



NEWS RELEASE

Biologics License Application for Narsoplimab in HSCT-TMA Accepted for Priority Review by U.S. FDA

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-- FDA sets PDUFA date of July 17, 2021 --

SEATTLE--(BUSINESS WIRE)--Jan. 19, 2021-- Omeros Corporation (Nasdaq: OMER) announced today that the Biologics License Application (BLA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) has been accepted for filing by the U.S. Food and Drug Administration (FDA). The BLA has been granted Priority Review with an FDA action date of July 17, 2021 under the Prescription Drug User Fee Act (PDUFA). FDA also indicated in its filing letter that the Agency is not currently planning to hold an advisory committee meeting to discuss the BLA.

FDA grants Priority Review to applications for therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, prevention or diagnosis of serious conditions. Narsoplimab targets mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the lectin pathway of complement, and has received breakthrough therapy designations and orphan drug designations from FDA for each of HSCT-TMA and IgA nephropathy.

"The filing of our BLA by FDA marks an important milestone on the path to commercialization of narsoplimab," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "There is no FDA-approved product for the treatment of transplant-associated TMA, a frequently fatal complication of stem cell

transplantation. We appreciate FDA's collaborative approach throughout the development of our breakthrough therapy-designated product narsoplimab, and we are committed to continue working closely with the FDA review team to make the drug available to patients who need it."

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. 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 rolling 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. Omeros' MASP-3 inhibitor OMS906, which targets the complement system's alternative pathway, recently entered the clinic, and the company's PDE7 inhibitor OMS527 has successfully completed its Phase 1 trial. Omeros' pipeline holds a diverse group of preclinical programs including a novel antibody-generating technology and a proprietary GPCR platform through which it controls 54 new 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 small-molecule GPR174 inhibitors. For more information about Omeros and its programs, visit www.omeros.com.

About Hematopoietic Stem Cell Transplant-associated Thrombotic Microangiopathy

Hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) is a significant and often lethal complication of stem cell transplantation. This condition is a systemic, multifactorial disorder caused by endothelial cell damage induced by conditioning regimens, immunosuppressant therapies, infection, graft-versus-host disease, and other factors associated with stem cell transplantation. Endothelial damage, which activates the lectin pathway of complement, plays a central role in the development of HSCT-TMA. The condition occurs in both autologous and allogeneic transplants but is more common in the allogeneic population. In the United States and Europe, approximately 25,000 to 30,000 allogeneic transplants are performed annually. Recent reports in both adult and pediatric allogeneic stem cell transplant populations have found an approximately 40-percent incidence of HSCT-TMA, and high-risk features may be present in up to 80 percent of these patients. In severe cases of HSCT-TMA, mortality can exceed 90 percent and, even in those who survive, long-term renal sequelae (e.g., dialysis) are common. There is no approved therapy or standard of care for HSCT-TMA.

About Narsoplimab

Narsoplimab, also known as “OMS721,” is an investigational human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), a novel pro-inflammatory protein target and the effector enzyme of the lectin pathway of complement. Importantly, inhibition of MASP-2 does not appear to interfere with the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection. Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2.

A biologics license application (BLA) is under priority review by the U.S. FDA for use of narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), and the drug is in Phase 3 clinical programs for immunoglobulin A (IgA) nephropathy and atypical hemolytic uremic syndrome (aHUS). The FDA has granted narsoplimab breakthrough therapy designations for HSCT-TMA and for IgA nephropathy; orphan drug status for the prevention (inhibition) of complement-mediated thrombotic microangiopathies, for the treatment of HSCT-TMA and for the treatment of IgA nephropathy; and fast track designation for the treatment of patients with aHUS. The European Medicines Agency has granted orphan drug designation to narsoplimab for treatment in HSCT and for treatment of primary IgA nephropathy. For additional information regarding narsoplimab and its clinical trials, visit www.omeros.com/narsoplimab.

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, 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, risks associated with product commercialization and commercial operations, unproven preclinical and clinical development activities, the impact of COVID-19 on our business, financial condition and results of operations, regulatory oversight, changes in reimbursement and payment policies by government and commercial payers or the application of such policies, 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 (SEC) on March 2, 2020, as supplemented by our Quarterly Reports on Form 10-Q filed with the SEC 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 new information, future events or otherwise, except as required by applicable law.

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