



NEWS RELEASE

## Omeros Reports More Positive Data in OMS721 Phase 2 Trial in Renal Diseases

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-- Phase 3 Program Slated for This Year --

SEATTLE--(BUSINESS WIRE)--Mar. 30, 2017-- Omeros Corporation (NASDAQ: OMER) today announced additional positive data from the company's Phase 2 clinical trial of OMS721 for the treatment of serious kidney disorders, which frequently lead to end-stage renal disease and dialysis. OMS721 is Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the complement system's lectin pathway. The clinical trial data include results from additional study patients treated with OMS721 as well as longer-term follow-up on earlier enrolled patients. The new data corroborate and expand on trial results reported in the fourth quarter of 2016. Based on the uniformly positive data in the fully enrolled cohort of OMS721-treated patients with immunoglobulin A nephropathy (IgAN), Omeros recently met with the FDA to discuss the Phase 3 development program.

"The clinical responses in my IgA nephropathy patients treated with OMS721 are truly impressive," stated Geoffrey Block, M.D., Director of Clinical Research at Denver Nephrology. "These are patients with significant renal impairment who had not responded to steroid therapy. Each OMS721-treated patient substantially improved while markedly reducing or stopping steroid use. Equally impressive is that, after OMS721 treatment was completed, a legacy effect of continued improvement was observed in each patient. I look forward to participating in the Phase 3 clinical trial and to working with Omeros to make this important drug broadly available to patients."

The Phase 2 open-label trial is evaluating OMS721 across four different types of complement-associated kidney diseases: IgAN, membranous nephropathy, lupus nephritis, and complement component 3 (C3) glomerulopathy. To meet enrollment criteria, patients must have high levels of urinary protein (a marker used by nephrologists to assess disease activity) despite well-controlled blood pressure with stable dosing of renin-angiotensin system inhibitors and ongoing treatment with a corticosteroid, thereby ensuring that study patients are unlikely to improve spontaneously. Patients are treated with OMS721 for a total of 12 weeks: four weeks maintaining their entry corticosteroid dose; four weeks of corticosteroid tapering, if tolerated; and four weeks of resultant corticosteroid dose maintenance. Patients are then followed post-treatment for six weeks.

The trial assesses the effect of OMS721 on urine protein measures that are predictive of kidney failure, namely urine albumin/creatinine ratio (uACR) and total 24-hour urine protein excretion, and on the ability to reduce steroid dosing. Data were analyzed for the pre-specified IgAN cohort of four patients (three have completed treatment in the study and the fourth is finishing treatment).

Treatment effects across all IgAN patients were highly consistent, the magnitude of which are associated with improved renal survival. Notably, uACR values continued to improve after dosing was completed. In the three patients who completed treatment, the mean baseline uACR was 1,400 mg/g and reached 671 mg/g at the end of treatment (52 percent decrease;  $p = 0.02$ ), continuing to decrease to 380 mg/g by the end of the follow-up period. Measures of 24-hour urine protein excretion tracked uACRs, with a mean reduction from 3,728 mg/day to 1,340 mg/day (64 percent decrease;  $p = 0.02$ ). To date, after eight weeks of treatment, the fourth patient's uACR dropped from 1,628 mg/g to 733 mg/g, a decrease of 55 percent. Partial remission is defined as greater than 50 percent reduction in 24-hour urine protein excretion. In the patients who completed treatment, 24-hour urine protein levels decreased by approximately 50 to 80 percent. Concurrently, daily steroid doses for all patients were substantially reduced or completely eliminated.

"The OMS721 data in IgAN patients demonstrate a strength and rapidity of clinical response that I have not seen with other agents in development," said Jonathan Barratt, Ph.D., F.R.C.P., Professor of Renal Medicine in the Department of Infection, Immunity & Inflammation at University of Leicester and Honorary Consultant Nephrologist at Leicester General Hospital. "There currently is no approved therapy for IgA nephropathy. The mechanism of IgA nephropathy – and proteinuria in general – has been closely linked to the lectin pathway of complement, and OMS721 directly targets the pathway's effector enzyme MASP-2. This could uniquely position OMS721 not only for the treatment of IgA nephropathy but for a host of other kidney disorders as well."

Encouraging results have also been observed in lupus nephritis. Four of five patients showed a substantial (mean of 69 percent) reduction in 24-hour urine protein excretion over the treatment period. The fifth patient experienced a systemic disease flare and showed a substantial increase. The majority of lupus responders were able to taper their

steroid doses. Three patients with membranous nephropathy, a disease with inherent variability, have completed treatment with mixed results. Additional analyses are continuing in these patient groups.

Consistent with all other OMS721 clinical trials, no significant safety concerns have been observed. The most commonly reported adverse events in this trial are fatigue and anemia.

Omeros met with FDA recently to discuss these data and Phase 3 development. Following review of the data, FDA suggested that Omeros apply for breakthrough therapy designation in IgAN. The discussion included accelerated approval and an expedited approach to full approval based on an endpoint of proteinuria, which could be faster than accelerated approval. Omeros is preparing its breakthrough application and a Phase 3 protocol for discussion with FDA. The Phase 3 trial in IgAN is expected to begin this year.

“We’re pleased with the consistently positive data seen in IgAN patients, further expanding the strong OMS721 clinical results beyond those previously reported in aHUS and stem-cell transplant patients,” stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. “We are submitting our breakthrough therapy application to FDA and look forward to working closely with U.S. and international regulators as we advance through our Phase 3 clinical programs across multiple indications for OMS721.”

No treatments are approved for IgAN, an orphan disease but the most common primary glomerular disease globally. With an annual incidence of approximately 1 per 100,000, it is estimated that 1 in 1,400 persons in the U.S. will develop IgAN in his or her lifetime. As many as 40 percent of them will develop end-stage renal disease.

## 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. 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. The FDA has granted OMS721 both 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 the critical activator of the human complement system's alternative pathway, 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-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, 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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 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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