



NEWS RELEASE

Omeros Provides Regulatory Update on Biologics License Application for Narsoplimab in the Treatment of HSCT-TMA

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SEATTLE--(BUSINESS WIRE)--Oct. 1, 2021-- Omeros Corporation (Nasdaq: OMER) today announced that the U.S. Food and Drug Administration (FDA) notified the company that, as part of FDA's ongoing review of the company's Biologics License Application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. FDA stated that the notification does not reflect a final decision on the information under review.

FDA did not provide specific details of the deficiencies in its notification; however, in a meeting held on September 30, 2021, FDA expressed its intention to work with Omeros to resolve any issues as expeditiously as possible, but the company does not currently expect any such resolution to occur by the October 17, 2021 target action date under the Prescription Drug User Fee Act (PDUFA). Omeros is evaluating potential next steps as it awaits additional information from FDA and plans to obtain FDA approval for narsoplimab in HSCT-TMA, a frequently lethal complication of HSCT for which there is no FDA-approved treatment, as quickly as possible.

Narsoplimab is the first drug candidate submitted to FDA for approval in HSCT-TMA. It has Breakthrough Therapy and Orphan designations in both HSCT-TMA and IgA nephropathy. The BLA for narsoplimab in HSCT-TMA was

accepted for filing in January 2021 under FDA's Priority Review program.

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, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders. Its commercial product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% continues to gain market share in cataract surgery. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application under priority review by FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, atypical hemolytic uremic syndrome and COVID-19. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is in a Phase 1 clinical trial, and the company's PDE7 inhibitor program OMS527, targeting addiction and movement disorders, has successfully completed a Phase 1 trial. Omeros' pipeline holds a diverse group of preclinical programs including a proprietary-asset-enabled antibody-generating technology and a proprietary GPCR platform through which it controls 54 GPCR drug targets and their corresponding compounds. One of these novel targets, GPR174, modulates a new cancer immunity axis recently discovered by Omeros, and the company is advancing GPR174-targeting antibodies and small-molecule inhibitors. 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 interactions and communications with FDA, FDA's review of Omeros' BLA for narsoplimab in HSCT-TMA and Omeros' pursuit of regulatory approval for narsoplimab in HSCT-TMA, 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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