



NEWS RELEASE

Omeros Submits Narsoplimab Marketing Authorization Application to the European Medicines Agency for the Treatment of TA-TMA

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SEATTLE--(BUSINESS WIRE)--Jun. 27, 2025-- Omeros Corporation (Nasdaq: OMER) today announced the recent submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).

The MAA includes response-based analyses in narsoplimab-treated TA-TMA patients as well as analyses comparing overall survival between narsoplimab-treated patients and a well-matched external control group. Collectively, the results demonstrate a 61% response rate and, compared to the matched external control, a three-fold improvement in overall survival. The submission also includes outcomes in over 130 TA-TMA patients treated with narsoplimab under Omeros' expanded access program.

Narsoplimab has been granted orphan drug designation by the EMA for treatment in hematopoietic stem cell transplant, enabling review of the MAA through the centralized procedure. This allows for a single marketing authorization to cover all EU member states and the European Economic Area countries of Iceland, Liechtenstein and Norway.

The review procedure begins in mid-July and will follow a standard review timeline. The Committee for Medicinal

Products for Human Use (CHMP) will conduct the scientific assessment and will issue an opinion at the end of the review. This opinion is typically adopted by the European Commission, with a final decision expected in mid-2026.

The MAA submission follows the acceptance for review by the U.S. Food and Drug Administration (FDA) of the resubmission of the Biologics License Application (BLA) for narsoplimab for the treatment of TA-TMA. The resubmission was assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 25, 2025.

About Narsoplimab

Narsoplimab, also known as “OMS721,” is an investigational fully 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 has been demonstrated to leave intact the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection. A biologics license application (BLA) for use of narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) is under review by the U.S. Food and Drug Administration (FDA) and Omeros has submitted the corresponding European MAA. FDA has granted narsoplimab breakthrough therapy and orphan drug designations for TA-TMA and orphan drug status for the prevention (inhibition) of complement-mediated thrombotic microangiopathies. The European Medicines Agency has granted orphan drug designation to narsoplimab for treatment in hematopoietic stem-cell transplant.

About Hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA)

Hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-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 TA-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 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 TA-TMA, and high-risk features may be present in up to 80 percent of these patients. In severe cases of TA-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 TA-TMA.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing

first-in-class small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders, including complement-mediated diseases and cancers, as well as addictive and compulsive disorders. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application under review by FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Omeros' long-acting MASP-2 inhibitor OMS1029 has successfully completed Phase 1 single- and multiple-ascending dose clinical studies. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is in clinical development for paroxysmal nocturnal hemoglobinuria and complement 3 glomerulopathy. Funded by the National Institute on Drug Abuse, Omeros' lead phosphodiesterase 7 inhibitor OMS527 is in clinical development for the treatment of cocaine use disorder. Omeros also is advancing a broad portfolio of novel cellular and molecular immuno-oncology programs. 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 "aim," "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, including statements regarding the anticipated review process and timing of FDA action on the resubmitted BLA for narsoplimab in the United States, the anticipated review process and timing of EMA action on the MAA submission, the prospects for obtaining FDA or EMA approval of narsoplimab in any indication, and expectations regarding the sufficiency and availability of our capital resources to fund current and planned operations, including the potential commercialization of narsoplimab if it is approved by FDA or the EMA, 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, unfavorable or unexpected regulatory conclusions or interpretations related to the clinical data, external registry data, statistical analyses or other information and data included in the narsoplimab BLA or narsoplimab MAA, inability to respond satisfactorily to information requests during regulatory review of the narsoplimab BLA or MAA, potential differences between the diagnostic criteria used in our pivotal trial and in the external registry, and whether FDA and the EMA determine the registry used in our statistical analysis is sufficiently representative of TA-TMA patients, unanticipated or unexpected outcomes or requirements of regulatory processes in relevant jurisdictions, our financial condition and results of operations, including our ability to raise additional capital for our operations on favorable terms or at all, regulatory processes and oversight, challenges associated with manufacture or supply of our products to support clinical trials, regulatory inspections and/or commercial sale

following any marketing approval, 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 our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2025 and in subsequent reports filed with the Securities and Exchange Commission. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume 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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