



NEWS RELEASE

Omeros Corporation Receives Interim Response from FDA on Formal Dispute Resolution Request for Narsoplimab

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SEATTLE--(BUSINESS WIRE)--Aug. 17, 2022-- Omeros Corporation (Nasdaq: OMER) today announced that the United States Food and Drug Administration (FDA) provided an interim response to the company's formal dispute resolution request submitted to the Agency in June, appealing the earlier decision by the FDA review division to issue a complete response letter for the biologics license application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Formal dispute resolution is an official pathway that enables a sponsor to appeal a decision by an FDA division to a higher authority within the Agency, in this case the Office of New Drugs (OND). As part of FDA's standard procedures for dispute resolution, Omeros and OND met last month to discuss the appeal. Per FDA guidelines for formal dispute resolution, a final decision from OND was to be rendered within 30 calendar days of the meeting unless the deciding official in OND required additional information. According to FDA's interim response, the deciding official is collecting additional information, and a response to Omeros' appeal will be provided within 30 days from the date that the additional information is collected and any required follow-up is conducted by the deciding official.

There is no approved treatment for HSCT-TMA. The first drug candidate submitted to FDA for approval in HSCT-TMA, narsoplimab has Breakthrough Therapy and Orphan-Drug designations in this disorder as well as in IgA nephropathy.

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 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. 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 Omeros' pursuit of regulatory approval for narsoplimab in HSCT-TMA, including expectations regarding the timing and potential or anticipated outcomes of its formal dispute resolution request 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, unanticipated or unexpected outcomes of regulatory processes in relevant jurisdictions, unproven preclinical and clinical development activities, changes in our financial condition and results of operations, challenges associated with manufacture or supply of our investigational drug candidates, 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, 2022. 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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