



NEWS RELEASE

Omeros' Narsoplimab Receives Positive Opinion from European Medicines Agency for Pediatric Investigation Plan Required for MAA Submission

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– Includes Deferral for PIP Completion Until After Approval of Marketing Authorization Application –

SEATTLE--(BUSINESS WIRE)--Oct. 29, 2019-- Omeros Corporation (Nasdaq: OMER) today announced that the Pediatric Committee (PDCO) of the European Medicines Agency (EMA) has issued a positive opinion for the company's pediatric investigation plan (PIP) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Narsoplimab, also referred to as OMS721, is Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2).

Acceptance of the PIP paves the way for submission under the European Commission's centralized procedure of a Marketing Authorization Application (MAA) for narsoplimab in the treatment of HSCT-TMA. A PIP outlining a development program for the investigational product in the pediatric population must be agreed with PDCO as a prerequisite to EMA's acceptance of an MAA. The narsoplimab PIP provides a study plan to evaluate the safety and effectiveness of the drug for HSCT-TMA in patients from 1 month through 17 years of age. Omeros received a deferral for completion of its pediatric plan until after EMA approval of the narsoplimab MAA. With successful completion of the PIP, narsoplimab would be eligible for up to an additional two years of marketing exclusivity.

In addition to its planned MAA, Omeros recently initiated the rolling submission of its biologics license application

(BLA) to the U.S. Food and Drug Administration (FDA) for narsoplimab in HSCT-TMA. Omeros will work with FDA to allow the same study plan outlined in the PIP to form the basis for a Written Request from FDA to extend marketing exclusivity for narsoplimab under the Best Pharmaceuticals for Children Act. Successful completion of the pediatric plan would add up to six months to the longest applicable U.S. non-patent exclusivity period.

“We appreciate EMA’s guidance through the successful PIP review process for narsoplimab in stem cell transplant-associated TMA,” said Gregory A. Demopulos, M.D., chairman and chief executive officer of Omeros. “We believe that the clinical response to narsoplimab seen across our pivotal clinical trial and compassionate use bodes well for the additional young patients who will receive the drug in our PIP study. Until this study begins, pediatric patients who don’t qualify for or can’t logistically participate in a narsoplimab clinical study can continue to have access to the drug through our expanding compassionate use program. We have submitted a substantial portion of our BLA and are working on the remaining sections and on our MAA, and we look forward to making narsoplimab available internationally for adults and children who need it.”

Narsoplimab has orphan drug designation in both the U.S. and in Europe for HSCT-TMA and has breakthrough therapy designation (BTD) in the U.S. Narsoplimab also has been awarded BTD for immunoglobulin A nephropathy (IgAN), and Phase 3 programs for narsoplimab are ongoing in IgAN and atypical hemolytic uremic syndrome.

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. Fueled by the successful commercialization of **OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%**, Omeros has multiple clinical-stage development programs focused on complement-mediated diseases 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.

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.

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). 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. In addition to narsoplimab, Omeros is developing small-molecule inhibitors and second-generation antibodies against MASP-2.

Omeros also has identified MASP-3 as the key activator of the 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 the first half of next year.

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," "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, and the therapeutic application of Omeros' research findings, 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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