



NEWS RELEASE

Omeros Announces Clinical Strategy to Accelerate Pediatric Development of OMS721 for the Treatment of Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy (HSCT-TMA)

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– EMA Confirmed OMS721 Eligibility for European Centralized Marketing Authorization Application Review –

SEATTLE--(BUSINESS WIRE)--Dec. 6, 2018-- Omeros Corporation (Nasdaq: OMER) today announced that it has submitted a pediatric investigational plan (PIP) for the use of OMS721 for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) to the European Medicines Association (EMA). A pediatric study plan (PSP) is also under development for submission to the U.S. Food and Drug Administration (FDA). OMS721 is Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the lectin pathway of the complement system. OMS721 was awarded breakthrough therapy designation for the treatment of high-risk HSCT-TMA earlier this year. Thrombotic microangiopathy is a life-threatening complication of HSCT, with mortality reported to be greater than 90 percent in high-risk patients.

In addition to the data in adult HSCT-TMA patients forming the basis for its U.S. Biologics License Application (BLA) and E.U. Marketing Authorization Application (MAA) currently in preparation, Omeros is proposing a plan including

a small study in pediatric patients that will accelerate development of OMS721 for the treatment of HSCT-TMA in children. Rather than deferring initiation of a pediatric clinical trial until after approval in the E.U. or foregoing the study in the U.S., which is an option for an orphan drug, Omeros is proposing to initiate assessment of OMS721 in the pediatric population prior to approval in view of the strong OMS721 data observed to date and the significant unmet medical need. Because OMS721 has been designated as an orphan medicinal product in the EU, successful completion of an agreed PIP will provide two additional years of market exclusivity in member states of the European Union, and in Norway, Liechtenstein, and Iceland.

Omeros is also developing a PSP for submission to the FDA. Successful completion of an agreed PSP in response to a Written Request from FDA provides an additional 6 months of market exclusivity in the United States. OMS721 also has been granted orphan drug designation for the treatment of HSCT-TMA by the FDA. Although the requirement for pediatric studies is waived for drugs with orphan drug designation, pursuing a PSP can help accelerate pediatric treatment in the U.S. and provide additional market exclusivity.

A large prospective study reported that approximately 40% of pediatric patients who undergo HSCT will develop TMA and approximately 80% of these patients will have high-risk features.

“All of us at Omeros and treating physicians are confident that OMS721 is saving lives,” stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. “Children, like adults, develop life-threatening HSCT-TMA and do not have approved therapies available. Approval of OMS721 for pediatric HSCT-TMA will help remove treatment barriers for this vulnerable population and we expect will allow OMS721 to save many more lives.”

Omeros has also received notification from EMA of eligibility for the centralized procedure for submission and review of its MAA for OMS721 in the treatment of HSCT-TMA. The EMA's centralized procedure allows submission of a single MAA that, when approved, authorizes the drug to be marketed in all European Union member states and European Free Trade Association countries rather than requiring separate national approvals.

About Omeros' MASP Programs

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 is the effector enzyme of the lectin pathway, one of the principal complement activation pathways. 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 its abnormal function is associated with a wide range of autoimmune disorders. MASP-2

is generated by the liver and is then released into circulation. Adult humans who are genetically deficient in one of the proteins that activate MASP-2 do not appear to be detrimentally affected by the deficiency. OMS721 is Omeros' lead human MASP-2 antibody.

Phase 3 clinical programs are in progress for OMS721 in atypical hemolytic uremic syndrome (aHUS), in immunoglobulin A (IgA) nephropathy and in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Also, two Phase 2 trials are ongoing. One is continuing to enroll IgA nephropathy patients and has already generated positive data in patients with IgA nephropathy and with lupus nephritis; the other is enrolling and has reported positive data in patients with HSCT-TMA and in patients with aHUS. OMS721 can be administered both intravenously and subcutaneously, and Omeros expects to commercialize each formulation of OMS721 for different therapeutic indications. In parallel, Omeros is developing small-molecule inhibitors of MASP-2. Based on requests from treating physicians, Omeros has established a compassionate-use program for OMS721, which is active in both the U.S. and Europe. The FDA has granted OMS721 breakthrough therapy designation for IgA nephropathy and for high-risk HSCT-TMA, orphan drug status for the prevention (inhibition) of complement-mediated thrombotic microangiopathies and for the treatment of IgA nephropathy, and fast track designation for the treatment of patients with aHUS.

Omeros also has identified MASP-3 as responsible for the conversion of pro-factor D to factor D and as a critical activator of the human complement system's alternative pathway. The alternative pathway is linked to a wide range of immune-related disorders. In addition to its lectin pathway inhibitors, the company is advancing its development of antibodies and small-molecule inhibitors against MASP-3 to block activation of the alternative pathway. Omeros has initiated the manufacturing scale-up process of its MASP-3 antibodies in preparation for clinical trials.

About Omeros Corporation

Omeros is a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases and disorders of the central nervous system. The company's drug product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is marketed 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 other IOL replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a diverse group of preclinical programs and a proprietary G protein-

coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and corresponding compounds, a number of which are in preclinical development. The company also exclusively possesses a novel antibody-generating platform.

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,” “confident,” “could,” “estimate,” “expect,” “future,” “goal,” “intend,” “likely,” “look forward to,” “may,” “on track,” “plan,” “potential,” “predict,” “project,” “prospects,” “should,” “slated,” “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 and commercial operations, unproven preclinical and clinical development activities, regulatory oversight, intellectual property claims, competitive developments, litigation, 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 November 8, 2018. 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.

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