

Omeros Reports Additional Positive Results from OMS824 Program

Written by Australian Business

SEATTLE, Sept. 12, 2013 /PRNewswire/ -- Omeros Corporation (NASDAQ: [OMER](#)) today announced positive data from the Company's Phase 1 clinical trial evaluating the pharmacokinetics of OMS824, the lead compound in Omeros' phosphodiesterase 10 (PDE10) program, further supporting that OMS824 can achieve superior target engagement with lesser side effects compared to other PDE10 inhibitors in development. With these data and the previously announced encouraging results from the OMS824 positron emission tomography (PET) clinical trial, Omeros is advancing OMS824 into Phase 2 clinical programs. 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.

The OMS824 Phase 1 clinical trial included single- and multiple-dose escalation studies that enrolled 100 healthy male subjects: 60 subjects received a single dose of OMS824, 24 subjects received multiple doses for seven to 10 days, and 16 subjects received placebo. The data announced today are at the highest multiple-dose level administered and, at this dose, OMS824 was well tolerated and the only apparent drug-related adverse events were mild. Almost all adverse events were self-limiting, resolving during the 10-day dosing period. In May of this year, Omeros reported that a lower dose evaluated in an ongoing PET clinical trial demonstrated target engagement greater than had previously been reported for any PDE10 inhibitor (an average of approximately 50-percent and a maximum of approximately 70-percent engagement) without the dose-limiting side effects seen with other PDE10 inhibitors. Pharmacokinetic data at the high dose announced today showed an approximately two-fold increase in plasma concentration over that of the dose used in the earlier-reported PET trial. This same high dose level is scheduled to be evaluated in the ongoing PET trial and is expected to demonstrate substantially higher target engagement. The Phase 1 clinical trial results predict that OMS824, at well-tolerated doses, will effectively inhibit PDE10 and support continuing development for the treatment of Huntington's disease, schizophrenia and other central nervous system disorders.

"These findings are unprecedented based on our knowledge of the work to date in the area of PDE10 inhibition and could result in a significant competitive advantage across a range of CNS indications," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "With this further confirmation of the unique pharmacology of our PDE10 inhibitor, Omeros is well positioned to initiate Phase 2 programs in schizophrenia and Huntington's disease before year-end."

About Omeros' PDE10 Program PDE10 is an enzyme that is expressed in areas of the brain

Omeros Reports Additional Positive Results from OMS824 Program

Written by Australian Business

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 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 six 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 pharmaceutical industry. 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 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 the potential competitive advantages of OMS824, including its therapeutic benefits; that it will advance OMS824 into Phase 2 clinical programs for Huntington's disease and schizophrenia before year end; regarding the potential qualities of OMS824; regarding demonstration of target engagement in the PET trial; 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 pharmaceutical industry. 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

Omeros Reports Additional Positive Results from OMS824 Program

Written by Australian Business

forward-looking statements publicly, even if new information becomes available in the future.

SOURCE Omeros Corporation