SEATTLE, Oct. 2, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) announced today that the New Drug Application (NDA) for its ophthalmology product, OMS302, has been confirmed for filing by the U.S. Food and Drug Administration (FDA), which means that the application, submitted in July of this year, is sufficiently complete to permit a substantive review. The company also announced that its Marketing Authorization Application (MAA) for OMS302, submitted last month, has been validated by the European Medicines Agency (EMA). Validation of the MAA confirms that the submission package is administratively complete and is ready for formal review by
Europe's
Committee for Medicinal Products for Human Use (CHMP).

Omeros is seeking approval of OMS302 for use during intraocular lens replacement (ILR) surgery for the maintenance of intraoperative mydriasis (pupil dilation), prevention of intraoperative miosis (pupil constriction), and reduction of postoperative ocular pain. The NDA will undergo FDA's standard review, and the MAA has been designated for EMA's centralized procedure in which a recommendation for approval by CHMP would cover approval for marketing of OMS302 across all European Union Member States and other countries in the European Economic Area.

"The acceptance for filing of our NDA by the FDA and validation of our MAA by the EMA mark important milestones on the path toward the commercial launch of OMS302 expected in 2014," stated Gregory A. Demopulos, M.D., chairman and chief executive officer of Omeros. "We look forward to continuing to work with the FDA and CHMP as they conduct their reviews."

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' NDA for OMS302 has been accepted for filing by the FDA and its MAA for OMS302 has been validated by the EMA.

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 small-molecule and protein therapeutics targeting inflammation, coagulopathies and disorders of the central nervous system. Derived from its proprietary PharmacoSurgery ® platform, the Company's lead drug product, OMS302 for lens replacement surgery, is currently under review for marketing approval by both the US Food and Drug Administration and the European Medicines Agency with commercial launch planned for 2014. Omeros' five other clinical programs are focused on schizophrenia, Huntington's disease and cognitive impairment; addictive and compulsive disorders; complement-related diseases; and preventing problems associated with surgical procedures. Omeros also has a proprietary GPCR platform, which is making available an unprecedented number of new GPCR drug targets and corresponding compounds to the pharmaceutical industry for drug development.

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 date of the planned market launch of OMS302. 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 August 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.

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