



NEWS RELEASE

Omeros Corporation Announces Publication of Study Results on the Impact of OMIDRIA on Opioid Use and Pain

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-- Study Demonstrates Opioid-Sparing Requirement of OMIDRIA for CMS Packaging Exclusion --

SEATTLE--(BUSINESS WIRE)--Nov. 4, 2019-- Omeros Corporation (Nasdaq: OMER) today announced that results of a prospective, controlled study showing that its FDA-approved ophthalmic drug OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% reduces use of the opioid fentanyl during cataract surgery while also reducing surgical pain were published today in the peer-reviewed journal *Clinical Ophthalmology*. The article, *The Effect of Phenylephrine/Ketorolac Intracameral Solution 1%/0.3% on Pain and Opioid Use During Cataract Surgery*, is authored by the study investigator Eric D. Donnenfeld, M.D., Clinical Professor of Ophthalmology at New York University and recent past president of the American Society of Cataract and Refractive Surgery. OMIDRIA is approved by FDA for prevention of miosis (pupil constriction) and for reduction in postoperative pain for adults and pediatric patients undergoing cataract or lens replacement surgery.

The study objectives were to evaluate the effect of OMIDRIA compared to epinephrine on perioperative fentanyl use and pain in patients undergoing cataract surgery. Sixty patients were prospectively assigned to have either OMIDRIA (41 patients) or epinephrine (19 patients) added to the irrigation solution used during surgery. Patients in the OMIDRIA group were 6.7 times more likely **NOT** to require fentanyl, with 9.8 percent of OMIDRIA patients

requiring fentanyl versus 42.1 percent of epinephrine patients ($P = 0.006$). In addition, mean visual analog scale (VAS of 0-10) pain scores were significantly (48.9 percent) lower in the OMIDRIA group than in the epinephrine group (2.3 vs 4.5; $P < 0.0001$). The proportion of patients with VAS scores ≤ 3 (considered no to minimal pain) was significantly greater in the OMIDRIA group (85.0 percent) than in the epinephrine group (31.6 percent; $P < 0.0001$). OMIDRIA patients also were 94 percent less likely to require fentanyl or to have moderate-to-severe pain (VAS ≥ 4) than patients receiving epinephrine (odds ratio 0.06; 95 percent confidence interval 0.02-0.24).

“Our study found that OMIDRIA cut intraoperative pain scores in half while markedly reducing the need for fentanyl during cataract surgery,” said Dr. Donnenfeld. “Fentanyl is a mainstay of anesthesia during cataract surgery. The ability of OMIDRIA to reduce pain and the need for fentanyl is a welcome advance for cataract surgery patients, a population already at risk for increased exposure to and dependence on opioids. OMIDRIA is the only drug used during cataract surgery that has demonstrated these important benefits.”

Deaths in the U.S. from synthetic opioids, especially fentanyl, have increased more than 10-fold between 2013 and 2018 and are now involved in twice as many deaths as heroin. Reduction of opioid use in cataract surgery patients is a public health focus and many studies have shown that the use of intraoperative opioids is associated with an increased postoperative opioid requirement. Cataract surgery patients who receive an opioid prescription are 1.6 times more likely to be using opioids long-term than those who are not prescribed an opioid following cataract surgery.

Congress and CMS understand the public health risk associated with opioid exposure and CMS is required under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act to review payments under its outpatient prospective payment system (OPPS) for opioids and evidence-based non-opioid alternatives for pain management with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. In its 2020 OPPS final rule published on November 1, CMS did not add any products to the non-opioid exclusion from packaged payment. Although CMS had received an analysis of the Donnenfeld data, CMS specifically requested peer-reviewed published evidence and the Donnenfeld study had not yet been published at the time the final rule was issued. With the publication of the Donnenfeld opioid-sparing data, Omeros believes that OMIDRIA meets all of CMS' requirements for the non-opioid exclusion.

“The results of this study represent yet another example of real-world evidence demonstrating the benefits of OMIDRIA,” stated Gregory A. Demopulos, MD, chairman and chief executive officer of Omeros. “Omeros supports CMS' intention and Congress' mandate to remove incentives that lead to increased opioid use, and we are optimistic that CMS will recognize the clear and convincing evidence that packaging OMIDRIA does create such a perverse incentive. OMIDRIA can be readily accessed by veterans as well as commercially insured and Med Advantage patients. We look forward to working with CMS to reduce opioid use and improve patient care by

ensuring long-term access to OMIDRIA for Medicare Part B beneficiaries.”

CMS stated in the final rule that it will continue to analyze the evidence in support of the benefits of OMIDRIA and monitor utilization of this drug, and Omeros intends to address CMS’ OMIDRIA-related comments. Omeros also plans to continue its administrative and legislative efforts to secure ongoing separate payment for OMIDRIA beyond the drug’s current pass-through extension. OMIDRIA continues to receive separate payment from CMS under its pass-through extension until October 1, 2020.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. In addition to its commercial product **OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%**, Omeros has multiple clinical-stage development programs focused on complement-mediated diseases and substance abuse, as well as a diverse group of preclinical programs including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis recently discovered by Omeros. Small-molecule inhibitors of GPR174 are part of Omeros’ proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and their corresponding compounds. The company also exclusively possesses a novel antibody-generating platform.

About OMIDRIA®

Omeros’ OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is the first and only FDA-approved product of its kind and is marketed in the U.S. for use during cataract surgery or intraocular lens replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. OMIDRIA also is the only NSAID-containing product FDA-approved for intraocular use. In post-launch studies across conventional and femtosecond laser-assisted cataract surgery, OMIDRIA has been shown (1) to be effective in patients with intraoperative floppy iris syndrome (IFIS), pseudoexfoliation and other ophthalmic conditions, (2) to significantly reduce complication rates, use of pupil-expanding devices, and surgical times, and (3) to significantly improve uncorrected visual acuity on the first day following cataract surgery. While OMIDRIA is broadly indicated for use in cataract surgery, the above outcomes are not in its currently approved labeling.

Important Safety Information for OMIDRIA®

Systemic exposure of phenylephrine may cause elevations in blood pressure. In clinical trials, the most common reported ocular adverse reactions at two percent or greater are eye irritation, posterior capsule opacification,

increased intraocular pressure, and anterior chamber inflammation; incidence of adverse events was similar between placebo-treated and OMIDRIA-treated patients. OMIDRIA must be added to irrigation solution prior to intraocular use.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the “safe harbor” created by those sections for such statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “likely,” “look forward to,” “may,” “on track,” “plan,” “potential,” “predict,” “project,” “prospects,” “scheduled,” “should,” “slated,” “targeting,” “will,” “would” and similar expressions and variations thereof. Forward-looking statements, including statements regarding payment and reimbursement status, expectations for continued separate payment for OMIDRIA and expected qualification for an exception from packaged payment, are based on management’s beliefs and assumptions and on information available to management only as of the date of this press release. Omeros’ actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, availability and timing of data from ongoing clinical trials and the results of such trials, changes in regulatory policy, political factors, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading “Risk Factors” in the company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2019. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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