



Press Release

European Medicines Agency Approves Positive Opinion on Omeros' Pediatric Investigation Plan for OMS302

-- Submission of Marketing Authorization Application Remains on Track for Mid-Year--

SEATTLE, July 2, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) today announced that the European Medicines Agency (EMA) approved a positive opinion issued by the European Pediatrics Committee (PDCO) agreeing to the Company's Pediatric Investigation Plan (PIP) for OMS302. EMA's approval of PDCO's positive opinion is a prerequisite for submission of the OMS302 Marketing Authorization Application (MAA) and, on completion of the post-marketing pediatric study, leads to an additional six months of patent exclusivity for OMS302 in Europe. OMS302, added to standard irrigation solution used during ophthalmological procedures, is Omeros' proprietary PharmacoSurgery™ product designed to maintain intraoperative mydriasis (pupil dilation), prevent surgically induced miosis (pupil constriction), and reduce postoperative pain resulting from cataract and other lens replacement surgery.

Omeros' PIP provides a study plan to evaluate the drug's safety and efficacy in patients 13-17 years old. Omeros received a waiver for studying the use of OMS302 in patients younger than 13 years and a deferral to complete the clinical study following EMA approval. With completion of the study as specified under the PIP, Omeros will be eligible to receive an additional six months of marketing exclusivity for OMS302 in the European Union (E.U.). This six-month period would extend beyond the expiration of Omeros' patents directed to OMS302, which will expire in the E.U. in 2023 for issued patents and 2033 for patents expected to issue from currently pending patent applications. This six-month extension is in addition to a supplementary protection certificate, which together could provide up to another five and one half years of market exclusivity for OMS302. Omeros is pursuing a similar but separate process in the U.S. for studying the use of OMS302 in pediatric patients, which is expected to lead to additional marketing exclusivity in the U.S. Submission of the New Drug Application (NDA) for OMS302 in the U.S. will precede the MAA submission, and both applications will include additional stability data to extend expiry dating at the time of expected commercial launch.

"Although cataract surgery in pediatric patients is uncommon, we expect that OMS302 will provide similar benefits to those that we have seen in adults undergoing lens replacement," stated Gregory A. Demopulos, M.D., chairman and chief executive officer of Omeros. "We will gain important clinical information

from the PIP study and, once completed, we expect to receive an additional six months of European marketing exclusivity. With agreement from the EMA on our pediatric plan, we remain on schedule for a mid-year submission of the OMS302 MAA, and we look forward to providing European ophthalmic surgeons and their patients access to the drug in 2014."

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 completed its successful OMS302 Phase 3 clinical program and expects to submit a New Drug Application to the U.S. Food and Drug Administration this quarter and a Marketing Authorization Application to the European Medicines Agency in mid-2013.

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 five 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, Omeros' expectations regarding its plans to complete the Pediatric Investigation Plan; potential market exclusivities for OMS302; the potential clinical benefits of OMS302; the timing for submission of a New Drug Application for OMS302 to the U.S. FDA and a Marketing Authorization Application for OMS302

to the European Medicines Agency; potential OMS302 marketing approval; 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

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