



NEWS RELEASE

Omeros Announces Successful Outcome of OMIDRIA® Pediatric Cataract Trial

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-- Six-Month Extension of Patent Exclusivity and Label Expansion Expected --

SEATTLE--(BUSINESS WIRE)--Nov. 21, 2016-- Omeros Corporation (NASDAQ: OMER) today announced the successful outcome of its recently completed post-marketing clinical trial of the effect of OMIDRIA® (phenylephrine and ketorolac injection) 1% / 0.3% in pediatric patients undergoing cataract surgery. OMIDRIA is approved by the FDA for use in adult patients undergoing cataract or intraocular lens replacement surgery to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain and is not currently approved for use in patients less than 18 years of age.

This pediatric trial enrolled approximately 70 children aged birth through 3 years undergoing cataract surgery. Patients received either OMIDRIA or phenylephrine added to the irrigation solution used during the surgical procedure. As directed by FDA and because cataracts are relatively rare in children, the trial was powered only to detect common adverse events and was not powered for efficacy. In the trial, OMIDRIA was safe and well tolerated with adverse event rates consistent with those seen in pediatric cataract surgery and similar in the OMIDRIA and phenylephrine groups. Mean pupil diameter numerically increased following administration of OMIDRIA. Mean postoperative pediatric pain scores of OMIDRIA-treated patients were low (generally less than 0.5 on a scale of 0-10) and were numerically lower in the OMIDRIA group relative to the phenylephrine group.

The pediatric trial was undertaken as an FDA post-marketing requirement under the Pediatric Research Equity Act and in fulfillment of FDA's Written Request provided under the Best Pharmaceuticals for Children Act. Successful completion of the trial, including submission of a supplemental New Drug Application (sNDA) that includes the full clinical study report and proposed labeling, fulfills the post-marketing requirement and results in eligibility for an additional 6 months of marketing exclusivity for OMIDRIA as well as label expansion to include information on dosing for pediatric patients. Following FDA's review of the sNDA, the FDA-approved indication and labeling for OMIDRIA will be updated to reflect the trial results. Although conducted in patients newborn to 3 years old, the FDA agreed that results from this trial can be extrapolated to patients through 18 years of age, and a label expansion would be expected to be applicable to that full age range.

"We're pleased with the positive results of this trial, in which OMIDRIA was shown to be safe and well tolerated in children and provides benefits in this younger population consistent with those in adults," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "We look forward to receiving extended patent exclusivity for OMIDRIA and to expanding its label to include pediatric patients without age limitation."

About OMIDRIA®

Omeros' OMIDRIA® (phenylephrine and ketorolac injection) 1% / 0.3% is the only FDA-approved product 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 in adults, the above outcomes are not in its currently approved labeling. Surgical time was not an endpoint in the OMIDRIA Phase 3 clinical trials and did not reach statistical significance in post hoc analysis of the Phase 3 data.

Important Risk 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 to 24 percent 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. OMIDRIA is not approved for use in children.

About Omeros Corporation

Omeros is a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Part of its proprietary PharmacoSurgery® platform, the company's first drug product, OMIDRIA® (phenylephrine and ketorolac injection) 1% / 0.3%, was broadly launched in the U.S. in April 2015. OMIDRIA is the first and only FDA-approved drug (1) for use during cataract surgery or intraocular lens (IOL) replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain and (2) that contains an NSAID for intraocular use. In the European Union, the European Commission has approved OMIDRIA for use in cataract surgery and lens replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; Huntington's disease and cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a proprietary G protein-coupled receptor (GPCR) platform, which is making available an unprecedented number of new GPCR drug targets and corresponding compounds to the pharmaceutical industry for drug development, and a platform used to generate antibodies.

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," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. Forward-looking statements 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, risks associated with product commercialization and commercial operations, unproven preclinical and clinical development activities, regulatory oversight, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading "Risk Factors" in the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2016. 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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