



Press Release

Omeros' Ophthalmology Product OMS302 Achieves Primary and Secondary Endpoints in Phase 3 Clinical Trial

-- Company to Host Conference Call Today at 9:00 a.m. EDT--

SEATTLE, March 13, 2012 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) today reported positive data from its Phase 3 clinical trial evaluating OMS302 in patients undergoing intraocular lens replacement surgery. OMS302 met its primary endpoint by demonstrating statistically significant ($p < 0.00001$) maintenance of intraoperative mydriasis (pupil dilation). OMS302 also demonstrated statistical superiority ($p < 0.00001$) over placebo in reduction of pain in the early postoperative period. The data for both endpoints are clinically meaningful. OMS302, added to standard irrigation solution used during ophthalmological procedures, is Omeros' proprietary PharmacoSurgery™ product designed to maintain intraoperative mydriasis and reduce postoperative pain and irritation resulting from cataract and other lens replacement surgery.

This multicenter, double-blind, Phase 3 clinical trial enrolled 405 patients randomized 1:1 to receive either OMS302 or placebo. The primary endpoint was maintenance of intraoperative mydriasis (pupil dilation), which is critical to the safety and surgical ease of lens replacement surgery. Pupil constriction during surgery increases the risk of injury to intraocular structures and can substantially prolong surgical time. In addition to statistical superiority over placebo in maintenance of mydriasis and the secondary endpoint of reduced postoperative pain, OMS302 achieved p values of less than 0.05 in a series of other clinically relevant measures.

In this study, OMS302 was well-tolerated. The most common adverse events were those related to surgery, specifically eye pain, eye inflammation, headache and increased intraocular pressure. The incidence of these adverse events was similar between OMS302- and placebo-treated patients. The complete data are expected to be presented at an upcoming major ophthalmology meeting. Omeros also plans to publish the data in a leading peer-reviewed ophthalmology journal.

"The data from this study are compelling and demonstrate that OMS302 addresses a universal need in lens replacement surgery," stated Alan S. Crandall, M.D., director of glaucoma and cataract, senior vice chairman of ophthalmology and visual sciences at the Moran Eye Center, University of Utah, and past president of the American Society of Cataract and Refractive Surgery. "Ophthalmologic surgeons are committed to successful outcomes for their patients, and maintenance of mydriasis and pain management are central to that success. Given the drug's demonstrated effects on these two challenges facing all lens replacement surgeons, I expect that OMS302 could become widely used."

"Maintenance of mydriasis throughout the procedure is essential for the safety of lens replacement surgery," stated Mark I. Rosenblatt, M.D., Ph.D., associate professor of ophthalmology, Weill Cornell Medical College. "A constricted pupil decreases the surgeon's operative field, which can make the procedure more difficult to perform and potentially increases the rates of complications, including rents in the lens capsule or the retention of cortical lens material with more frequent posterior capsular opacification or lens dislocation. In addition, the pain relief from this drug combination improves the surgical experience for the patient and assists the surgeon in pain management during the critical early postoperative period."

"This is an important day for Omeros. This achievement marks our transition to a company preparing, rather than hoping, to commercialize our first product," said Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "Following our recent successful meetings with U.S. and European regulators, we plan to begin enrolling patients in our second Phase 3 trial early next month and to submit marketing applications in both the U.S. and Europe in the first part of 2013."

Omeros' OMS302 Program

OMS302 is Omeros' product being developed for use during intraocular lens replacement (ILR) surgery, including cataract surgery and refractive lens exchange. OMS302 is a proprietary combination of ketorolac, an anti-inflammatory agent, and phenylephrine, a mydriatic (pupil dilating) agent. FDA-approved drugs containing each of these agents have been used in ophthalmological clinical practice for more than 15 years, and both are contained in generic, FDA-approved drugs.

ILR surgery involves replacement of the original lens of the eye with an artificial intraocular lens. These procedures are typically performed to replace a lens opacified by a cataract or to correct a refractive error of the lens (i.e., refractive lens exchange). OMS302 is added to standard irrigation solution used in ILR surgery and delivered intracamerally to maintain intraoperative mydriasis (pupil dilation), to prevent surgically induced miosis (pupil constriction), and to reduce postoperative pain and irritation. Maintenance of mydriasis is critical to the safety and surgical ease of the procedure. Intraoperative pupil constriction increases the risk of injury to intraocular structures and can substantially prolong surgical time.

About Ophthalmological Procedures (Cataract and Other Lens Replacement Surgery)

There are 3.6 million intraocular lens replacement procedures expected in the U.S. this year and 20 million worldwide, with a projected annual growth rate of three to four percent, resulting in over four million U.S. and 23 million worldwide procedures by 2016. An important segment of this market is premium lens procedures. The premium market includes toric, multifocal and accommodating lenses. In 2011, in the U.S., 16 percent of all lens replacement procedures were premium and that number is expected to grow to 26 percent in 2016. Refractive lens exchange is also a growing segment of the lens replacement market.

Conference Call and Webcast Today at 9:00 a.m. EDT

Omeros management will host a conference call today, March 13, at 9:00 a.m. EDT to discuss today's news. To access the live call by telephone, please dial 866-788-0541 (United States and Canada) or 857-350-1679 (International). The passcode is 98382880. In addition, the live conference call will be webcast and can be accessed on the "Events" page of the Company's website at <http://www.omeross.com>.

A replay of the webcast will be available on the Company's website for one week. A telephone replay will also be available for one week starting at 9:30 a.m. EDT today, which can be accessed by dialing 888-286-8010 (United States and Canada) or 617-801-6888 (International) and entering passcode 35583097.

About Omeros Corporation

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. The Company's most clinically advanced product candidates are derived from its proprietary PharmacoSurgery™ platform designed to improve clinical outcomes of patients undergoing a wide range of surgical and medical procedures. Omeros has four ongoing clinical development programs. Omeros may also have the near-term capability, through its GPCR program, to add a large number of new drug targets and their corresponding compounds to the market. Behind its clinical candidates and GPCR platform, Omeros is building a diverse pipeline of protein and small-molecule preclinical programs targeting inflammation, coagulopathies and central nervous system disorders.

Forward-Looking Statements

This press release contains forward-looking statements as defined within the Private Securities Litigation Reform Act of 1995, which are subject to the "safe harbor" created by those sections. These statements include, but are not limited to, statements regarding the potential benefits of OMS302; the Company's plans to present and publish the data from the Phase 3 clinical trial; OMS302's expected adoption by surgeons; Omeros' plans to begin enrolling patients in its second OMS302 Phase 3 trial early next month and to submit marketing applications in both the U.S. and Europe in the first part of 2013; the projected number of ophthalmological procedures in the U.S. and worldwide; and that Omeros may have capability, through its GPCR program, to add a large number of new drug targets and their corresponding compounds to the market. 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, 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 8, 2011. 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 publicly, even if new information becomes available in the future.

SOURCE Omeros Corporation

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