



NEWS RELEASE

Omeros Reports Final Efficacy and Safety Data from the Narsoplimab Pivotal Trial in HSCT-TMA

2020-10-22

-- Webcast Scheduled for Today at 8:30am ET--

SEATTLE--(BUSINESS WIRE)--Oct. 22, 2020-- Omeros Corporation (Nasdaq: OMER) today announced final data from its pivotal trial for narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), an often-lethal complication of stem-cell transplantation for which there is no approved therapy. Narsoplimab, an inhibitor of mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the lectin pathway and activator of the coagulation cascade, is being studied for the treatment of HSCT-TMA patients at high risk for poor outcomes. Narsoplimab has been awarded Breakthrough Therapy designation by U.S. FDA and is the subject of a rolling Biologics License Application (BLA) for HSCT-TMA. The nonclinical and CMC modules of the rolling BLA have already been submitted, and the final sections of the clinical module are in the publishing phase during which finalized documents are electronically processed and integrated for submission in the format required by FDA.

Omeros previously presented preliminary data from its pivotal HSCT-TMA trial. The final data reported today are those that are included in the BLA. In the 28-patient single-arm, open-label pivotal trial in adult HSCT-TMA patients, treatment consisted of narsoplimab administered intravenously once weekly for up to 8 weeks with an extended follow-up period. The study's patient population was very ill, with the large majority of study patients having multiple comorbidities at baseline (e.g., graft-versus-host disease, significant infections, multi-organ dysfunction,

etc.). The FDA-agreed primary endpoint (complete response) required clinical improvement in TMA markers (platelet count and lactate dehydrogenase [LDH]) and in organ function (renal, pulmonary, gastrointestinal or neurological) or freedom from transfusion. Secondary endpoints included 100-day and overall survival as well as change from baseline for individual laboratory markers (platelets, LDH, haptoglobin, hemoglobin and creatinine).

The final results on primary and key secondary endpoints include:

- 61% (95% CI: 40.6% to 78.5%) complete response rate (CRR) in the full analysis set (FAS; patient receiving at least one dose of narsoplimab; $p < 0.0001$ compared to 15% efficacy threshold agreed with FDA)
- 74% (95% CI: 51.6% to 89.8%) CRR in the per-protocol (PP) population (patients receiving the protocol-specified narsoplimab treatment for at least 4 weeks; $p < 0.0001$ compared to the 15% threshold)
- 100-day survival was 68% in the FAS, 83% in the PP population and 94% in complete responders
- Median overall survival was 274 days in the FAS, 361 days in the PP population and, for complete responders, was not estimable (more than half of the responders were alive at last follow-up)

Similar responses were observed across all patient subgroups defined by baseline characteristics, transplant characteristics and transplant complications. The majority of individual laboratory markers showed statistically significant improvement with the remainder numerically improving. Adverse events were typical of the post-HSCT population (e.g., fever, diarrhea, vomiting, nausea and neutropenia) and no safety signal of concern was identified. Six deaths occurred in the study, all from causes common in HSCT.

The data will be presented today at 8:30 a.m. ET by Miguel Perales, M.D, Chief of the Adult Bone Marrow Transplant Service at Memorial Sloan Kettering Cancer Center, and Alessandro Rambaldi, MD, Professor, Department of Oncology and Hematology-Oncology at the University of Milan and Head of the Hematology and Bone Marrow Transplant Unit at ASST Papa Giovanni XXIII in Bergamo, Italy.

Webcast Details

To access the live conference call via phone, please dial (844) 831-4029 from the United States and Canada or (920) 663-6278 internationally. The participant passcode is 7876969. Please dial in approximately 10 minutes prior to the start of the call.

To access the live or subsequently archived webcast and presentation materials on the internet, **click here** or go to the company's website at **www.omeross.com** and select "Events" under the Investors section of the website.

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, complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. In addition to its commercial product OMIDRIA (phenylephrine and ketorolac intraocular solution) 1%/0.3%, Omeros has multiple late-stage clinical development programs focused on complement-mediated disorders, including COVID-19, and substance abuse. A rolling biologics license application for narsoplimab, the company's lead MASP-2 inhibitor, in hematopoietic stem cell transplant-associated thrombotic microangiopathy is being completed for submission to the U.S. FDA. Omeros also has a diverse group of preclinical programs including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis recently discovered by Omeros. Small-molecule inhibitors of GPR174 are part of Omeros' proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and their corresponding compounds. 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," "can," "could," "estimate," "expect," "goal," "intend," "likely", "look forward to," "may," "on track," "plan," "potential," "predict," "project," "prospects," "scheduled," "should," "slated," "targeting," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including statements regarding anticipated regulatory submissions, the timing and results of ongoing or anticipated clinical trials, and the therapeutic application of Omeros' investigational product, 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 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 for the year ended December 31, 2019, filed with the Securities and Exchange Commission (SEC) on March 2, 2020, as supplemented by its Quarterly Report on Form 10-Q filed with the SEC on August 10, 2020 and subsequent filings with the SEC. 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, whether as a result of any new information, future events or otherwise, except as required by applicable law.

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