Osmotica Pharmaceuticals plc Announces Positive Topline Results of Phase III Clinical Trials of RVL-1201 (“RVL”) for Acquired Blepharoptosis (ptosis or droopy eyelid)

May 6, 2019

-Second Phase III Study 202 Meets Primary Endpoint; Provides Additional Evidence of Efficacy and Safety -

- Long-term Phase III Study 203 Provides Additional Evidence of Safety -

- Company to Host Conference Call on Tuesday, May 7th at 12pm ET with Dr. Chuck Slonim and Dr. Shane Kannarr -

BRIDGEWATER, N.J., May 06, 2019 (GLOBE NEWSWIRE) -- Osmotica Pharmaceuticals plc (“Osmotica” or the “Company”) (Nasdaq: OSMT), a fully integrated biopharmaceutical company, today announced positive topline results of its second Phase III efficacy and safety clinical trial (Study 202) of RVL (oxymetazoline hydrochloride ophthalmic solution, 0.1%) and long-term Phase III safety study (Study 203) for the treatment of ptosis (droopy eyelid).

“We are very pleased with the positive topline results of our second Phase III clinical Study 202 of RVL for the treatment of ptosis evaluating efficacy and safety compared to placebo. Our topline readout is consistent with our prior study results, which demonstrated a statistically significant improvement in the visual field of patients that were administered our once-daily drop. The topline readout also suggests that RVL was well tolerated by patients in this study. Given the positive topline results from this study, combined with our recently completed long-term safety Study 203, we intend to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2019. If approved, we could be on the market as early as the second half of 2020,” said Brian Markison, Chairman and Chief Executive Officer at Osmotica.

“We believe there is a large prevalence of ptosis and today there is no FDA-approved pharmacologic intervention for any of these patients. If approved, RVL would be the first non-surgical option available for patients. Administered as a single drop once daily, RVL has the potential to significantly improve the visual field of individuals living with the clinical sequelae of ptosis,” added Markison.

Study Design and Outcomes

Osmotica conducted a second Phase III, randomized, multicenter, double-masked, placebo-controlled, 6-week study (Study 202) to evaluate the efficacy and safety of a once-daily treatment of RVL compared to placebo for the treatment of ptosis.

Study 202 randomized 164 subjects (109 subjects on RVL and 55 subjects on placebo) in a 2:1 randomization scheme.

The primary efficacy endpoint was the mean change from baseline in the RVL group versus placebo group in the number of points seen on the top 4 rows of the Leicester Peripheral Field Test (LPFT) in the study eye at each of the following time points:

- Day 1 Hour 6
- Day 14 Hour 2

The increases at both time points in the number of points seen in the superior visual field (change in LPFT) in the RVL group compared to the placebo group were highly statistically significant ($p < 0.0001$). RVL administered once daily to patients was also generally well tolerated in this study. The overall incidence of adverse events (AEs) was similar to that of placebo.

The topline results from Study 202 are consistent with the results of Osmotica’s previously reported Phase III Study 201, which evaluated the efficacy and safety of RVL in patients with ptosis.

Additionally, Osmotica conducted a 12-week, randomized, multicenter, double-masked, placebo-controlled Phase III study (Study 203) to evaluate the long term safety of RVL compared with placebo in the treatment of ptosis. The study included 234 patients (157 RVL and 77 Placebo) who were randomized in a 2:1 ratio, receiving either RVL or placebo once a day. RVL was generally well tolerated in this study, and the AEs that were observed were predominantly mild in intensity. A total of 50 subjects (31.8%) in the RVL group and 23 subjects (29.9%) in the placebo group reported AEs. There were no deaths during the study. Two subjects in the RVL group experienced a Serious AE that were not considered related to study medication.

Conference Call

Brian Markison (Chief Executive Officer), JD Schaub (Chief Operating Officer), Tina deVries (EVP Research and Development), David Jacobs (VP Clinical Development), Dr. Chuck Slonim (Key Opinion Leader), and Dr. Shane Kannarr (Key Opinion Leader), will host a conference call as follows:

Date	Tuesday, May 7, 2019
Time	12:00 p.m. EDT
Toll free (U.S.)	(866) 672-5029
International	(409) 217-8312
Conference ID	7986401

Webcast (live and replay)	www.osmotica.com under the “Investor & News” section

The webcast will be archived for 30 days at the aforementioned URL.

About Acquired Blepharoptosis
Blepharoptosis is drooping of the upper eyelid that usually occurs from a partial or complete dysfunction of the muscles that elevate the upper eyelid. If FDA approved, RVL would be the first non-surgical treatment option for patients with acquired blepharoptosis.

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. Our diversified product portfolio in the specialty neurology and women's health therapeutic areas, together with our non-promoted complex formulations of generic drugs, form the foundation of our unwavering commitment to improve patients' lives.

Osmotica has a late-stage development pipeline highlighted by two NDA candidates that recently completed Phase III clinical trials: arbaclofen extended-release tablets for spasticity in multiple sclerosis patients and RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for the treatment of blepharoptosis, or droopy eyelid.

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 results of operations, financial condition, liquidity, prospects, financial guidance, growth plan, strategies, trends and other events, particularly relating to sales of current products and the development, approval and introduction of new products, FDA and other regulatory applications, approvals and actions, the continuation of historical trends, our ability to operate our business under our new capital and operating structure, and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs. 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; our dependence on a limited number of products; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of legal proceedings; our ability to service our substantial debt; our ability to raise additional capital; 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 dependence on our major customers; 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.

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

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