



NEWS RELEASE

FDA Grants Breakthrough Therapy Designation to Omeros' MASP-2 Inhibitor OMS721 for the Treatment of IgA Nephropathy

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- Omeros' Second Phase 3 Clinical Program for OMS721 Slated to Begin this Year -

SEATTLE--(BUSINESS WIRE)--Jun. 13, 2017-- Omeros Corporation (NASDAQ: OMER) today announced that the US Food and Drug Administration (FDA) has granted breakthrough therapy designation to OMS721 for the treatment of Immunoglobulin A (IgA) nephropathy. 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.

Breakthrough therapy designation was granted based on data from Omeros' Phase 2 clinical trial evaluating OMS721 in patients with IgA nephropathy and other kidney diseases. The data were recently presented at the 54th European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) Congress in Madrid. Proteinuria is an important marker for disease progression in patients with IgA nephropathy, and improvement in proteinuria is associated with improved clinical outcomes. The clinical trial data show unprecedented improvement in proteinuria following only 12 weeks of OMS721 treatment, with a 77-percent mean reduction in urine albumin-to-creatinine ratios ($p = 0.026$) and a 73-percent mean reduction in 24-hour urine protein levels ($p = 0.013$). In response, many physicians attending ERA-EDTA in Madrid and representing centers across Europe, the U.S. and

Asia that manage large numbers of IgA nephropathy patients asked to participate in Omeros' planned Phase 3 clinical trial. These physicians have been added to the ongoing clinical site evaluation for the Phase 3 clinical program.

FDA's breakthrough therapy designation enables expedited development and review of a drug candidate for the treatment of a serious or life-threatening disease. Preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies is required. Benefits of breakthrough therapy designation include the eligibility for priority review of the application and rolling submission of portions of the application. FDA personnel, including senior management, provide guidance to the company to determine the most efficient route to approval. OMS721 is the only drug candidate in development for the treatment of IgA nephropathy that has been granted breakthrough therapy designation by FDA.

"We are pleased that FDA has granted breakthrough designation to OMS721 for IgA nephropathy and appreciate the Agency's recognition of the potential importance of OMS721 in the treatment of this disease," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "OMS721 appears to be helping IgA nephropathy patients with a rapidity and magnitude not previously seen with any other therapy, and we look forward to working closely with the FDA to accelerate its development."

There is no approved treatment for IgA nephropathy. The most common primary glomerulopathy globally, it accounts for up to 10 percent of all dialysis patients. In the U.S. alone, an estimated 120,000 to 180,000 patients have this disease. Approximately 40 percent of IgA nephropathy patients develop end-stage renal disease, a life-threatening condition, within 20 to 30 years following diagnosis.

OMS721 is also being evaluated in a Phase 3 clinical program for atypical hemolytic uremic syndrome and in a Phase 2 clinical program for hematopoietic stem cell transplant-associated thrombotic microangiopathy.

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 program for OMS721 in atypical hemolytic uremic syndrome (aHUS) is in progress. Also, two Phase 2 trials are ongoing. One is evaluating OMS721 in glomerulonephropathies, which has generated positive data in patients with immunoglobulin A (IgA) nephropathy and with lupus nephritis; the other has reported positive data both in patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TMA) and in those with aHUS. One or more additional OMS721 Phase 3 clinical programs are planned to initiate this year in IgA nephropathy and in stem cell transplant-associated TMA. OMS721 can be administered intravenously, and Omeros also expects to commercialize OMS721 for one or more therapeutic indications as a subcutaneous injection. 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 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 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 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 proprietary G protein-coupled receptor (GPCR) platform and 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 May 10, 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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