



NEWS RELEASE

FDA Confirms Omeros' Schedule for Rolling Review of the Company's BLA for Narsoplimab in the Treatment of HSCT-TMA

2019-09-11

– Omeros Remains On Track to Initiate the Submission Next Quarter –

SEATTLE--(BUSINESS WIRE)--Sep. 11, 2019-- Omeros Corporation (Nasdaq: OMER) announced that the United States Food and Drug Administration (FDA) agreed with the company's proposed schedule for the rolling review of the Biologics License Application (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).

Consistent with the agreed schedule, the company is on track to submit the BLA's first sections, which will include the nonclinical and clinical pharmacology data, in the first half of next quarter.

Under its rolling review process, FDA can review components of a marketing application as they are submitted rather than requiring all components to be received prior to initiating review, allowing faster review of the application. The BLA for narsoplimab, because of the drug's breakthrough therapy designation from FDA for the treatment of HSCT-TMA, is also eligible for priority review, which shortens the standard FDA review cycle by four months.

Omeros referenced FDA's agreement with the company's proposed schedule for its rolling BLA during a webcast

presentation given yesterday by Gregory A. Demopoulos, M.D., Omeros' chairman and chief executive officer, at the H.C. Wainwright 21st Annual Global Investment Conference. Omeros has received informational requests from investors regarding this agreement. In addition to the information contained in this release, an archived recording of the webcast presentation can be accessed on the Investors & News/Events section of Omeros' website at www.omeros.com.

About Omeros Corporation

Omeros is a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. The company's drug product OMIDRIA (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is marketed in the U.S. for use during cataract surgery or intraocular lens (IOL) replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In the European Union, the European Commission has approved OMIDRIA for use in cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a diverse group of preclinical programs and a proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and corresponding compounds, a number of which are in preclinical development. The company also exclusively possesses a novel antibody-generating platform.

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," "plan," "potential," "predict," "project," "prospects," "should," "slated," "targeting," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including statements regarding anticipated regulatory submissions, Omeros' research and development programs 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.

Source: Omeros Corporation

View source version on businesswire.com: <https://www.businesswire.com/news/home/20190911005310/en/>

Source: Omeros Corporation

Jennifer Cook Williams

Cook Williams Communications, Inc.

Investor and Media Relations

360.668.3701

jennifer@cwcomm.org