



NEWS RELEASE

Omeros Corporation Reports Recovery and Survival of All Patients in Study Evaluating Narsoplimab for Treatment of COVID-19-Associated Acute Respiratory Distress Syndrome

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- All six patients, requiring mechanical ventilation prior to treatment, recovered, survived and were discharged from the hospital
- Narsoplimab treatment was associated with rapid and sustained improvement across all assessed markers of endothelial/cellular damage and/or inflammation
- Omeros is in discussions with U.S. government agencies regarding acceleration of narsoplimab manufacturing for use in COVID-19 patients
- Conference call and webcast today at 8:30 a.m. ET, 5:30 a.m. PT

SEATTLE--(BUSINESS WIRE)--Aug. 10, 2020-- Omeros Corporation (Nasdaq: OMER) today reported the results of a compassionate-use study evaluating narsoplimab, Omeros' investigational human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), in the treatment of COVID-19 patients with Acute Respiratory Distress Syndrome (ARDS), a severe and life-threatening symptom of COVID-19. All patients initially

required mechanical ventilation, and all recovered and survived with narsoplimab treatment. A manuscript detailing the results of the study has been accepted for publication in the peer-reviewed journal Immunobiology. A pre-publication copy of the manuscript can be accessed at <https://www.sciencedirect.com/science/article/pii/S0171298520304459>.

Rationale for the use of narsoplimab for treatment of COVID-19 patients with ARDS

In COVID-19, ARDS and thrombotic events are frequent, life-threatening complications. Autopsies commonly show arterial thrombosis and severe endothelial damage. Endothelial damage, which can play an early and central pathogenic role in ARDS and thrombosis, activates the lectin pathway of complement. MASP-2, the lectin pathway's effector enzyme and the target for narsoplimab, binds the nucleocapsid protein of severe acute respiratory syndrome-associated coronavirus-2 (SARS-CoV-2) – the virus responsible for COVID-19 – resulting in complement activation and lung injury. Numerous articles have been published detailing and further confirming specific aspects of the central role of endothelial injury, activation of the complement system and the lectin pathway and thrombosis development in COVID-19.

Narsoplimab also has been evaluated in patients in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), another often-lethal thrombotic disorder associated with endothelial damage. In its pivotal HSCT-TMA trial, narsoplimab-treated patients demonstrated marked improvement in laboratory and clinical endpoints and unexpected survival. With FDA's Breakthrough Therapy designation, submission of a rolling Biologics Licensing Application for narsoplimab is underway in this indication.

In addition to its inhibitory effect on lectin pathway activation, narsoplimab has been shown to block microvascular injury-associated thrombus formation as well as MASP-2-mediated activation of thrombin, kallikrein and factor XII. These unique anticoagulant effects may provide therapeutic benefits in both HSCT-TMA and COVID-19. Importantly, narsoplimab leaves the complement system's classical pathway and adaptive immune response fully intact, and does not appear to increase infection risk.

Study Origin

The study was initiated in response to a request from treating physicians at the Papa Giovanni XXIII Hospital in Bergamo, Italy. The principal investigator, Alessandro Rambaldi, MD, Professor of Hematology at the University of Milan and Head of the Department of Hematology and Oncology at Papa Giovanni, was a lead investigator in the pivotal trial for narsoplimab in HSCT-TMA. Given the clinical and pathologic similarities between COVID-19 and HSCT-TMA, Professor Rambaldi requested that narsoplimab be made available under compassionate use for patients at his hospital in Bergamo, the initial epicenter of the COVID-19 pandemic in Europe.

“The patients that we treated with narsoplimab were critically ill, and the uniformly successful outcomes were truly impressive,” said Professor Rambaldi. “Also of importance in this terribly sick population studied, the drug was well tolerated, showing no adverse effects. The pathophysiology of COVID-19 appears to be consistent with that of stem cell transplant-associated TMA, and the mechanism of the lectin pathway inhibitor narsoplimab looks to be well suited to treat the often-lethal manifestations of both disorders. The outcomes in these six patients provide further evidence of the potential role of narsoplimab in treating diseases caused by endothelial damage.”

