NEWS RELEASE

Omeros Corporation Announces Positive Results from Phase 1 Study of its Lead PDE7 Inhibitor in Development for Addiction

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-- Phase 1 study results show excellent safety and PK profile consistent with once-daily dosing --

SEATTLE--(BUSINESS WIRE)--Sep. 16, 2019-- Omeros Corporation (Nasdaq: OMER) today announced positive results from its Phase 1 study with the lead compound in its OMS527 program. The OMS527 program is developing phosphodiesterase 7 (PDE7) inhibitors for the treatment of addictions and compulsive disorders as well as movement disorders. The Phase 1 study included single-ascending-dose and multiple-ascending-dose cohorts and was conducted in healthy volunteers.

In the double blind, randomized Phase 1 study, the study drug, referred to as OMS182399, was administered to 47 healthy volunteers and met the primary endpoints of safety and tolerability. In the single-ascending-dose part of the study, fasted subjects received single oral doses of placebo or OMS182399 in five sequential ascending-dose cohorts. The study also included a single-dose cohort in non-fasting (i.e., fed) subjects. In the multiple-ascending-dose part of the study, non-fasting subjects received oral doses of placebo or OMS182399 once a day for 14 days in three sequential ascending-dose cohorts.

The study demonstrated that OMS182399 was safe and well-tolerated over the dose ranges tested. The number of subjects reporting any treatment-emergent adverse event (TEAE) was 2 out of 12 (16.7 percent) and 8 out of 35

(22.9 percent) in the placebo and active groups, respectively. All TEAEs were mild in intensity and transient, the most frequent being headache; no serious AE or lab-related AE was reported, and there was no dose dependency of AEs observed. No TEAE occurred in the highest dose group in the single-ascending-dose part of the study (n=6).

Importantly, OMS182399 showed a favorable and dose-proportional pharmacokinetic (PK) profile supporting once-daily dosing, and there was no apparent food effect on plasma exposure to OMS182399.

"We are pleased with the results of our OMS527 Phase 1 study," said Gregory A. Demopulos, MD, chief executive officer of Omeros Corporation. “The data demonstrate good tolerability, dose proportionality in plasma exposure, a PK profile that is highly consistent with once-daily dosing, and no safety concerns. We expect that our OMS527 program will deliver first-in-class PDE7 inhibitors for the treatment of addiction and compulsive disorders.”

Preclinical data show efficacy across multiple types of addiction and compulsive disorders, including nicotine, cocaine, opioids, alcohol, and binge eating. Omeros’ PDE7 inhibitors reduce craving and relapse but do not appear to be addictive nor to depress pleasure from normal activities (e.g., social interaction, sex, eating, etc.), both of which are often shortcomings of current commercial addiction therapies. Tens of millions of people in the U.S. suffer from substance addiction, with an estimated societal cost of nearly $1 trillion.

The initial target planned for the OMS527 program is nicotine addiction. The single largest preventable cause of death and disease in the U.S. is tobacco use, with a national death toll of nearly half a million people annually. Smoking-related illness in the U.S. costs over $300 billion a year and, in 2016, an estimated 38 million adults in the U.S. were current cigarette smokers. Omeros also intends to advance PDE7 inhibitors into clinical trials in other addiction disorders.

Omeros discovered the link between PDE7 and (1) addiction and compulsive disorders and (2) movement disorders, and the company holds broad patents in the U.S. and internationally directed to PDE7 inhibitors for the treatment of all of these disorders. Omeros has also elucidated the mechanism by which its proprietary PDE7 inhibitors modulate dopamine levels in the areas of the brain responsible for addiction and compulsion, and a manuscript detailing this mechanism has been submitted for peer-reviewed publication.

About Omeros Corporation

Omeros is a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. The company’s drug product OMIDRIA (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is marketed in the U.S. for use during cataract surgery or intraocular lens (IOL) replacement to

maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In the European Union, the European Commission has approved OMIDRIA for use in cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a diverse group of preclinical programs and a proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and corresponding compounds, a number of which are in preclinical development. The company also exclusively possesses a novel antibody-generating platform.

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. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “likely”, “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “prospects,” “should,” “slated,” “targeting,” “will,” “would” and similar expressions and variations thereof. Forward-looking statements, including statements regarding Omeros’ research and development programs and the therapeutic application of Omeros’ research findings, 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, uncertainties inherent in research and development such as the risk that results of future clinical or preclinical studies may be different from those suggested by earlier results, regulatory oversight, intellectual property claims, competitive developments, litigation, and 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 1, 2019. 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, even if new information becomes available in the future.

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Jennifer Cook Williams

Cook Williams Communications, Inc.
Investor and Media Relations
360.668.3701
jennifer@cwcomm.org