



NEWS RELEASE

## Omeros' Investigational New Drug Application for OMS906 Cleared by FDA

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-- Paroxysmal Nocturnal Hemoglobinuria Slated as Initial Indication --

SEATTLE--(BUSINESS WIRE)--Aug. 31, 2020-- Omeros Corporation today announced that its Investigational New Drug Application (IND) to begin clinical trials with OMS906 has been cleared by the U.S. Food and Drug Administration (FDA). OMS906 is the company's lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-3 (MASP-3), the key activator of the complement system's alternative pathway.

FDA's clearance of the IND allows the initiation of the clinical program for OMS906. A Phase 1, placebo-controlled, double-blind, single-ascending-dose and multiple-ascending-dose study will evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of OMS906 administered subcutaneously and intravenously to healthy subjects. Enrollment is planned to begin in early September. The trial will provide additional information regarding the anticipated OMS906 dosing regimen in patients, which is targeted for once monthly subcutaneous administration. Following adequate Phase 1 data collection and analysis, the initial Phase 2 clinical trial is planned in patients with life-threatening paroxysmal nocturnal hemoglobinuria (PNH), a rare disease characterized by red blood cell destruction, blood clots and impaired bone marrow function.

"FDA's decision clears the way for us to begin clinical trials with OMS906," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "Based on its mechanism of action, we believe that OMS906 will

demonstrate a better safety profile and/or more convenient dosing than other drugs on the market or in development for PNH. By inhibiting MASP-3, the key activator of the alternative pathway of complement, the potential indications for OMS906 are expansive. The therapeutic rationale for MASP-3 inhibition and OMS906 are sound, and we look forward to seeing what the drug will do in the clinic.”

MASP-3 is responsible for the conversion of pro-factor D to factor D. It is believed to be the premier target in the alternative pathway with the lowest native circulating level and low relative clearance compared to the other alternative pathway proteins. Also, unlike C5 and C3 blockers, MASP-3 inhibition leaves intact the lytic arm of the classical pathway, important for fighting infection. Omeros has created a broad intellectual property position directed to the use of MASP-3 inhibitors, including OMS906, for the treatment of a wide range of disorders related to dysfunction or excessive activation of the complement system’s alternative pathway. As part of its complement franchise, Omeros also broadly controls the inhibition of MASP-2, the effector enzyme of the lectin pathway of complement. A rolling biologics license application (BLA) for Omeros’ lead MASP-2 inhibitor narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) is targeted for completion this quarter. Narsoplimab is also in Phase 3 clinical programs for immunoglobulin A (IgA) nephropathy and atypical hemolytic uremic syndrome and is being advanced to treat critically ill patients with COVID-19.

## About OMS906

OMS906 is an investigational human monoclonal antibody targeting mannan-binding lectin-associated serine protease-3 (MASP-3), the key activator of the complement system’s alternative pathway. The complement system plays a central role in inflammation and becomes activated as a result of tissue damage or microbial infection. Responsible for the conversion of pro-factor D to factor D, MASP-3 is believed to be the premier target in the alternative pathway – it has the lowest native circulating level and low relative clearance compared to the other alternative pathway proteins and, unlike C5 and C3 blockers, MASP-3 inhibition leaves intact the lytic arm of the classical pathway, important for fighting infection. MASP-3 inhibitors are thought to have preventive or therapeutic effects across a broad range of diseases including paroxysmal nocturnal hemoglobinuria (PNH), 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. Through its growing intellectual property position, Omeros controls the use of MASP-3 inhibitors across a wide range of alternative pathway-related diseases and disorders.

## 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, complement-mediated diseases, disorders of the central nervous system and immune-related

diseases, including cancers. In addition to its commercial product OMIDRIA (phenylephrine and ketorolac intraocular solution) 1%/0.3%, Omeros has multiple late-stage clinical development programs focused on complement-mediated disorders, including COVID-19, and substance abuse. A rolling biologics license application for narsoplimab, the company's lead MASP-2 inhibitor, in hematopoietic stem cell transplant-associated thrombotic microangiopathy is being completed for submission to the U.S. FDA. Omeros also has a diverse group of preclinical programs including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis recently discovered by Omeros. Small-molecule inhibitors of GPR174 are part of Omeros' proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and their corresponding compounds. 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," "can," "could," "estimate," "expect," "goal," "intend," "likely", "look forward to," "may," "on track," "plan," "potential," "predict," "project," "prospects," "scheduled," "should," "slated," "targeting," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including statements regarding anticipated regulatory submissions, expectations regarding regulatory exclusivities, the timing and results of ongoing or anticipated clinical trials, and the therapeutic application of Omeros' investigational product, 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, availability and timing of data from clinical trials and the results of such trials, unproven preclinical and clinical development activities, 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 for the year ended December 31, 2019, filed with the Securities and Exchange Commission (SEC) on March 2, 2020, as supplemented by its Quarterly Report on Form 10-Q filed with the SEC on May 11, 2020 and subsequent filings with the SEC. 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 any new information, future events or otherwise, except as required by applicable law.

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