



NEWS RELEASE

Report of Successful OMS721 Treatment of Patient with Both Stem Cell Transplant-Associated Thrombotic Microangiopathy and Graft-versus-Host Disease Presented at EBMT Annual Meeting

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-- Results May Expand Target for Omeros' Planned Phase 3 Program in HCT-TMA --

SEATTLE--(BUSINESS WIRE)--Oct. 20, 2017-- Omeros Corporation (NASDAQ: OMER) today announced the presentation of a case report of a patient having co-existing hematopoietic stem cell transplant-associated thrombotic microangiopathy (HCT-TMA) and graft-versus-host disease (GvHD), which both resolved following OMS721 treatment. This case was presented this morning at the European Society for Blood and Marrow Transplantation (EBMT) Crash Course on Diagnosis and Treatment of Noninfectious Complications after HCT in Granada, Spain. The presentation, "Effective Treatment of GvHD-Associated Transplant-Associated Microangiopathy with a Novel Inhibitor of the Lectin Pathway of Complement," was made by Chiara Caprioli, M.D. of the Hematology and Bone Marrow Transplant Unit, Azienda Ospedaliera Papa Giovanni XXIII, in Bergamo, Italy.

The patient was a participant in Omeros' ongoing Phase 2 uncontrolled clinical trial of thrombotic microangiopathies, including HCT-TMA. 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 considered to be at high risk for poor outcomes, including mortality.

Prior to enrollment in the OMS721 trial, the patient had undergone HCT for T-cell acute lymphoblastic leukemia. His post-transplant course was complicated by multiple episodes of steroid-refractory grade IV (life-threatening) GvHD, cytomegalovirus infection, and HCT-TMA. After two prior episodes of GvHD, the patient presented with bloody diarrhea. Intestinal biopsy demonstrated both HCT-TMA and GvHD. No infections were identified. Notably, the patient also had new onset neurological symptoms of paresthesias, tetraparesis, and a neurogenic bladder, which have been reported as neurological manifestations of GvHD and TMA. The patient was unable to walk due to the tetraparesis and required blood transfusions at least once daily. Hematological markers demonstrated HCT-TMA with thrombocytopenia, elevated lactate dehydrogenase (LDH), and schistocytes. Two weeks prior to initiation of treatment with OMS721, his immunosuppression (cyclosporine) had been decreased and, given his history of steroid-refractory GvHD, he was receiving only low-dose corticosteroids. He received no other GvHD treatment.

After two OMS721 doses, his bloody diarrhea resolved and his hematological markers improved. After four OMS721 doses, he was able to walk with help. He completed eight weeks of OMS721 treatment and has been doing well at home. All signs and symptoms of HCT-TMA and all clinical symptoms of GvHD have resolved. His neurological symptoms have continued to improve.

“This patient’s marked response to OMS721 treatment was very gratifying,” stated Anna Grassi, M.D., Director of the Bone Marrow Transplant Unit at the Azienda Ospedaliera Papa Giovanni XXIII. “The cause of his neurological symptoms is not clear, but may be a manifestation of GvHD or other endothelial injury. Prior to OMS721 treatment, this patient was deteriorating and at high risk for early death. The improvement of GvHD, HCT-TMA, and the neurological symptoms following OMS721 treatment is promising.”

“This case reinforces recent thinking that endothelial injury is a common cause of post-transplant complications in our patients,” stated Professor Alessandro Rambaldi, Director of Department of Hematology and Oncology, Azienda Ospedaliera Papa Giovanni XXIII. “This patient’s course suggests that inhibition of the lectin pathway may be beneficial in the treatment of HCT-complicating endothelial syndromes beyond TMA, including GvHD. I look forward to further study of this pathway and treatment.”

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.

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.

The most frequently reported adverse events in HCT patients treated with OMS721 have been nausea and diarrhea, neither of which investigators have deemed “drug-related.” One possibly treatment-related serious adverse event has been reported because the investigator could not rule out a contribution from OMS721. This patient was neutropenic, developed sepsis and subsequently died. Neutropenic sepsis is a common complication of HCT. Other infection-related deaths have occurred in the trial at times when the patients were not receiving OMS721 treatment (i.e., in the screening or follow-up periods).

“Our OMS721 clinical trials continue to yield exciting data,” stated Gregory A. Demopoulos M.D., chairman and chief executive officer of Omeros. “Potential treatment of both HCT-TMA and GvHD is consistent with our understanding of lectin pathway activation in the setting of endothelial injury. We continue to treat patients with OMS721 who have a high likelihood of mortality and the results to date have been impressive. We plan to initiate later this year a Phase 3 program in HCT-TMA and will discuss with regulators approaches to expand the program to assess GvHD as well.”

In addition to its clinical program in HCT-TMA, OMS721 is being evaluated in Phase 3 clinical programs for atypical hemolytic uremic syndrome and for immunoglobulin A nephropathy (IgAN). OMS721 has received breakthrough therapy designation from FDA for IgAN and Omeros is in discussions with FDA for breakthrough designation for the drug in HCT-TMA. Omeros also is applying for the European Medicines Agency’s Priority Medicines (PRIME) program for OMS721 in each of IgAN and HCT-TMA.

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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