



Press Release

Investigational New Drug Application Cleared by FDA for OMS824 in Huntington's Disease

-- Clinical Trial in Patients with Huntington's Disease Slated to Begin Next Quarter

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SEATTLE, May 23, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: OMER) today announced that its Investigational New Drug Application (IND) to evaluate OMS824 in Huntington's disease has been cleared by the U.S. Food and Drug Administration (FDA). OMS824 selectively inhibits phosphodiesterase 10 (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. OMS824 has shown promising results in animal models directly relevant to Huntington's disease and, as previously announced, OMS824 was well tolerated and exhibited favorable pharmacokinetic properties in a Phase 1 clinical program. Omeros plans to advance OMS824 into Phase 2 clinical trials for Huntington's disease next quarter and for schizophrenia later this year, the OMS824 IND for use in patients with schizophrenia having already been cleared by the FDA.

Omeros also announced today that it has requested Orphan Drug Designation from the FDA for OMS824 in the treatment of Huntington's disease. Orphan-designated drugs are eligible for incentives such as a faster approval process and additional market exclusivity. This designation is granted to drugs that are expected to provide significant therapeutic advantage over existing treatments and that target conditions affecting 200,000 or fewer U.S. patients annually. 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. Omeros recently announced that it has requested Fast Track designation for OMS824 in the treatment for Huntington's disease. Fast Track designation is reserved for drugs being developed to treat life-threatening conditions with the potential to address unmet medical needs and typically provides priority review status.

"Cognitive impairment is a hallmark of Huntington's disease and schizophrenia, and there currently are no drugs that improve cognition in either disorder," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "In Huntington's disease, OMS824 also has the potential to improve motor control and to reduce the rate of neurodegeneration, slowing disease progression. We are pleased

that the FDA has now cleared the way for us to evaluate OMS824 in both patients with Huntington's disease and schizophrenia, and we look forward to initiating enrollment in our Phase 2 clinical trials."

About Orphan Drug Status

Orphan drug designation is granted by the FDA's Office of Orphan Products Development for drugs that are expected to provide significant therapeutic advantage over existing treatments and that target conditions affecting 200,000 or fewer U.S. patients annually. 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 FDA's Fast Track Program

The FDA's Fast Track program facilitates the development of drugs intended to treat serious or life-threatening conditions and that have the potential to address unmet medical needs. Fast Track drugs are eligible for more frequent and timely meetings with the FDA to discuss the development plan and to ensure that data needed for approval are collected appropriately. Drugs in the Fast Track program typically are granted priority review status and their respective New Drug Applications are accepted and reviewed by the FDA as rolling submissions.

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. Cognitive dysfunction is responsible for substantial disability in these diseases and is not 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 psychiatric manifestations, such 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 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 that it will advance OMS824 into Phase 2 clinical programs for Huntington's disease and schizophrenia this year; regarding the potential therapeutic benefits of OMS824; and that it 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.

SOURCE Omeros Corporation

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