



Press Release

Omeros Obtains Regulatory Approval to Initiate Phase 1 Clinical Trial for Lead Antibody in MASP-2 Program

-- Enrollment Expected to Begin Next Month --

SEATTLE, June 13, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) today announced that it has obtained regulatory clearance to start the Phase 1 clinical trial evaluating OMS721, the Company's lead human monoclonal antibody from its mannan-binding lectin-associated serine protease-2 (MASP-2) program. The first clinical trial with OMS721 will be conducted in Europe and will evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of OMS721 administered subcutaneously in healthy subjects. Omeros plans to follow this study with a clinical trial evaluating OMS721 in patients with atypical hemolytic uremic syndrome (aHUS), a rare but life-threatening form of thrombotic microangiopathy (TMA). Enrollment in the initial clinical trial is scheduled to begin next month.

Omeros has filed for orphan drug designation in the United States for the use of OMS721 to treat aHUS and will request orphan drug designation in Europe as well. Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2.

OMS721 selectively inhibits MASP-2, a novel pro-inflammatory protein involved in activation of the complement system, which is an important component of the immune system and plays a role in the inflammatory response to tissue damage or microbial infection. By selectively inhibiting MASP-2, OMS721 blocks the lectin pathway of the complement system while leaving intact the classical pathway, which represents the acquired immune response to infection.

Omeros' previously reported preclinical findings indicate that blockade of MASP-2 by OMS721 may have a preventive or therapeutic effect in the treatment of aHUS and other life-threatening TMAs, such as hemolytic uremic syndrome and thrombotic thrombocytopenic purpura, as well as a wide range of additional disorders, including age-related macular degeneration, ischemia-reperfusion injury and transplant-related complications.

"We are pleased that the European regulatory authorities have cleared the way for us to evaluate the potential of OMS721 in humans," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "The lectin pathway appears to play an important role across a wide range of serious disorders. The preclinical data for OMS721 are strong, and we continue to drive the clinical development of the antibody."

About Omeros' MASP-2 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 its abnormal function is associated with a wide range of autoimmune disorders. MASP-2 is generated by the liver and is then released into the 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. Therefore, Omeros believes that it may be possible to deliver MASP-2 antibodies systemically and OMS721, its lead MASP-2 antibody, is designed to be self-administered by 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 is advancing the development of antibodies that would block activation of the alternative pathway alone or in combination with the lectin pathway.

About Omeros Corporation

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. The Company's most clinically advanced product candidates, OMS302 for lens replacement surgery and OMS103HP for arthroscopy, are derived from its proprietary PharmacoSurgery™ platform designed to improve clinical outcomes of patients undergoing a wide range of surgical and medical procedures. Omeros has five clinical development programs. Omeros may also have the near-term capability, through its GPCR program, to add a large number of new drug targets and their corresponding compounds to the market. Behind its clinical candidates and GPCR platform, Omeros is building a diverse pipeline of protein and small-molecule preclinical programs targeting inflammation, coagulopathies and central nervous system disorders.

Forward-Looking Statements

This press release contains forward-looking statements as defined within the Private Securities Litigation Reform Act of 1995, which are subject to the "safe harbor" created by those sections. These statements include, but are not limited to, Omeros' expectations regarding when it will commence clinical trials evaluating OMS721; Omeros' plans to request orphan drug designation in Europe; the potential indications that OMS721 may treat; the potential advantages of OMS721 over current treatments; and that Omeros may have capability, through its GPCR program, to add a large number of new drug targets and their corresponding compounds to the market. 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, 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 9, 2013. 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 publicly, even if new information becomes available in the future.

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