



NEWS RELEASE

Omeros Announces Publication Highlighting Survival Outcomes in TA-TMA Patients Treated with Narsoplimab Under Its Global Expanded Access Program

2025-09-02

SEATTLE--(BUSINESS WIRE)--Sep. 2, 2025-- Omeros Corporation (Nasdaq: OMER) today announced the publication of a peer-reviewed manuscript in the American Journal of Hematology detailing survival outcomes in adult and pediatric patients with life-threatening transplant-associated thrombotic microangiopathy (TA-TMA) treated with narsoplimab through a global expanded access program (EAP). Narsoplimab inhibits MASP-2, the effector enzyme of the lectin pathway of complement, and is currently under review for marketing approval by both the U.S. FDA and the European Medicines Agency.

Authored by an international panel of pediatric and adult transplant experts, the manuscript – titled “Narsoplimab Results in Excellent Survival in Adults and Children with Hematopoietic Cell Transplant Associated Thrombotic Microangiopathy (TA-TMA)” – reports survival outcomes in patients treated with narsoplimab as first-line therapy and in those who failed prior treatments, including C5 inhibitors. Consistent with previous narsoplimab clinical studies, no safety signals of concern were observed. The full manuscript is **available online**.

About Narsoplimab

Narsoplimab (OMS721) is an investigational, fully human monoclonal antibody that inhibits mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the lectin pathway of complement. Unlike other complement inhibitors, narsoplimab preserves the lytic function of the classical pathway, which is critical for antibody-mediated immune defense against infection.

A biologics license application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) is currently under review by the FDA, and a corresponding marketing authorisation application (MAA) is under review by the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use. Narsoplimab has received breakthrough therapy and orphan drug designations from the FDA for TA-TMA and for the prevention (inhibition) of complement-mediated thrombotic microangiopathies. The EMA has granted orphan drug designation for narsoplimab in hematopoietic stem-cell transplant.

About Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy

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

TA-TMA occurs in both autologous and allogeneic transplants, with higher prevalence in the latter. Approximately 30,000 allogeneic transplants are performed annually in the U.S and Europe. Recent studies estimate a 40-percent incidence of TA-TMA in allogeneic transplants, with high-risk features in up to 80 percent of cases. Mortality in severe TA-TMA can exceed 90 percent, and survivors often face long-term renal complications, including dialysis. Currently, there is no approved therapy or established standard of care for TA-TMA.

About Omeros Corporation

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing, and commercializing first-in-class small-molecule and protein therapeutics for large-market and orphan immunologic indications – 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 narsoplimab marketing applications are under review by both the U.S. FDA and the European Medicines Agency for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. OMS1029, Omeros' long-acting MASP-2 inhibitor, has successfully completed Phase 1 clinical trials. OMS906 targeting MASP-3, the key activator of the alternative pathway of complement, is in late-stage development for paroxysmal nocturnal hemoglobinuria and C3

glomerulopathy. OMS527, a phosphodiesterase 7 inhibitor, is in clinical development for cocaine use disorder, fully funded by the National Institute on Drug Abuse. Omeros is also advancing a robust pipeline of novel immuno-oncology programs.

For more information visit **www.omeros.com**.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20250902558830/en/>

Jennifer Cook Williams

Cook Williams Communications, Inc.

Investor and Media Relations

IR@omeros.com

Source: Omeros Corporation