



NEWS RELEASE

Omeros Announces Agreement with FDA on Primary Endpoint for Narsoplimab BLA in Stem Cell Transplant-Associated TMA

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-- All Criteria for the Response-Based Endpoint Now Finalized --

SEATTLE--(BUSINESS WIRE)--Jul. 11, 2019-- Omeros Corporation today announced agreement with the U.S. Food and Drug Administration (FDA) on the response-based primary endpoint for its pivotal trial to support the biologics license application (BLA) for narsoplimab to treat hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).

Narsoplimab, also known as "OMS721," is Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2). There is no approved product for the treatment or prevention of HSCT-TMA, and narsoplimab is the only drug in development for the treatment of HSCT-TMA to be granted FDA's breakthrough therapy designation.

As previously reported, FDA had already agreed to the majority of the criteria proposed for the response-based primary endpoint, and today's announced agreement with FDA has finalized the remaining components of the endpoint. The response-based primary endpoint for HSCT-TMA requires a showing of both a beneficial effect on the underlying HSCT-TMA disease process and a meaningful improvement in patients' clinical status. The endpoint includes laboratory measures and markers of organ function as well as platelet and red blood cell transfusion

burden.

Based on a review of the available data from the open-label, single-arm, pivotal trial, Omeros is confident that the study will meet the primary endpoint.

With finalization of the primary endpoint, the next steps for the planned commercialization of narsoplimab for HSCT-TMA are to:

- complete the ongoing data collection from medical records of patients already treated with narsoplimab in the clinical trial or under compassionate use. This will enable preparation of complete patient narratives for inclusion in the clinical sections of the BLA and of the marketing authorization application (MAA), which is being prepared for submission to the European Medicines Agency (EMA). No additional patients are needed for submission of the BLA to support approval of narsoplimab in this indication.
- meet with the program's EMA rapporteurs, scheduled to begin this summer, to refine further the path to European approval. Omeros intends to harmonize the contents of the MAA and BLA.
- complete and submit the BLA and MAA. FDA has previously confirmed that Omeros may submit this BLA on a rolling basis, and the company is finalizing for review by FDA its proposed schedule of module submissions under that rolling BLA. As also previously reported, the nonclinical sections of the BLA have been written and are expected to comprise the first module of the BLA submission. EMA does not have a similar rolling submission process.

"Through continued collaboration with FDA, we've now reached agreement on the full set of criteria for the primary endpoint for our narsoplimab pivotal trial in patients with stem cell transplant-associated TMA," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "Based on review of the available data, we're confident in both the magnitude and rate of response – as defined by the agreed criteria – that we're seeing with narsoplimab in these patients. The path has now been cleared for us to complete and submit the BLA, and we look forward to making narsoplimab available as quickly as possible to patients who need it."

Hematopoietic stem cell transplant-associated TMA is a significant, costly and often lethal complication of stem cell transplants. This condition is a systemic, multifactorial disorder caused by endothelial cell damage induced by infection, graft-versus-host disease, and therapies used as part of stem cell transplantation. In addition to TMA, veno-occlusive disease, diffuse alveolar hemorrhage and a range of other disorders are associated with endothelial cell damage. Collectively, these disorders comprise the endothelial injury syndrome. The lectin pathway of complement is activated by endothelial damage, and narsoplimab specifically targets MASP-2, the effector enzyme of the lectin pathway.

About Omeros' Complement Programs

Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2, a novel pro-inflammatory protein target involved in activation of the complement system, which is an important component of the immune system. The complement system plays a role in the inflammatory response and becomes activated as a result of tissue damage or microbial infection. MASP-2 is the effector enzyme of the lectin pathway, one of the principal complement activation pathways. 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, and its abnormal function is associated with a wide range of autoimmune disorders. MASP-2 is generated by the liver and is then released into circulation. Gene-targeted MASP-2-deficient mice and humans with MASP-2 gene polymorphisms that affect MASP-2 serum levels and MASP-2 functional activity are generally healthy with no obvious adverse phenotype.

Phase 3 clinical programs are in progress for narsoplimab, Omeros' lead MASP-2 inhibitor also known as "OMS721," in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), in immunoglobulin A (IgA) nephropathy, and in atypical hemolytic uremic syndrome (aHUS). Narsoplimab can be administered both intravenously and subcutaneously, and Omeros expects to commercialize each formulation of narsoplimab for different therapeutic indications. In parallel, Omeros is developing small-molecule inhibitors of MASP-2. Based on requests from treating physicians, Omeros has established a compassionate-use program for narsoplimab, which is active in both the U.S. and Europe. 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.

Omeros also has identified MASP-3 as the key activator of the human complement system's alternative pathway and as the enzyme responsible for the conversion of pro-factor D to factor D. The alternative pathway is linked to a wide range of immune-related disorders. In addition to its lectin pathway inhibitors, the company is advancing its development of antibodies and small-molecule inhibitors against MASP-3 to block activation of the alternative pathway. Omeros is scaling up the manufacturing of its MASP-3 antibodies in preparation for clinical trials slated for next year. In addition to its MASP-2- and MASP-3-specific programs, Omeros is developing bi-specific inhibitors of MASP-2/MASP-3.

About Omeros Corporation

Omeros is a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system and immune-related

diseases, including cancers. The company's drug product OMIDRIA (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is marketed in the U.S. for use during cataract surgery or intraocular lens (IOL) replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In the European Union, the European Commission has approved OMIDRIA for use in cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a diverse group of preclinical programs and a proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and corresponding compounds, a number of which are in preclinical development. The company also exclusively possesses a novel antibody-generating platform.

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," "plan," "potential," "predict," "project," "prospects," "should," "slated," "targeting," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including statements regarding anticipated regulatory submissions and approval, 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, availability and timing of data from ongoing clinical trials and the results of such trials, unproven preclinical and clinical development activities, regulatory oversight, 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 on March 1, 2019. 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, even if new information becomes available in the future.

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Jennifer Cook Williams

Cook Williams Communications, Inc.

Investor and Media Relations

360.668.3701

jennifer@cwcomm.org