



Press Release

Omeros Files Orphan Drug Application for Treatment of Atypical Hemolytic Uremic Syndrome with OMS721

-- Orphan Drug Designation Could Provide Financial Incentives and Faster Regulatory Review --

SEATTLE, April 17, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) today announced that it has filed an Application for Orphan Drug Designation with the U.S. Food and Drug Administration (FDA) for OMS721, the lead human monoclonal antibody in Omeros' mannan-binding lectin-associated serine protease-2 (MASP-2) program, for use in the treatment of atypical hemolytic uremic syndrome (aHUS). As Omeros previously announced, based on positive preclinical data in thrombotic microangiopathy (TMA), the first indication planned for OMS721 clinical trials is aHUS, a rare but life-threatening form of TMA. Orphan drug designation is granted to treatments that are expected to provide significant therapeutic advantage over existing treatments and that target conditions affecting 200,000 or fewer U.S. patients per year. Orphan-designated drugs are eligible for incentives such as a faster approval process and additional market exclusivity.

Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2, a novel pro-inflammatory protein involved in activation of the complement system – an important component of the immune system. The complement system plays a role in the inflammatory response to tissue damage or microbial infection. OMS721 selectively inhibits MASP-2, blocking the lectin pathway of the complement system while leaving intact the classical pathway, which represents the acquired immune response to infection. Soliris[®] (eculizumab), which received orphan drug status for aHUS and is the only currently approved therapy for that indication, inhibits microbial killing by the classical pathway, increasing the risk of infection for the patient. By targeting only the lectin pathway and leaving the classical pathway intact, OMS721 should not have this increased infection risk. In addition, Soliris requires a 20-minute to two-hour intravenous infusion in a medical facility, while OMS721 is designed to be self-administered by subcutaneous injection, which would be more convenient for patients.

"We believe that OMS721 meets the criteria for orphan drug designation, representing a significant therapeutic advance over currently available treatments for aHUS," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "We plan to file for the same designation in Europe, and we remain on track to begin clinical trials early this summer. The potential indications for OMS721 span a wide range of attractive markets in both orphan and highly prevalent diseases, and we are excited to evaluate its efficacy in patients."

About Orphan Drug Status

Orphan drug designation is granted by the FDA's Office of Orphan Products Development for treatments that are expected to provide significant therapeutic advantage over existing treatments and that target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation qualifies a company for several benefits under the Orphan Drug Act of 1983. The benefits apply across all stages of drug development and include accelerated approval process; seven years of market exclusivity following marketing approval; tax credits on U.S. clinical trials; eligibility for orphan drug grants; and waiver of certain administrative fees.

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.

Omeros also believes that it has identified the proteins that activate the 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 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 that it may obtain orphan drug designation for OMS721; the potential indications that OMS721 may treat; the potential advantages of OMS721 over current treatments; when OMS721 will begin clinical development; that it will apply for orphan drug designation for OMS721 in Europe; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 18, 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.

SOURCE Omeros Corporation

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