



NEWS RELEASE

Omeros Corporation Provides Update of Ongoing Zaltenibart Phase 3 PNH Clinical Trial Program

2025-03-21

-- Phase 3 Data Needed for BLA Submission Expected in the Fourth Quarter 2026 --

SEATTLE--(BUSINESS WIRE)--Mar. 21, 2025-- Omeros Corporation (Nasdaq: OMER) today reported that clinical trial site activation for enrollment is underway for the company's Phase 3 program evaluating zaltenibart in paroxysmal nocturnal hemoglobinuria (PNH). Zaltenibart (OMS906) is Omeros' investigational inhibitor of MASP-3, the key and most proximal activator of the alternative pathway of complement. Zaltenibart inhibits the intravascular hemolysis treated by C5 inhibitors as well as the extravascular hemolysis caused by C5 inhibitors in patients suffering from PNH while leaving intact the infection-fighting lytic arm of the classical pathway of complement.

A total of 120 clinical investigative sites across 30 countries have been chosen for clinical trial participation in the zaltenibart Phase 3 program in PNH, a good number of which have already identified pools of PNH patients ready to participate in the zaltenibart trials, and Omeros continues collaborating with sites to identify additional eligible and already available PNH patients. Data needed for submission of the biologics licensing application (BLA) and global approval dossiers for zaltenibart in PNH remain on track for the fourth quarter of 2026.

The Phase 3 clinical trials will evaluate intravenous zaltenibart dosed once every eight weeks. Currently marketed upstream complement inhibitors require dosing orally twice daily, orally three times daily in conjunction with C5 inhibitor treatment, or subcutaneous infusions twice weekly. Zaltenibart's conveniently infrequent dosing together

with its ability to inhibit both intravascular and extravascular hemolysis provide a meaningful differentiation from the other PNH therapies. Phase 2 data have previously been presented at the American Society of Hematology and European Hematology Association Annual Meetings and demonstrate that zaltenibart effectively inhibits both intravascular and extravascular hemolysis while achieving gender-normal hemoglobin levels in both men and women. No safety signal of concern has been observed with zaltenibart.

The zaltenibart Phase 3 program includes two clinical trials, one in patients who are not receiving complement-inhibitor treatment at the time of study entry and another in patients who have an inadequate response to treatment with either ravulizumab or eculizumab. Both clinical trials compare the efficacy and safety of zaltenibart monotherapy to that of the C5 inhibitors eculizumab and ravulizumab, and both FDA and European regulators have agreed with the trial designs. All zaltenibart drug product required for the Phase 3 program has been manufactured, and comparator C5 inhibitors have been sourced. These study designs provide head-to-head comparisons and should provide data to demonstrate superiority of zaltenibart over the C5 inhibitors in these patient populations. These comparison data may form the basis for comparative superiority claims for promotion, enhanced market access, and pricing reflective of zaltenibart's advantages. In further preparation for potential commercialization of zaltenibart, recommendations regarding patient-reported-outcome (PRO) measures were sought and received from the German Federal Joint Committee, the decision-making body in the German healthcare system that specifies which medical treatments are reimbursed by the statutory health insurance funds and specialized in PRO measures. Recommended PRO measures were incorporated into the zaltenibart Phase 3 design and are expected to be helpful in securing appropriate pricing.

"All of us at Omeros are pleased that the Phase 3 clinical program for zaltenibart is well underway," said Gregory A. Demopoulos, M.D., Omeros' Chairman and CEO. "The zaltenibart Phase 2 data have demonstrated important differentiators from currently marketed agents, and we expect those same advantages to be evidenced in the Phase 3 trials, which are similar in design to our Phase 2 trials. We continue to refine and optimize the potential commercial impact of the zaltenibart advantages, and we look forward to our Phase 3 readout late next year and to bringing a better treatment option to PNH patients and their physicians. Based on the data to date, zaltenibart is a premier alternative pathway inhibitor, and we plan to continue expanding alternative pathway indications for our drug."

The global market size for PNH is reported at \$3.8 billion dollars in 2023 and projected at over \$11.7 billion dollars in 2034. Currently, a Phase 2 clinical trial of zaltenibart to treat C3 glomerulopathy is ongoing, and additional indications related to the alternative pathway are being evaluated for clinical trials.

About Zaltenibart (OMS906)

Zaltenibart is an investigational human monoclonal antibody targeting mannan-binding lectin-associated serine

protease-3 (MASP-3), the key and most proximal activator of the complement system's alternative pathway. The complement system is a critical part of innate immunity and plays a central role in host homeostasis and defense against pathogens. Responsible for the conversion of pro-complement factor D to complement factor D, MASP-3 is believed to be the premier target in the alternative pathway – it has the lowest native circulating level and low relative clearance compared to the other alternative pathway proteins and, unlike C5 and C3 blockers, MASP-3 inhibition leaves intact the lytic arm of the classical pathway, important for fighting infection. Also, unlike other components of the alternative pathway, MASP-3 is believed not to be an acute phase reactant, which could provide a significant advantage to MASP-3 inhibitors, like zaltenibart, over other alternative pathway inhibitors. MASP-3 inhibitors are thought to have preventive or therapeutic effects across a broad range of diseases including paroxysmal nocturnal hemoglobinuria (PNH), hemolytic uremic syndrome (HUS), atypical HUS, traumatic brain injury, arthritis, geographic atrophy or “dry” macular degeneration, ischemia-reperfusion injury, transplant-related complications and other immune-related disorders.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing first-in-class small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders, including complement-mediated diseases and cancers, as well as 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. Omeros' long-acting MASP-2 inhibitor OMS1029 has successfully completed Phase 1 single- and multiple-ascending dose clinical studies. Zaltenibart, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing toward Phase 3 clinical trials for paroxysmal nocturnal hemoglobinuria and complement 3 glomerulopathy. Funded by the National Institute on Drug Abuse, Omeros' lead phosphodiesterase 7 inhibitor OMS527 is in clinical development for the treatment of cocaine use disorder. Omeros also is advancing a broad portfolio of novel cellular and molecular immuno-oncology programs. 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 “aim,” “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 the anticipated enrollment of patients in clinical trials, statements regarding the availability and timing of data readouts from clinical trials, and statements regarding the anticipated therapeutic benefit or commercial prospects of Omeros' drug candidates 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, unfavorable results of clinical development activities, unavailability of capital resources to support planned development activities, regulatory processes and oversight, challenges associated with conducting clinical trials, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2024, and in our subsequently filed Quarterly Reports on Form 10-Q. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume 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/20250321322641/en/>

Jennifer Cook Williams

Cook Williams Communications, Inc.

Investor and Media Relations

IR@omeros.com

Source: Omeros Corporation