NEWS RELEASE

Omeros Corporation Announces Update on European Marketing Authorization Application for Narsoplimab in TA-TMA

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SEATTLE--(BUSINESS WIRE)-- Omeros Corporation (Nasdaq: OMER) announced today an update on the review by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) of the company's marketing authorization application (MAA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).

Following an oral explanation meeting with the CHMP held this week, at which Omeros presented its position together with four international experts in hematopoietic cell transplantation, Omeros was informed that the CHMP has adopted a negative opinion on the MAA for narsoplimab in TA-TMA.

Omeros intends to request re-examination of the CHMP opinion and, as part of that procedure, to seek review of the matter by an Ad Hoc Expert Group (AHEG), an independent panel of external scientific and clinical experts to be convened by EMA based on relevant expertise in the indication and related clinical considerations.

Narsoplimab was approved under the brand name YARTEMLEA® by the U.S. Food and Drug Administration (FDA) in December 2025. Broadly indicated for all TA-TMA patients two years of age and older, it is the first and only treatment to receive regulatory approval for TA-TMA. YARTEMLEA targets MASP-2, the effector enzyme of the lectin pathway of complement and, with a unique safety profile, is the only systemic complement inhibitor on the market

without a boxed warning, risk evaluation and mitigation strategy (REMS), or vaccination requirement.

“We are disappointed by the CHMP’s opinion, particularly given the lethal nature of TA-TMA, the absence of an approved treatment for this condition in Europe, and the totality of the clinical trial and real-world data supporting narsoplimab’s efficacy and safety,” said Gregory A. Demopulos, M.D., chairman and chief executive officer of Omeros. “We look forward to meeting with the AHEG and believe strongly that YARTEMLEA warrants approval in Europe, just as it received approval in the U.S. In the meantime, we plan to continue providing YARTEMLEA to TA-TMA patients under our global compassionate use program, prioritizing children. Given drug supply and access constraints, however, compassionate use in Europe can reach only a fraction of the patients who could be treated following EMA approval. While regulatory review progresses, we will work to make YARTEMLEA available to patients who need it and to prevent avoidable deaths from TA-TMA.”

The MAA is supported by clinical data from Omeros’ pivotal trial of narsoplimab in TA-TMA, together with analyses comparing survival in narsoplimab-treated patients to survival in an external registry of TA-TMA patients who did not receive narsoplimab, as well as by the company’s compassionate use program. These are the same data on which FDA based its approval of narsoplimab for TA-TMA.

About Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy

Hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) is a severe and often-fatal complication of hematopoietic stem cell transplantation in adults and children. TA-TMA is driven by systemic endothelial injury triggered by conditioning regimens, immunosuppressants, infection, graft-versus-host disease, and other transplant-related factors, with activation of the lectin pathway of complement playing a central role in disease pathogenesis.

TA-TMA can occur following both autologous and allogeneic transplant, with higher prevalence after allogeneic procedures. Approximately 30,000 allogeneic transplants are performed annually in the U.S. and Europe. Recent studies estimate that TA-TMA develops in up to 56 percent of allogeneic transplant recipients. Mortality in severe TA-TMA can exceed 90 percent, and survivors frequently face long-term renal complications, including dialysis dependence.

About YARTEMLEA® (narsoplimab-wuug)

YARTEMLEA® (narsoplimab-wuug), a fully human monoclonal antibody, is the first and only approved inhibitor of the lectin pathway of complement. YARTEMLEA inhibits mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the lectin pathway. In hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA), MASP-2 inhibition prevents lectin pathway-mediated cellular injury, including

endothelial damage in small blood vessels, and thrombus formation. By selectively blocking activation of the lectin pathway, YARTEMLEA preserves classical and alternative pathway activity, including functions essential to the adaptive immune response.

YARTEMLEA is approved by the U.S. FDA for the treatment of TA-TMA in adults and children ages two years and older.

IMPORTANT SAFETY INFORMATION FOR YARTEMLEA

Contraindications

None.

Warnings and Precautions

Serious and life-threatening infections, regardless of causality or relatedness to YARTEMLEA, were reported in 36% (10/28) of clinical trial patients treated with YARTEMLEA, including sepsis, viral infections, pneumonia, bacteremia, fungal infection, gastroenteritis, respiratory tract infections, and urosepsis. If YARTEMLEA is administered to patients with active infections, monitor closely for signs and symptoms of worsening infection and treat promptly.

Adverse Reactions

The most common adverse reactions (≥ 20%), regardless of causality or relatedness to YARTEMLEA, were viral infections, sepsis, hemorrhage, diarrhea, vomiting, nausea, neutropenia, pyrexia, fatigue, and hypokalemia.

Use in Specific Populations

Pregnancy: Available data on the use of YARTEMLEA during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

Lactation: There are no data on the presence of YARTEMLEA in human milk, the effects on the breastfed child, or the effects on milk production.

To report suspected adverse reactions, contact Omeros Corporation at 1-844-YARTEM1 (1-844-927-8361), or contact FDA at 1-800-FDA-1088 or through **FDA MedWatch**.

Please see the **Full Prescribing Information** for YARTEMLEA.

About Omeros Corporation

Omeros is an innovative biotechnology company that discovers and develops first-in-class protein and small-molecule therapeutics for both large-market and orphan indications, with a focus on complement-mediated diseases, cancers, and addictive or compulsive disorders. Omeros' lead complement inhibitor YARTEMLEA® (narsoplimab-wuug), which targets the lectin pathway's effector enzyme MASP-2, is FDA-approved and commercially available in the U.S. for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) in adult and pediatric patients aged two years and older. OMS1029, Omeros' long-acting MASP-2 inhibitor, has successfully completed Phase 1 clinical trials.

Under a recently announced asset purchase and licensing agreement, Novo Nordisk acquired global rights to zaltenibart (formerly OMS906), an inhibitor of MASP-3, the alternative pathway's key activator, which is in clinical development for PNH and other alternative pathway indications, along with associated intellectual property and related assets. Omeros' pipeline also includes OMS527, a phosphodiesterase 7 inhibitor in clinical development for cocaine use disorder, which is fully funded by the National Institute on Drug Abuse, and a growing portfolio of novel recombinant antibodies targeting multidrug-resistant organisms and novel molecular and cellular therapeutic programs for oncology. 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, including statements regarding the anticipated therapeutic benefits of drug candidates within our development pipeline, statements of intention or expectations regarding our marketing authorization application for narsoplimab in Europe, plans and expectations regarding commercialization of narsoplimab in the European Union following any EMA approval, ability to consummate licensing, partnering or other transactions and the benefits, if any, we would receive from any such transactions, expectations regarding the sufficiency and availability of our capital resources to fund current and planned operations, including the commercialization of YARTEMLEA® 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 our marketing authorization application or our inability to respond satisfactorily to information requests during regulatory review, 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 or complete other transactions 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, 2026 and in our subsequently filed Quarterly Reports on Form 10-Q. 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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