



NEWS RELEASE

Omeros Data Show Continued Improvement in Patients with IgA Nephropathy Treated with OMS721

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– Sustained Proteinuria Reduction and GFR Improvement in up to One-Year Follow-up Data –

SEATTLE--(BUSINESS WIRE)--Aug. 14, 2017-- Omeros Corporation (NASDAQ: OMER) today announced additional follow-up data from patients with immunoglobulin A (IgA) nephropathy treated with OMS721 in the Phase 2 clinical trial of glomerulonephropathy. 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.

As presented in June 2017 at the 54th Congress of the European Renal Association-European Dialysis and Transplant Association, patients with IgA nephropathy demonstrated clinically and statistically significant improvement in proteinuria during the course of the clinical trial. After these patients completed the trial, the clinical investigator continued to follow them per standard of care. Follow-up data up to approximately one year after completion of treatment are available.

As previously reported, all four IgA nephropathy patients in the clinical trial demonstrated a substantial reduction in proteinuria measured by both 24-hour urine protein excretion levels and urinary albumin/creatinine ratios (uACRs). In post-trial follow-up, urine protein/creatinine ratios (uPCR) were measured by the investigator according to his practice standard. For purposes of post-hoc comparisons of proteinuria during and after the clinical trial, each post-trial uPCR value was converted to uACR (Zhao, Clin J Am Soc Nephrol 2016;11:947-55).

In follow-up, three of the four patients have maintained reductions in proteinuria. In these three patients uACRs remained reduced at 14 percent, 23 percent, and 24 percent of the patients' baseline values prior to OMS721 treatment. In addition, a suggestion of improvement in estimated glomerular filtration rate (eGFR), a measure of renal function, was observed in 3 of the 4 patients after the trial. The patient with the most severe reduction in kidney function demonstrated eGFR improvement from 30 mL/min/1.73 m² to 47 mL/min/1.73 m², an improvement of 57 percent. OMS721 was well-tolerated in the clinical trial with fatigue and anemia the most commonly reported adverse events.

"The persistent reduction of proteinuria following completion of OMS721 treatment in these patients is impressive and provides additional evidence of the important role of the lectin pathway in IgA nephropathy," stated Geoffrey Block, M.D., director of clinical research at Denver Nephrology. "The improvements observed in eGFRs also suggest that OMS721 could provide further benefit to patients by potentially precluding or substantially extending the time to the need for dialysis and reducing the risk of complications associated with progression of chronic kidney disease."

Omeros has initiated a Phase 3 clinical program for OMS721 in IgA nephropathy and expects to begin a Phase 3 clinical trial in this disease later this year. FDA has granted OMS721 both breakthrough and orphan designations in IgA nephropathy.

"The durable reduction in proteinuria that we're seeing with OMS721 for one year after cessation of treatment is unprecedented in my experience," 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. "With this one-year follow-up, we are also seeing improvement in eGFR, which usually takes significantly longer to be evident. Two of the four patients demonstrated a slight increase, with one of the patients showing an exciting response of 50 percent improvement."

There is no approved treatment for IgA nephropathy, the most common primary glomerulopathy globally. The disease is responsible 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. Up to 40 percent of IgA nephropathy patients develop end-stage renal disease, a life-threatening condition, within 20 years following diagnosis.

"The sustained duration of effect of OMS721 post-treatment underscores the drug's potential for episodic dosing in IgA nephropathy," said Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "We look forward to working with FDA to finalize the protocol for our Phase 3 clinical trial and open enrollment to IgA nephropathy patients later this year."

In addition to its Phase 3 program in IgA nephropathy, 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 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 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. 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 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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