



NEWS RELEASE

Omeros Requests Fast Track Designation for OMS721 for the Treatment of IgA Nephropathy

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-- Phase 3 Clinical Program Planned for 2017 --

SEATTLE--(BUSINESS WIRE)--Oct. 31, 2016-- Omeros Corporation (NASDAQ: OMER) today announced that it has requested fast track designation from the U.S. Food and Drug Administration (FDA) for the development of OMS721 for the treatment of patients with immunoglobulin A (IgA) nephropathy (also known as Berger's disease). The company recently reported positive data ($p = 0.017$) from the company's Phase 2 clinical trial of OMS721 for the treatment of kidney disorders, including IgA nephropathy, none of which currently have an approved treatment and all of which frequently lead to end-stage renal disease and dialysis. OMS721 significantly improved key endpoints of renal function and patients achieved partial remission with just 12 weeks of dosing. With similar outcomes in additional patients, the company plans to pursue accelerated approval. 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.

FDA's fast track program streamlines the development of drugs intended to treat serious or life-threatening conditions and that have the potential to address unmet medical needs. Fast track drugs are eligible for more frequent and timely meetings with FDA to discuss the development plan and to ensure that data needed for approval are collected appropriately. Drugs in the fast track program typically are granted priority review status and their respective New Drug Applications are accepted and reviewed by the FDA as rolling submissions. If granted,

fast track designation is expected to expedite Omeros' Phase 3 program for OMS721 in IgA nephropathy, which is planned to initiate next year.

FDA already has granted fast track designation for OMS721 in patients with atypical hemolytic uremic syndrome (aHUS) and orphan designation for OMS721 in patients with thrombotic microangiopathies (TMAs), including aHUS and hematopoietic stem cell-associated TMAs (HSCT-TMAs). In addition to positive Phase 2 data in IgA nephropathy and membranous nephropathy, Omeros has reported positive data from Phase 2 clinical trials in both aHUS and HSCT-TMAs. Following guidance from FDA and from the European Medicines Agency, Omeros plans to open enrollment for its single Phase 3 trial in patients with aHUS later this year. Based on discussions with the FDA, the company is also pursuing breakthrough therapy designation for OMS721 in IgA nephropathy and in HSCT-TMAs, neither of which has any approved treatment.

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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