



NEWS RELEASE

Omeros' Narsoplimab Pivotal Trial Data Shared in Oral Presentation at 2021 Annual Congress of the European Hematology Association

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-- Data on Organ Function Improvement Presented by Chief of Adult Bone Marrow Transplant Service at Memorial Sloan Kettering --

SEATTLE--(BUSINESS WIRE)--Jun. 14, 2021-- Omeros Corporation (Nasdaq: OMER) today announced that data on organ function improvement from its pivotal trial of narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) were shared during an oral presentation at the virtual edition of the 26th Congress of the European Hematology Association (EHA). The **presentation, entitled Narsoplimab (OMS721) Treatment Contributes to Improvements in Organ Function in Adult Patients with High-Risk Transplant-Associated Thrombotic Microangiopathy**, was delivered last Friday by Miguel-Angel Perales, M.D., Chief of Adult Bone Marrow Transplant Service at Memorial Sloan Kettering Cancer Center. The organ function improvement data presented underscore the potential of narsoplimab as a significant advance in the treatment of often fatal HSCT-TMA.

The trial's findings include:

- The study population was high-risk, with 93 percent having multiple risk factors for poor outcomes, and highly reflective of "real-world" clinical practice

- At baseline:
 - 75% of patients had kidney dysfunction
 - 57% had neurologic dysfunction
 - 18% had pulmonary dysfunction
 - 50% had multiple organ TMA involvement
 - 86% had significant infection
 - 68% had graft versus host disease (GVHD)
- 61% of the intent-to-treat (ITT) population (any patient receiving at least 1 dose of narsoplimab) and 74% of the per-protocol (PP) population (those patients receiving ≥ 4 weeks of dosing) responded to narsoplimab based on improvement in laboratory TMA markers (platelet count improvement and reduction in LDH levels) and clinical status (organ function or freedom from transfusion)
- 74% of eligible patients in the ITT population experienced improvement in organ function (67%, 50% and 100% in kidney, neurologic, or gastrointestinal function, respectively); 77% of eligible patients in the PP population experienced organ function improvement
- 48% of eligible patients in the ITT population and 55% in the PP population experienced freedom from transfusion
- Narsoplimab was well tolerated in this very sick population
 - The most common adverse events were pyrexia, diarrhea, vomiting, nausea, neutropenia, fatigue, and hypokalemia, all common in HSCT
 - Six patients died during the core study period due to causes common in HSCT
 - There were no study discontinuations due to non-fatal adverse events

Detailed data and findings from the study are being submitted to a peer-reviewed scientific journal for publication.

Dr. Perales' question-and-answer panel discussion for his presentation is scheduled for Tuesday, June 15, at 1:00-1:45 pm CEST/7:00-7:45 am EDT and will be available to registered attendees through the EHA Congress virtual platform.

In severe cases of HSCT-TMA, mortality can exceed 90 percent and, even in those who survive, significant morbidity is common with chronic organ injury often persisting. There is no approved treatment for HSCT-TMA. A Biologics License Application for use of narsoplimab in the treatment of HSCT-TMA is under Priority Review by the US Food and Drug Administration (FDA) with a Prescription Drug User Fee Act action date of October 17, 2021.

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 HSCT-TMA, and the drug is in Phase 3 clinical programs for immunoglobulin A (IgA) nephropathy and atypical hemolytic uremic syndrome (aHUS). Narsoplimab is also being evaluated for the treatment of COVID-19 as part of the I-SPY-COVID-19 platform trial sponsored by Quantum Leap Healthcare Collaborative. 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.

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, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders. 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 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. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is in a Phase 1 clinical trial, and the company's PDE7 inhibitor program OMS527, targeting addiction and movement disorders, has successfully completed a Phase 1 trial. Omeros' pipeline holds a diverse group of preclinical programs including a proprietary-asset-enabled antibody-generating technology and a proprietary GPCR platform through which it controls 54 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 GPR174-targeting antibodies and small-molecule inhibitors. For more information about Omeros and its programs, visit www.omeros.com.

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