



NEWS RELEASE

Omeros Reports Additional and Consistently Positive Data for OMS721 in Patients with Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy

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-- Preparing to Initiate Phase 3 Clinical Program --

SEATTLE, Oct. 26, 2017 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) today announced further positive data from the company's ongoing Phase 2 study of OMS721 evaluating patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (HCT-TMA). Initial positive data from this study have been presented at the 2017 combined annual meetings of the Center for International Blood & Marrow Transplant Research (CIBMTR) and the American Society for Blood and Marrow Transplantation (ASBMT).

The Phase 2 protocol provides for patients to receive weekly OMS721 treatments for four or eight weeks, at the discretion of the investigator. To be eligible for enrollment, HCT-TMA patients are required to be adults with post-transplant TMA persisting at least two weeks following calcineurin inhibitor modification (conservative treatment). This population is at high risk for poor outcomes, including mortality. These patients often have severe co-existing conditions, and mortality rates have been reported to be as high as 100 percent.

A total of 14 HCT-TMA patients have been enrolled to date in the ongoing Phase 2 study. Eight patients have completed the protocol-specified treatment. Another four patients either withdrew consent or were discontinued

by the investigator after only two to three weeks of treatment with OMS721. Three of the four patients for whom OMS721 treatment was discontinued early experienced deterioration of their conditions and subsequently died; the other patient, per protocol, was not followed and disposition is unknown. Two other patients are currently receiving OMS721 treatment.

Substantial and statistically significant improvements in markers of TMA activity, specifically mean platelet count, mean lactate dehydrogenase (LDH), and mean haptoglobin again were seen in this expanded number of study patients. At the end of protocol-allowed treatment, the mean platelet count (normal range: 150,000 – 400,000 x 10⁶/mL) increased from 19,610 x 10⁶/mL at baseline to 56,570 x 10⁶/mL (p < 0.05). The mean LDH (normal range: 125-220 U/L) decreased from 624 U/L at baseline to 303 U/L (p < 0.01). The mean haptoglobin (normal range: 14-268 mg/dL) increased from 9 mg/dL at baseline to 134 mg/dL (p < 0.01). Mean creatinine remained stable at approximately 120 mmol/L (normal range: 63-104 mmol/L) but a large majority of patients had co-existing conditions for which they were receiving nephrotoxic medications. Other serious co-existing conditions included graft versus host disease (GvHD), cytomegalovirus and human herpes virus 6 infections, prior sepsis, hemorrhagic alveolitis, and residual underlying malignancies.

OMS721 has been well tolerated and no safety concerns have been identified. The most commonly reported adverse events were diarrhea and nausea.

Two HCT-TMA case reports have also been presented. One patient was an adolescent girl who did not tolerate eculizumab treatment, but responded well to compassionate use OMS721 treatment. She was able to discontinue hemodialysis as well as platelet transfusions that she required daily when first treated with OMS721. Her case was presented by her treating physician last March at the 43rd Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT).

The second was a study patient who had a difficult post-transplant course, including steroid-resistant GvHD and cytomegalovirus infection. He developed TMA that did not respond to conservative measures and had co-existing GvHD with multiple neurological complications and was unable to walk. Following OMS721 treatment, his TMA and GvHD resolved and his neurological complications improved. He was able to walk and has been discharged in stable condition. His neurological status has continued to improve. This patient was reported last week at the EBMT Crash Course on Diagnosis and Treatment of Noninfectious Complications after HCT.

"Patients with stem cell-associated TMA continue to show robust improvement when treated with OMS721," stated Gregory A. Demopoulos M.D., chairman and chief executive officer of Omeros. "These are complex patients with severe co-morbidities and high mortality rates with no approved treatment option, and yet OMS721 has consistently managed their TMAs and also appears to improve GvHD, a frequent and deadly complication of TMA. We look forward to working with global regulatory agencies to start our OMS721 Phase 3 clinical trial in patients

with HCT-TMA."

While Omeros collects additional data through continued enrollment of the Phase 2 TMA study, the company is preparing to initiate an OMS721 Phase 3 clinical trial in patients with HCT-TMA and, for this indication, is pursuing FDA's breakthrough therapy designation and the European Medicines Agency's Priority Medicines (PRIME) status. For IgA nephropathy, OMS721 already has received breakthrough therapy designation from FDA and is also applying for PRIME status. Phase 3 clinical programs are in progress evaluating OMS721 in both IgA nephropathy and atypical hemolytic uremic syndrome.

About HCT-TMA

Thrombotic microangiopathy is a potentially life-threatening complication of HCT. Approximately 20,000 HCT procedures are performed in the U.S. annually, and TMA is reported to occur in approximately 10 to 25 percent of HCT patients. Although the kidney is the most commonly affected organ, HCT-TMA is a multi-system disorder and can also manifest clinically in the lungs, gastrointestinal tract and central nervous system. Reported mortality in patients with multi-organ involvement is greater than 90%. Even in patients who survive acute episodes, HCT-TMA increases the risk for chronic kidney disease and end-stage renal disease.

About Graft-versus-Host Disease

Graft-versus-host disease is a common complication of HCT. Both acute and chronic forms exist and result from donor immune cells recognizing the recipient patient as foreign tissue. This triggers an immune response against the recipient patient. Acute GvHD occurs in up to 50% or more of patients who receive allogeneic transplants. Acute GvHD most commonly targets the skin, gastrointestinal tract, and liver, but can also affect the kidney, eye, lung, and blood cells. Chronic GvHD occurs in approximately 40% of patients who receive allogeneic transplants and most commonly affects the skin, liver, eye, gastrointestinal tract and lungs. Both acute and chronic GvHD are related to significant morbidity and mortality.

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.

Following discussions with both the FDA and the European Medicines Agency, a Phase 3 clinical program for OMS721 in atypical hemolytic uremic syndrome (aHUS) is in progress. A second Phase 3 clinical program for OMS721 has been initiated in immunoglobulin A (IgA) nephropathy. Also, two Phase 2 trials are ongoing. One is continuing to enroll OMS721 in IgA nephropathy following an earlier Phase 2 trial that generated positive data in patients with IgA nephropathy and with lupus nephritis; the other is enrolling and has reported positive data both in patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TMA). A third Phase 3 program could begin later this year in stem cell transplant-associated TMA. 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, orphan drug status for the prevention (inhibition) of complement-mediated TMAs 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 is preparing to initiate manufacturing scale-up of its MASP-3 antibodies in advance of 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 injection) 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; Huntington's disease and 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," "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 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 August 8, 2017. 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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