acquired blepharoptosis. The study results, combined with the simplicity of using a once-daily eye drop, would make RVL-1201 a very welcome addition to our treatment armamentarium if approved by the FDA, where the only current option is surgery,” said Michael Korenfeld, MD, founder of Comprehensive Eye Care in Washington, Missouri.

“Since optometrists are the first line of care for ptosis patients and there are no pharmacologic options approved for treatment, if approved, RVL-1201 would be an exciting therapeutic option. As a safe, effective, and simple pharmaceutical treatment for acquired blepharoptosis, RVL-1201 may provide optometrists with an opportunity to build their practices and also retain their patients who currently must be referred for surgical treatment,” said Shane Foster OD, owner of Athens Eye Care in Athens, Ohio.

Phase III Trials Assessing Efficacy and Safety of RVL-1201

Two clinical trials in the U.S., Study RVL-1201-201 and Study RVL-1201-202 were conducted to demonstrate the efficacy of RVL-1201. Both were multicenter, double-masked, placebo-controlled clinical trials of 6 weeks' duration. The studies compared once-daily RVL-1201 with placebo (vehicle) in subjects with acquired blepharoptosis. The primary efficacy endpoint was the mean change from baseline in the number of points seen on the Leicester Peripheral Field Test, which measures the superior (upper) field of vision. Secondary efficacy endpoints included change from baseline in marginal reflex distance (MRD1), which measures the distance from the center pupillary light reflex to the central margin of the upper eyelid. Safety assessments included adverse event monitoring and reporting, vital sign monitoring, and ophthalmic examination.

A third clinical trial conducted in the U.S., Study RVL-1201-203, assessed the long-term safety of RVL-1201. The study was a multicenter, double-masked, placebo-controlled trial conducted over 84 days. The primary endpoint was safety as assessed by adverse event monitoring and reporting throughout the study. Additional assessments included tolerability and ophthalmic examination (pupil diameter, Snellen visual acuity, corneal fluorescein staining, and intraocular pressure).

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.

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. The 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. If approved, RVL-1201 will be the first pharmacologic treatment option for the wide range of patients suffering from droopy eyelids.

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

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