



NEWS RELEASE

Omeros Corporation Confirms OMS721 Phase 3 Development Plan with European Medicines Agency

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-- One Single-Arm, Open-Label Phase 3 Pivotal Trial Planned to Support Approval in Both Europe and the U.S. --

SEATTLE, July 28, 2016 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) today announced that it has received scientific advice from the European Medicines Agency (EMA) in connection with the company's OMS721 Phase 3 program for the treatment of atypical hemolytic uremic syndrome (aHUS). Based on this EMA advice, the company plans to run the same, single Phase 3 clinical program to support OMS721 marketing approval applications in both the U.S. and in the European Union for the treatment of aHUS. OMS721 is Omeros' lead human monoclonal antibody in its mannan-binding lectin-associated serine protease-2 (MASP-2) program for the treatment of thrombotic microangiopathies (TMAs), including aHUS and hematopoietic stem cell transplant-related (HSCT) TMAs, and for the treatment of complement-related renal diseases. Omeros plans to commercialize OMS721 initially for administration as a subcutaneous injection.

The company met with the EMA's Scientific Advice Working Party earlier this month to discuss the requirements for a successful European Marketing Authorization Application (MAA) for OMS721 in the treatment of aHUS. The advice provided to Omeros by the EMA is generally consistent with that received from the U.S. Food and Drug Administration (FDA) earlier this year and will allow Omeros to submit applications for approval in the U.S. and in the European Union based on a single data set, which includes the results from one pivotal clinical trial – a single-arm (i.e., no control arm), open-label study in patients with newly diagnosed or ongoing aHUS. As also agreed with

the FDA, the EMA will allow the safety of OMS721 to be demonstrated in patients with diseases other than aHUS. Patient enrollment numbers required for European approval are consistent with Omeros' plans for accelerated approval in the U.S.

Initiation of enrollment in the aHUS Phase 3 clinical trial is planned for late this year. The Phase 3 program will include patients from the Phase 2 TMA trial. In addition to the ongoing trial in patients with aHUS, Phase 2 trials are currently underway evaluating OMS721 in patients with (1) HSCT-related TMAs, (2) thrombotic thrombocytopenic purpura or (3) complement-related renal disease. In the U.S., OMS721 has received both orphan designation for the treatment of TMAs and fast-track status for the treatment of aHUS, and the company plans to request orphan designation in Europe.

"We are pleased with the advice that we received from EMA, which further solidifies the company's strategy to commercialize OMS721," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "FDA's and EMA's advice are consistent and outline a clear and feasible Phase 3 development path for OMS721. We look forward to completing the single Phase 3 trial for both regulatory agencies and to making OMS721 widely available to patients with aHUS."

About Omeros' MASP Program

Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2, a novel pro-inflammatory protein target involved in activation of the complement system, which is an important component of the immune system. The complement system plays a role in the inflammatory response and becomes activated as a result of tissue damage or microbial infection. MASP-2 appears to be unique to, and required for the function of, one of the principal complement activation pathways, known as the lectin pathway. Importantly, inhibition of MASP-2 does not appear to interfere with the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection and is associated with a wide range of autoimmune disorders. Adults who are genetically deficient in one of the proteins that activate MASP-2 do not appear to be detrimentally affected by the deficiency. Omeros has received both orphan drug status and fast track designation from the U.S. FDA for its lead human MASP-2 antibody OMS721. Omeros has an ongoing Phase 3 clinical program for OMS721 in atypical hemolytic uremic syndrome, an ongoing Phase 2 program targeting hematopoietic stem cell transplant-related thrombotic microangiopathy as well as thrombotic thrombocytopenic purpura and another ongoing Phase 2 program targeting complement-related renal diseases. An investigator-requested compassionate use program for OMS721 is also underway. OMS721 has demonstrated no safety concerns in human trials or chronic toxicity studies. In addition to potential intravenous administration, Omeros plans to commercialize OMS721 for one or more therapeutic indications as a subcutaneous injection.

Omeros also believes that it has identified the protein that activates the complement system's alternative pathway

in humans, which is linked to a wide range of immune-related disorders. In addition to its MASP-2 program focused on antibody and small-molecule inhibitors of the lectin pathway, the company has another complement program, OMS906, which is advancing the development of antibodies and small molecules targeting MASP-3 that block activation of the alternative pathway. Omeros exclusively controls inhibition of the effector enzyme of the lectin pathway (MASP-2) and inhibition of the protein activator of the alternative pathway (MASP-3), allowing the company to target with unprecedented precision diseases caused by dysregulation of one or both of these pathways.

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. Derived from 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 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. 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 five clinical-stage development programs focused on: complement-related thrombotic microangiopathies; complement-mediated glomerulopathies; Huntington's disease and cognitive impairment; addictive and compulsive disorders; and preventing problems associated with urologic surgical procedures. In addition, Omeros 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, 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 including with respect to OMIDRIA[®], Omeros' ability to partner and commercialize OMIDRIA in the Middle East and Europe, Omeros' unproven preclinical and clinical development activities, regulatory oversight, intellectual property claims, competitive developments, litigation including pending patent litigation related to an application seeking approval from the FDA

to market a generic version of OMIDRIA, 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 May 10, 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.

Contact:

Jennifer Cook Williams

Cook Williams Communications, Inc.

Investor and Media Relations

360.668.3701

jennifer@cwcomm.org

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