



NEWS RELEASE

Omeros Corporation Reports Narsoplimab Treatment Results in Critically Ill COVID-19 Patients in I-SPY COVID Trial

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-- Reduction in Mortality Risk with Narsoplimab --

SEATTLE--(BUSINESS WIRE)--Sep. 15, 2022-- Omeros Corporation (Nasdaq: OMER) today reported results from the narsoplimab arm of the I-SPY COVID Trial, sponsored by Quantum Leap Healthcare Collaborative (QLHC). Analysis in the randomized patient population shows that the addition of narsoplimab to treatment of critically ill patients with COVID-19 reduces the mortality risk (hazard ratio [HR]=0.81, with probability [HR <1] equal to 0.77).

Narsoplimab showed the largest reduction in mortality risk to date across all drugs reported from the I-SPY COVID Trial.

There were 91 patients randomized to the narsoplimab arm of the trial across 27 participating US sites. The 91 randomized patients were compared to the 116 patients concurrently randomized to the control arm. All patients received standard of care including dexamethasone and remdesivir. Bayesian statistics were prespecified and employed for analyses.

Narsoplimab was to be administered at a dose of 4 mg/kg given as a 30-minute intravenous infusion (up to a maximum of 370 mg per infusion) twice weekly for the earlier of a total of 4 weeks (i.e., 9 doses) or until hospital discharge. However, in approximately half of the patients who died in the narsoplimab group, narsoplimab was not

given or was prematurely stopped, with those patients dying 9 to 35 days later. Despite narsoplimab treatment exposure in a limited number of patients in this trial, a substantial efficacy signal was observed in reducing the risk of mortality for critically ill COVID-19 patients.

Narsoplimab was not observed to shorten the time to recovery in critically ill patients with COVID-19 in this study. The study did not identify any new safety signals for narsoplimab in the setting of critically ill COVID-19 patients.

The I-SPY COVID Trial was designed for rapid screening of agents that show promise for two primary endpoints in critically ill COVID-19 patients: the time to recovery (defined as reduction in oxygen demand) and the risk of mortality. The study utilizes QLHC's adaptive platform trial design methodology, which focuses on the simultaneous, efficient assessment of multiple investigational agents. To streamline enrollment and allow rapid assessment of multiple drugs as required during the pandemic, the platform trial's initial design included a requirement that patients be randomized prior to consenting to trial participation. While the motivation for this sequence and the analysis of the consented population is outlined in **The I-SPY COVID Adaptive Platform Trial for COVID-19 Acute Respiratory Failure: Rationale, Design and Operations**, such analyses have risk of bias. To protect against potential bias associated with analysis only in the consented population, QLHC also prespecified analyses based on all randomized patients (the industry-standard intent-to-treat population).

Substantial imbalance in the consented population was detected and created a marked and statistically significant bias against the narsoplimab arm, rendering analysis of the consented population meaningless. However, as pre-specified by the analysis plan, the I-SPY trial's data monitoring committee terminated the narsoplimab arm based on the biased analyses in the consented population prior to reaching the maximum of 125 patients. Neither the trial's futility nor graduation criteria had been met in the analysis of the randomized population at the time the narsoplimab arm was terminated.

Avoiding similarly biased outcomes in future trial arms, QLHC subsequently revised the protocol for its I-SPY COVID Trial to obtain patient consent prior to randomization.

"We appreciate QLHC's efforts to accelerate the identification of effective therapeutics against COVID-19 and are pleased that, despite the trial's challenges inherent in that objective, a survival benefit was reported for narsoplimab," said Gregory A. Demopoulos, M.D., Omeros' Chairman and Chief Executive Officer. "Work continues in our laboratories both in Seattle and at the University of Cambridge to build on our published findings on the role of the lectin pathway and the MASP-2 inhibitor narsoplimab in severe acute COVID-19, PASC or long COVID, and other related life-threatening infections as well as on our set of assays to identify at-risk patients early in these diseases."

Narsoplimab has been used internationally under an expanded access program to treat successfully patients with severe acute COVID-19. In addition, recent publications demonstrate the role of lectin pathway hyperactivation in

hypocomplementemia and secondary infection risk in patients with severe COVID-19 and **narsoplimab's ability to restore complement function** in those patients.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application (BLA) pending before FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, COVID-19, and atypical hemolytic uremic syndrome. Omeros' long-acting MASP-2 inhibitor OMS1029 is currently in a Phase 1 clinical trial. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing in clinical programs for paroxysmal nocturnal hemoglobinuria (PNH), complement 3 (C3) glomerulopathy and one or more related indications. For more information about Omeros and its programs, visit www.omeros.com.

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," "objective," "plan," "potential," "predict," "project," "should," "slate," "target," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including expectations with regard to future development of narsoplimab for treatment of COVID-19, 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, risks associated with product commercialization and commercial operations, regulatory processes and oversight, 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 (SEC) on March 1, 2021. 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 new information, future events or otherwise, except as required by applicable law.

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