



NEWS RELEASE

Patient Dosing Initiated for OMS721 Phase 2 Program in Renal Diseases

2016-04-20

-- Study Provides an Opportunity for Breakthrough Therapy Designation and Subsequent Accelerated Approval --

SEATTLE--(BUSINESS WIRE)--Apr. 20, 2016-- Omeros Corporation (NASDAQ: OMER) today announced initiation of patient dosing in its OMS721 Phase 2 program in corticosteroid-dependent renal diseases. The Phase 2 clinical trial of OMS721, the company's lead mannan-binding lectin-associated serine protease-2 (MASP-2) inhibitor being developed for complement-related diseases, is evaluating the effects of OMS721 on kidney function in patients with corticosteroid-dependent renal diseases. This new trial expands the company's MASP platform, which includes an OMS721 Phase 3 program in progress for the treatment of atypical hemolytic uremic syndrome (aHUS) as well as an ongoing Phase 2 program of OMS721 for the treatment of other thrombotic microangiopathies (TMAs).

This new Phase 2 clinical trial includes patients with corticosteroid-dependent IgA nephropathy, membranous nephropathy, C3 glomerulopathy and lupus nephritis. Evidence implicates the complement system, and specifically the lectin pathway, in the pathogenesis of each of these serious diseases. Despite ongoing treatment with corticosteroids, these patients have evidence of progressive kidney disease and are at high risk for kidney failure and dialysis. Continued corticosteroid use carries significant patient risks and is associated with serious side effects. There are no FDA-approved treatments for corticosteroid-dependent patients who have persistent renal inflammation. Treatments for these diseases that improve kidney function, slow disease progression or avoid long-

term corticosteroid use would meet a significant unmet medical need.

The Phase 2 clinical trial is enrolling a total of approximately 16 patients across separate cohorts for each disease. The trial is evaluating markers of kidney injury and will assess whether OMS721 allows a reduction in diseased patients' corticosteroid requirements. Patients will receive 12 weeks of OMS721 treatment and will undergo protocol-prescribed corticosteroid tapering. Data from this trial are expected in the second half of this year or the first half of 2017. Given the seriousness of the diseases included in this Phase 2 program and the lack of available therapies, if this trial demonstrates evidence that OMS721 improves kidney function, slows disease progression or reduces corticosteroid use in these patients, Omeros intends to request breakthrough therapy designation from the FDA and to initiate a Phase 3 program that meets the requirements for accelerated approval.

"We are making excellent progress in our Phase 2 program in corticosteroid-dependent renal diseases," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "These are devastating diseases – patients are at high risk and need treatment options. Providing a treatment benefit to any of these patient groups would be a major therapeutic advance. Given the severity of disease, similar to our OMS721 Phase 3 aHUS program, treatment effects can be identified in small numbers of patients without a control group. This is consistent with our OMS721 strategy of targeting rare diseases for which our drug could have a meaningful impact on quality of life."

About Omeros' MASP 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 appears to be unique to, and required for the function of, one of the principal complement activation pathways, known as the lectin pathway. 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 is associated with a wide range of autoimmune disorders. 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. Omeros has an ongoing Phase 3 clinical program for OMS721 in atypical hemolytic uremic syndrome, an ongoing Phase 2 program targeting thrombotic thrombocytopenic purpura and stem cell transplant-related thrombotic microangiopathies and an ongoing Phase 2 program targeting complement-related renal diseases. An investigator-requested compassionate use program for OMS721 is also underway. OMS721 has demonstrated no safety concerns in human trials or chronic toxicity studies. In addition to potential intravenous administration, Omeros plans to commercialize OMS721 for one or more therapeutic indications as a subcutaneous injection.

Omeros also believes that it has identified the proteins that activate 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's OMS906 program is advancing the development of antibodies targeting MASP-3 that 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. Derived from 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 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 lens replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has five clinical-stage development programs focused on: complement-related thrombotic microangiopathies; complement-mediated glomerulopathies; Huntington's disease and cognitive impairment; addictive and compulsive disorders; and preventing problems associated with urologic surgical procedures. In addition, Omeros has a proprietary 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 including with respect to OMIDRIA®, Omeros' ability to partner and commercialize OMIDRIA in Europe, Omeros' unproven preclinical and clinical development activities, regulatory oversight, intellectual property claims, competitive developments, litigation including pending patent litigation related to an application seeking approval from the FDA to market a generic version of OMIDRIA, 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 15, 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.

View source version on businesswire.com: <http://www.businesswire.com/news/home/20160420005585/en/>

Source: Omeros Corporation

Cook Williams Communications, Inc.

Jennifer Cook Williams

Investor and Media Relations

360.668.3701

jennifer@cwcomm.org