Study Results

In this study, the first time a lectin-pathway inhibitor was used to treat COVID-19, six COVID-19 patients with ARDS requiring continuous positive airway pressure (CPAP) or intubation received narsoplimab. The median age of the patients was 57 years (range 47 – 63 years), 83 percent were men, and all had comorbidities. At baseline, circulating endothelial cell (CEC) counts and serum levels of interleukin-6 (IL-6), interleukin-8 (IL-8), C-reactive protein (CRP), lactate dehydrogenase (LDH), D-dimer and aspartate aminotransferase (AST) – all markers of endothelial/cellular damage and/or inflammation – were significantly elevated. Narsoplimab treatment was begun within 48 hours of initiation of mechanical ventilation. Dosing occurred twice weekly for two to four weeks.

- All narsoplimab-treated patients recovered, survived and were discharged from the hospital
- Narsoplimab treatment was associated with rapid and sustained reduction across all assessed markers of endothelial/cellular damage and/or inflammation – CEC, IL-6, IL-8, CRP, LDH, D-dimer and AST
 - Temporal patterns of laboratory markers were consistent with the observed clinical improvement
 - In particular, CEC counts appear to be a reliable tool to evaluate endothelial damage and treatment response in this disease
 - The temporal improvement of IL-6 and IL-8 with narsoplimab treatment suggests that lectin pathway activation may precede cytokine elevation in COVID-19 and that lectin pathway inhibition has a beneficial effect on the cytokine storm described in patients with COVID-19 infection
- The courses of two patients (one requiring intubation and the other on CPAP) were further complicated by massive bilateral pulmonary thromboses, and both patients recovered with narsoplimab, possibly benefitting from the drug’s anticoagulant effects
- Narsoplimab was well tolerated in the study and no adverse drug reactions were reported
- Two control groups with similar entry criteria and baseline characteristics were used for retrospective comparison, both showing substantial mortality rates at 32 percent and 53 percent

“We are excited by the results in Bergamo,” stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. “The work at Papa Giovanni, for the first time, puts many of the COVID-19 pieces together – endothelial injury and the pathophysiology of COVID-19, complement activation and clinical evidence of the

potential therapeutic role of the lectin pathway inhibitor narsoplimab in treating this disease. We look forward to being able to make narsoplimab broadly available to hospitalized COVID-19 patients.”

U.S. Government Support

Discussions are progressing between Omeros and offices in the Department of Health and Human Services, including the Biomedical Advanced Research and Development Authority (BARDA), along with the National Institutes of Health Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program regarding potential funding to accelerate large-scale manufacturing to enable broader availability of narsoplimab for COVID-19 patients and for other COVID-19-related programmatic activities.

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, in clinical studies, inhibition of MASP-2 has not appeared 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.

Omeros has completed a pivotal trial of narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) and submission of a rolling Biologics License Application is underway. Phase 3 clinical programs are also in progress for narsoplimab in immunoglobulin A (IgA) nephropathy, and in atypical hemolytic uremic syndrome (aHUS). 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.

Conference Call and Webcast Details

Omeros’ management will host a webcast and conference call to present the results of a compassionate-use study evaluating narsoplimab in the treatment of COVID-19 patients with ARDS. The call will be held today at 8:30 a.m. Eastern Time; 5:30 a.m. Pacific Time. To access the live conference call via phone, please dial (888) 771-4371 from the United States and Canada or (847) 585-4405 internationally. The participant passcode is 49889435. 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, go to <https://edge.media-server.com/mmc/p/drfb96md> or the company's website at www.omeros.com and select "Events" under the Investors section of the website. To access the live webcast, please connect to the website at least 15 minutes prior to the call to allow for any software download that may be necessary.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting 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 clinical-stage development programs focused on complement-mediated disorders and substance abuse. In addition, the company 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, expectations regarding regulatory exclusivities, the timing and results of ongoing or anticipated clinical trials, anticipated outcomes of discussions with government agencies, and the expectations regarding the therapeutic utility of Omeros' investigational product in COVID-19 and other indications, 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 on March 2, 2020, as supplemented by the Company's 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 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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