



Press Release

FDA Grants Orphan Drug Designation to Omeros' OMS824 for Huntington's Disease

-- Phase 2 Clinical Trial in Huntington's Disease Slated to Begin This Year --

SEATTLE, Sept. 30, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) announced that OMS824, its phosphodiesterase 10 (PDE10) inhibitor, has received orphan drug designation from the U.S. Food and Drug Administration for the treatment of Huntington's disease. OMS824 selectively inhibits PDE10, an enzyme expressed in areas of the brain linked to a wide range of diseases that affect cognition, including Huntington's disease and schizophrenia. As previously reported, Phase 1 clinical results in healthy subjects demonstrated that OMS824 is well tolerated and suggest that it has a better clinical therapeutic index or "safety factor" than other PDE10 inhibitors in development. Omeros plans to begin a Phase 2 clinical trial evaluating OMS824 in patients with Huntington's disease later this year. A Phase 2 clinical trial of the drug is already underway in patients with schizophrenia.

Orphan designation by the FDA is granted to promote the development of drugs that target conditions affecting 200,000 or fewer U.S. patients annually and that are expected to provide significant therapeutic advantage over existing treatments. It qualifies a company for benefits that apply across all stages of drug development, including 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.

Huntington's disease is estimated to affect approximately 31,000 U.S. patients annually, and the only FDA-approved treatment for the disease is tetrabenazine, which is indicated for Huntington's-related movement disorders. OMS824 has the potential to improve the cognitive and psychiatric abnormalities as well as the movement disorders associated with the disease.

"Orphan designation by the FDA will help to accelerate the development of OMS824 and recognizes the important work conducted at Omeros," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "The manifestations of Huntington's are devastating to both Huntington's patients and their families, yet there is only one currently approved therapeutic and it is focused on a single symptom of the disease. OMS824 holds the promise of expanding treatment across the constellation of debilitating effects of Huntington's. We look forward to working with the FDA to advance the clinical evaluation of OMS824 in patients suffering from Huntington's disease and plan to initiate enrollment in a Phase 2 trial later this year."

About Omeros' PDE10 Program

PDE10 is an enzyme that is expressed in areas of the brain linked to diseases that affect

cognition and psychomotor functions, including Huntington's disease and schizophrenia. Huntington's disease is a hereditary neurodegenerative disorder that leads to movement, cognition, and behavioral abnormalities and premature death. Schizophrenia is a group of severe brain disorders characterized by an abnormal interpretation of reality, which can manifest as delusions, hallucinations, and/or disordered thinking and behavior. Cognitive dysfunction is responsible for substantial disability in both of these diseases and is not meaningfully improved by current medications. Omeros' proprietary compound OMS824 inhibits PDE10 and is being developed for the treatment of cognitive disorders. In addition to potential benefits on cognition, OMS824 could also improve the motor and psychiatric abnormalities in Huntington's disease as well as the positive (e.g., hallucinations) and negative (e.g., flat affect) symptoms of schizophrenia.

About Omeros Corporation

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics targeting inflammation, coagulopathies and disorders of the central nervous system. Derived from its proprietary PharmacoSurgery® platform, the Company's lead drug product, OMS302 for lens replacement surgery, is currently under review for marketing approval by both the US Food and Drug Administration and the European Medicines Agency with commercial launch planned for 2014. Omeros' five other clinical programs are focused on schizophrenia, Huntington's disease and cognitive impairment; addictive and compulsive disorders; complement-related diseases; and preventing problems associated with surgical procedures. Omeros also 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.

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. These statements include, but are not limited to, Omeros' expectations regarding a Phase 2 clinical trial later this year; the clinical therapeutic index or "safety factor" of OMS824; that OMS824 has the potential to improve the cognitive and psychiatric abnormalities as well as the movement disorders associated with Huntington's disease; and regarding the potential therapeutic benefits and qualities of OMS824. 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 August 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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