



NEWS RELEASE

Omeros Announces Positive Data from OMS721 Phase 2 Trial in Patients with Stem Cell Transplant-Associated Thrombotic Microangiopathy

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-- Targeted Indications for the Company's MASP-2 Inhibitor Continue to Expand --

SEATTLE--(BUSINESS WIRE)--Oct. 20, 2016-- Omeros Corporation (NASDAQ: OMER) today announced positive results in patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) from the company's Phase 2 clinical trial of OMS721 in TMAs, with clinically meaningful improvement in measures of red blood cell destruction, specifically lactate dehydrogenase (LDH) and haptoglobin levels ($p < 0.01$ and $p < 0.06$, respectively). Severe HSCT-TMAs carry a high mortality rate. OMS721 is Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2). In addition to its Phase 2 clinical program in TMAs, OMS721 is currently in a Phase 3 program for patients suffering from atypical hemolytic uremic syndrome and in a Phase 2 program for renal diseases, including immunoglobulin A (IgA) nephropathy (or Berger's disease) and membranous nephropathy.

All HSCT-TMA patients in the Phase 2 open-label clinical trial are adults who had received stem-cell transplantation for hematological malignancies. Inclusion criteria for these patients included low platelet count, hemolytic anemia (i.e., destruction of red blood cells within small blood vessels) and the requirement that the patients had not responded to attempted treatment of the TMA with modification of their immunosuppressive drugs. Changing the

immunosuppressive regimen is common practice in HSCT patients who develop a TMA, and those who do not respond to these drug changes frequently die. Three HSCT-TMA patients, all of whom had failed immunosuppressive modification, completed treatment with OMS721 for up to 8 weeks. Two other patients discontinued OMS721 early in their treatment courses, one later relapsed and the other's treatment was changed to palliative care only.

Across all three patients completing treatment, mean TMA markers improved over time. The mean LDH level decreased from a baseline of 672 U/L by as much as 380 U/L ($p < 0.01$). The mean haptoglobin increased over 1.54 g/L from a baseline of 0.33 g/L ($p < 0.06$). LDH and haptoglobin are measures of hemolytic anemia. The mean platelet count increased as much as 57,000/ μ L from a baseline of 18,000/ μ L but did not reach statistical significance in this small number of patients. Creatinine remained normal or improved, nearly normalizing, in two patients; one did not show improvement in creatinine but was receiving concomitant nephrotoxic drugs. On extended follow up, two patients remain stable and one experienced graft failure, which the investigator considers unrelated to OMS721 treatment.

No significant safety concerns have been observed. The most commonly reported adverse events in these patients have been abdominal pain, diarrhea, neutropenia and hypokalemia, all commonly seen in this patient population. An abstract has been submitted for presentation at the February 2017 Tandem Meeting of the American Society of Blood and Marrow Transplantation and the Center for International Blood and Marrow Transplant Research.

"These data are exciting," stated Samer Khaled, M.D., Assistant Clinical Professor of Hematology and Hematopoietic Cell Transplantation at City Of Hope in Duarte, California, and OMS721 clinical investigator. "The response in our patient was impressive, particularly since the patient had failed previous treatments. Lectin pathway inhibition could play a role in other post-transplant complications, and I look forward to continued development of OMS721 in stem cell transplantation."

Approximately 20,000 HSCT procedures are performed in the U.S. annually, and TMA is reported to occur in approximately 10 to 25 percent of HSCT patients. TMA most commonly affects the kidney but can also damage the lungs, gastrointestinal tract and central nervous system. Mortality in patients who develop severe HSCT-TMA is greater than 90 percent.

"In addition to the data being collected in aHUS patients, these HSCT-TMA results expand the potential benefits of OMS721 to multiple thrombotic microangiopathy indications," stated Gregory A. Demopoulos M.D., chairman and chief executive officer of Omeros. "Stem cell transplantation is an expanding field and represents an attractive medical and commercial opportunity. We plan to discuss with FDA and international regulatory agencies the design of a single Phase 3 trial for HSCT-TMA and look forward to OMS721 addressing the significant unmet needs of patients across a wide range of hematologic, renal and other therapeutic indications."

About Omeros' MASP-2 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 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. Omeros has received both Orphan Drug status and Fast Track designation from the U.S. FDA for its lead human MASP-2 antibody OMS721. Following discussions with both the FDA and the European Medicines Agency, a Phase 3 program for OMS721 in atypical hemolytic uremic syndrome is in progress. Also, two Phase 2 trials are ongoing with one evaluating OMS721 in glomerulonephropathies, which has generated positive data in patients with immunoglobulin A (IgA) nephropathy and with membranous nephropathy, and the other in thrombotic microangiopathies (TMAs), with positive data reported in patients with hematopoietic stem cell transplant-associated TMA. In addition to potential intravenous administration, Omeros plans to commercialize OMS721 for one or more therapeutic indications as a subcutaneous injection and is also 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.

Omeros also has identified MASP-3 as the protein that is critical to the activation of the complement system's alternative pathway in humans, which 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.

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. Part of 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. OMIDRIA is the first and only FDA-approved drug (1) 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 and (2) that contains an NSAID for intraocular use. 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 clinical-stage development programs focused on: complement-related thrombotic microangiopathies; complement-mediated glomerulonephropathies; Huntington's disease and cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a proprietary G protein-coupled receptor (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, Omeros' 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 August 9, 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.

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