



NEWS RELEASE

Omeros Receives Complete Response Letter from FDA for Biologics License Application for Narsoplimab in the Treatment of HSCT-TMA

2021-10-18

-- Conference call today at 8:30 a.m. ET, 5:30 a.m. PT --

SEATTLE--(BUSINESS WIRE)--Oct. 18, 2021-- Omeros Corporation (Nasdaq: OMER) today announced that the company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).

Following HSCT, patients generally have complex clinical courses and are often severely ill. HSCT-TMA increases that complexity and worsens outcomes. In the CRL, FDA expressed difficulty in estimating the treatment effect of narsoplimab in HSCT-TMA and asserted that additional information will be needed to support regulatory approval. There were no chemistry, manufacturing and controls (CMC), safety, or non-clinical issues precluding approval raised in the CRL.

Omeros remains confident in the efficacy and safety data for narsoplimab in HSCT-TMA. The company worked closely with FDA on the clinical development plan, including with respect to both the single-arm trial to support approval and the definition of response as the primary endpoint.

Omeros plans to request a Type A meeting as soon as possible with FDA to discuss the CRL and determine the most expeditious path forward for the approval of narsoplimab in the treatment of HSCT-TMA.

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.

Conference Call Details

Omeros' management will host a conference call to discuss today's announcement. The call will be held today at 8:30 a.m. Eastern Time; 5:30 a.m. Pacific Time. To access the live conference call via phone, please dial (844) 831-4029 from the United States and Canada or (920) 663-6278 internationally. The participant passcode is 9549686. A telephone replay will be available for one week following the call and may be accessed by dialing (855) 859-2056 from the United States and Canada or (404) 537-3406 internationally. The replay passcode is 9549686.

To access the live or subsequently archived webcast of the conference call on the internet, go to the company's website at <https://investor.omeros.com/upcoming-events>.

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 Omeros is seeking FDA approval of narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Additional narsoplimab programs are 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.

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 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 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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