



NEWS RELEASE

Omeros Establishes Independent Academic Leadership Committee for its OMS721 Phase 3 Clinical Program in IgA Nephropathy

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-- Committee is Comprised of World Leaders in IgA Nephropathy and Renal Clinical Research --

SEATTLE--(BUSINESS WIRE)--Dec. 20, 2018-- Omeros Corporation (Nasdaq: OMER) announced today the formation of an independent Academic Leadership Committee (ALC) to support its Phase 3 clinical program for OMS721 in immunoglobulin A (IgA) nephropathy. The committee includes renowned leaders in nephrology and clinical research who will provide clinical guidance to Omeros as it advances its ongoing IgA nephropathy Phase 3 clinical trial ARTEMIS-IGAN.

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.

"Glomerular complement deposition is common in IgA nephropathy, and there is mounting evidence that the lectin pathway is a key complement player in the disease," said committee member Dr. Jürgen Floege, Director of the Department of Nephrology and Clinical Immunology at University Hospital Aachen, Germany. "Blocking MASP-2, the effector enzyme of the lectin pathway, holds the promise of not only halting progression of IgA nephropathy but modifying the pathology of the underlying disease."

The ALC is chaired by Richard Lafayette, MD, Professor of Medicine (Nephrology) and Director of the Glomerular Disease Center, Stanford University Medical Center.

“OMS721 data from both the first and second cohorts of the Phase 2 study show great promise,” said Dr Lafayette. “Despite high baseline proteinuria levels and longstanding established disease, the majority of IgA nephropathy patients treated with OMS721 in the Phase 2 trial demonstrated both a marked reduction in proteinuria and stable kidney function. The ALC is committed to help Omeros expedite its Phase 3 program toward regulatory approval and to change the treatment paradigm for IgA nephropathy.”

In addition to Drs. Lafayette and Floege, members of the ALC include:

- Jonathan Barratt, PhD, FRCP, Professor of Renal Medicine at the University of Leicester and Honorary Consultant Nephrologist at Leicester General Hospital
- Kevin Carroll, PhD, CStat, CSci, founder of KJC Statistics Ltd
- Heather Reich, MD, CM, PhD, FRCPC, Associate Professor and Gabor Zellerman Chair in Nephrology Research at the Toronto General Hospital Research Institute (TGHRI)
- Brad Rovin, MD, Director, Division of Nephrology and Vice-Chair of Research, Internal Medicine at The Ohio State University Wexner Medical Center
- James Tumlin, MD, private practitioner and clinical trialist, Georgia Nephrology

“About 30 percent of patients with IgA nephropathy will progress to end-stage kidney failure within 10 to 15 years of diagnosis, particularly those individuals with high loss of protein in the urine,” stated Dr. Rovin. In young adults, IgA nephropathy is one of the most common causes of end-stage kidney disease. Currently, there are no approved treatments for IgA nephropathy, and Omeros has developed a therapy targeting this population. The results from the Phase 2 trial have been impressive.”

OMS721 holds breakthrough therapy designation from FDA for the treatment of each of IgA nephropathy and hematopoietic stem cell transplant-associated thrombotic microangiopathy and is in Phase 3 clinical programs for both of these diseases as well as for atypical hemolytic uremic syndrome.

“The OMS721 Phase 3 clinical trial in IgA nephropathy is underway. Omeros has designed the trial thoughtfully and, due to the previously reported impressive reductions in proteinuria with OMS721, has to my knowledge, the unique possibility of obtaining full approval from FDA on an endpoint of proteinuria alone,” stated Dr. Jonathan Barratt. “Assessing the broad IgA nephropathy population with 24-hour urine protein in excess of 1 gram/day, as well as specifically targeting a population of patients with high proteinuria in excess of 2 grams/day, there are multiple opportunities for a successful outcome.”

No treatments are approved for IgA nephropathy. 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 IgA nephropathy in his or her lifetime.

“Our IgA nephropathy leadership committee brings together a group of preeminent nephrologists, disease experts and clinical researchers to help drive our Phase 3 trial, ARTEMIS-IGAN, to a successful outcome,” stated Gregory A. Demopoulos, MD, chairman and CEO of Omeros Corporation. “Committee members have been instrumental in assisting Omeros in the design and execution of the Phase 3 clinical trial as well as actively participating in key meetings with regulatory authorities. We are grateful to each of them for providing their time and expertise to advance the OMS721 IgA nephropathy program, both on behalf of Omeros and IgA patients worldwide.”

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. Gene-targeted MASP-2-deficient mice and humans with MASP-2 gene polymorphisms that affect MASP-2 serum levels and MASP-2 functional activity are generally healthy with no obvious adverse phenotype.

Phase 3 clinical programs are in progress for OMS721 in atypical hemolytic uremic syndrome (aHUS), in immunoglobulin A (IgA) nephropathy and in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Also, two Phase 2 trials are ongoing. One is continuing to enroll IgA nephropathy patients and has already generated positive data in patients with IgA nephropathy and with lupus nephritis; the other is enrolling and has reported positive data in patients with HSCT-TMA and in patients with aHUS. 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 and for high-risk HSCT-TMA, orphan drug status for the prevention (inhibition) of complement-mediated thrombotic microangiopathies 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 has initiated the manufacturing scale-up process of its MASP-3 antibodies in preparation for 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 intraocular solution) 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; 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," "future", "goal," "intend," "likely", "look forward to," "may," "on track", "opportunities", "plan," "potential," "predict," "project," "possibility", "prospects," "should," "slated," "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 November 8, 2018. 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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