



NEWS RELEASE

Omeros Announces Preliminary Results from Phase 1 Clinical Trial of OMS906

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-- Results show good safety and PK/PD profile consistent with low-dose, once-monthly subcutaneous dosing --

SEATTLE--(BUSINESS WIRE)--Jun. 9, 2021-- Omeros Corporation (Nasdaq: OMER), 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, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders, today announced preliminary results from the Phase 1 clinical trial of its MASP-3 inhibitor OMS906. The ongoing trial is designed as a randomized, double-blind, placebo-controlled study to assess the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of intravenous (IV) and subcutaneous (SC) administration of OMS906 to healthy adult volunteers. OMS906 has been well tolerated at all doses tested. Preliminary human PK and PD data are consistent with once-monthly SC dosing.

MASP-3, the key activator of the alternative pathway of complement, converts pro-complement factor D (pro-CFD) to mature CFD. Inhibition of MASP-3 by OMS906 in nonhuman primates reduces systemic levels of mature CFD to below the threshold of detection, correspondingly blocking the alternative pathway of complement. The OMS906 Phase 1 clinical trial design consists of both single- and multiple-ascending dose cohorts. Pharmacodynamic response to OMS906 in the Phase 1 trial is being assessed by quantitation of mature CFD in plasma. In the single-ascending dose stage, 48 subjects have been evaluated to date across a series of IV and SC doses. Findings include:

- OMS906, administered up to 5 mg/kg, has been well tolerated at all IV and SC doses tested with no apparent safety signals
- Single 3 mg/kg IV dose of OMS906 suppresses mature CFD below minimum detectable levels for 4 weeks
- Single lowest SC dose of OMS906 suppresses mature CFD at or below minimum detectable levels for 4 weeks
- Dose-dependent PK/PD profile across all cohorts is favorable and supports low-dose, once-monthly or less frequent subcutaneous dosing

The study is ongoing with additional single- and multiple-dose cohorts to determine the pharmacologic dose range and optimal frequency for subcutaneous administration.

“The data from the Phase 1 clinical trial to date confirm our expectations for the role and dosing of OMS906 in humans,” said Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. “The data validate, in humans, the function of MASP-3 – the key activator of the alternative pathway – as a regulator of CFD and support the potential of OMS906 as a safe and long-acting therapeutic for the treatment of alternative pathway-related diseases and disorders. Omeros has built a strong intellectual property position around MASP-3 inhibition, and we look forward to completing the current study and advancing to a Phase 2 clinical trial as quickly as possible.”

About Omeros’ MASP-3 Inhibitor Program

The complement system plays a key role in inflammation and becomes activated as a result of tissue damage or microbial infection. Omeros’ MASP-3 inhibitor program includes potent molecules selectively inhibiting mannan-binding lectin-associated serine protease-3 (MASP-3), the protein activator of the alternative pathway of complement (APC). APC inhibitors are thought to have preventive or therapeutic effects across a broad range of diseases including paroxysmal nocturnal hemoglobinuria, hemolytic uremic syndrome (HUS), atypical HUS, traumatic brain injury, arthritis, wet age-related macular degeneration, ischemia-reperfusion injury, transplant-related complications and other immune-related disorders. Omeros is developing both antibody and small molecules to block MASP-3. Through its growing intellectual property position, Omeros exclusively controls inhibitors of the protein activator of the alternative pathway (MASP-3) and, with its OMS721 program, inhibitors of the effector enzyme of the lectin pathway (MASP-2), allowing the company to target with unprecedented precision diseases caused by dysregulation of one or both of these pathways.

About Omeros Corporation

Omeros is a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting inflammation, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous

system disorders. Its commercial product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% continues to gain market share in cataract surgery. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application under priority review by FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, atypical hemolytic uremic syndrome and COVID-19. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is in a Phase 1 clinical trial, and the company's PDE7 inhibitor program OMS527, targeting addiction and movement disorders, has successfully completed a Phase 1 trial. Omeros' pipeline holds a diverse group of preclinical programs including a proprietary-asset-enabled antibody-generating technology and a proprietary GPCR platform through which it controls 54 GPCR drug targets and their corresponding compounds. One of these novel targets, GPR174, modulates a new cancer immunity axis recently discovered by Omeros, and the company is advancing GPR174-targeting antibodies and small-molecule inhibitors. For more information about Omeros and its programs, visit www.omeros.com.

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," "objective," "plan," "potential," "predict," "project," "should," "slate," "target," "will," "would" and similar expressions and variations thereof. 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, risks associated with product commercialization and commercial operations, unproven preclinical and clinical development activities, regulatory processes and oversight, challenges associated with manufacture or supply of our investigational products, intellectual property claims, competitive developments, 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 (SEC) on March 1, 2021. 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, whether as a result of new information, future events or otherwise, except as required by applicable law.

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Jennifer Cook Williams

Cook Williams Communications, Inc.

Investor and Media Relations

360.668.3701

jennifer@cwcomm.org

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