



Press Release

Omeros Submits New Drug Application to U.S. FDA for OMS302

- Submission of European Marketing Authorization Application Planned for this Quarter -

SEATTLE, Aug. 1, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) announced that the company recently submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration for approval of OMS302 for use in patients undergoing intraocular lens replacement (ILR) surgery. Added to standard irrigation solution used during ILR, OMS302 is Omeros' proprietary PharmacoSurgery™ product that, across multiple human trials, demonstrated clinically meaningful and statistically significant maintenance of intraoperative mydriasis (pupil dilation), prevention of intraoperative miosis (pupil constriction), and reduction of postoperative ocular pain.

In addition, Omeros plans to submit a Marketing Authorization Application to the European Medicines Agency (EMA) via the EMA's centralized procedure this quarter. The company has recently been granted designation by the EMA as a Small or Medium-Sized Enterprise (SME). Through the SME program, Omeros can benefit from elimination or reduction of certain fees related to the clinical development and approval processes in Europe for OMS302 and other Omeros products.

"OMS302 fills a need recognized by all ophthalmic surgeons and does so without requiring them to change their routine operating procedures," stated Eric B. Donnenfeld, M.D., clinical professor of ophthalmology at New York University and president of the American Society of Cataract and Refractive Surgery. "Based on the results of the clinical trials, OMS302 has the potential to improve outcomes in all lens replacement surgeries. I look forward to being able to use the product in my practice – it provides benefits to both patients and their surgeons."

"This NDA submission represents the culmination of a tremendous amount of work by the Omeros team and our collaborators and a major milestone for the company, our employees and our shareholders," said Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "We are preparing for a successful market launch of OMS302 and look forward to completing the transition from a development-stage to a commercial company. We expect that OMS302 will generate revenues that continue to drive our pipeline, yielding a long line of Omeros products to improve the lives of patients."

About Omeros' OMS302 Program

OMS302 is Omeros' product being developed for use during intraocular lens replacement (ILR), including cataract surgery and refractive lens exchange. OMS302 is a proprietary combination of the mydriatic (pupil dilating) agent phenylephrine and the anti-inflammatory

agent ketorolac. Omeros recently submitted a New Drug Application to the U.S. Food and Drug Administration and plans to submit a Marketing Authorization Application to the European Medicines Agency later this quarter.

ILR 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 and delivered within the eye to maintain intraoperative mydriasis (pupil dilation), to reduce 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 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, OMS302 for lens replacement surgery and OMS103HP for arthroscopy, 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 six 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 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. These statements include, but are not limited to, Omeros' expectations regarding the potential benefits of OMS302; the timing for submission of a Marketing Authorization Application for OMS302 to the European Medicines Agency; potential OMS302 marketing approval; the date of the expected market launch of OMS302, if regulatory approval is obtained; the potential benefits of Omeros' products; 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 May 9, 2013. 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

Jennifer Cook Williams, Cook Williams Communications, Inc., Investor and Media

Relations, +1-360-668-3701, jennifer@cwcomm.org

©2005-2012 Omeros Corporation, All rights reserved.