



NEWS RELEASE

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

2022-11-08

-- Decision Denies Omeros' Appeal Requesting Immediate Labeling Discussions --
-- Decision Proposes a Path Forward Based on Historical Survival Data --

SEATTLE--(BUSINESS WIRE)--Nov. 8, 2022-- Omeros Corporation (Nasdaq: OMER) today announced that the Office of New Drugs (OND) of the U.S. Food and Drug Administration (FDA) has reached a decision on the company's formal dispute resolution request appealing the issuance by FDA's Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) and the Division of Nonmalignant Hematology (the review division) of a complete response letter (CRL) concerning the biologics license application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).

In its formal dispute resolution request submitted to the Agency in June 2022, Omeros requested OND to direct the review division to accept resubmission of the existing BLA and to commence labeling discussions with the company immediately thereafter. Although that request was denied, the decision proposes a path forward for the resubmission of the BLA based on survival data from the completed pivotal trial versus an historical control group. Specifically, the decision proposes the resubmission of the narsoplimab BLA including a comparison of the existing response data from the completed pivotal trial to a threshold derived from an independent literature analysis and evidence of increased survival from patients in the pivotal trial compared to an appropriate historical control group. It also notes that persuasive evidence of superior survival versus a well-matched historical control group could be

sufficient even in the absence of the independent literature analysis. The specific approach to resubmission and its details would be determined through discussion with the review division.

Omeros is currently working through the details of the decision and potential next steps with its team of regulatory and legal advisors and will discuss this development further on its previously announced earnings call scheduled for tomorrow, November 9, 2022.

“While this decision does not allow us to begin labeling discussions now, it does provide paths forward based on collecting historical data with or without an independent literature review,” said Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. “There currently is no approved treatment for TA-TMA, and transplant physicians and their patients need one. We look forward to working with the Agency to obtain approval for narsoplimab as soon as possible.”

The first drug candidate submitted to FDA for approval in TA-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 (BLA) pending before FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-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 statements regarding prospects for obtaining FDA approval of narsoplimab in TA-TMA and potential next steps in relation to the biologics license application for narsoplimab following the receipt of FDA’s decision on Omeros’ 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.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20221108005540/en/>

Jennifer Cook Williams

Cook Williams Communications, Inc.

Investor and Media Relations

IR@omeros.com

Source: Omeros Corporation