



NEWS RELEASE

Omeros Finalizes with FDA Clinical Plan for OMS721 Approval in IgA Nephropathy

2019-01-17

--Additional Positive Data Reported from Second Cohort in Phase 2 Trial--

SEATTLE--(BUSINESS WIRE)--Jan. 17, 2019-- Omeros Corporation (Nasdaq: OMER) today announced that it has finalized its clinical plan for OMS721 submission and approval in immunoglobulin A nephropathy (IgAN) following a recent meeting with the U.S. Food and Drug Administration (FDA). OMS721 is Omeros' lead human monoclonal antibody targeting MASP-2, the effector enzyme of the complement system's lectin pathway. There is no approved treatment for IgA nephropathy.

FDA Meeting Update

Clinical results from the first and second cohorts of the Phase 2 trial in IgAN were part of the background materials provided to FDA for the recent meeting on the Phase 3 clinical program. During the FDA meeting, the following points were confirmed:

- The Phase 3 trial's primary endpoint of assessment of proteinuria was extended from 24 to 36 weeks at the company's request to allow for additional OMS721 dosing, if needed. This continues to provide OMS721 a path to accelerated, or even full, approval based on those 36-week proteinuria data in either (i) the entire patient population (patients with baseline proteinuria greater than 1 gm/24 hours) or (ii) the high-risk subpopulation (those with baseline proteinuria of at least 2 gm/24 hours).

- Given investigators' concerns about extended withholding of OMS721 treatment from any high-risk study patient initially randomized to the placebo-treated group, patients in that subpopulation will be allowed open-label treatment with OMS721 after at least 1 year of blinded treatment.

The OMS721 Phase 3 ARTEMIS-IGAN trial continues to enroll and will incorporate the beneficial changes noted above without any impact to study patients already enrolled. The trial is designed based on the positive results from the two previously reported Phase 2 cohorts – the first assessing patients who were receiving corticosteroids at time of enrollment and then tapered off steroids during the study and the second comprised of patients who were not taking steroids.

Additional Phase 2 Data

Additional data are available from patients in the second cohort of the Phase 2 trial who entered the extended follow-up period, all receiving OMS721 treatment during this period. The 8 patients in the extended follow-up period had longstanding IgA nephropathy (median time from diagnosis of 11.6 years) with significant comorbidities and significantly impaired renal function (median baseline estimated glomerular filtration rate (eGFR) of 35.7 mL/min/1.73 m²) with highly elevated baseline proteinuria levels (median of 3,786 mg/24 hours). The data, based on the last observation point for each patient, confirm the positive results seen earlier:

- eGFR measurements have remained stable, consistent with preservation of renal function
- 61 percent median reduction in proteinuria from baseline (across all 8 patients, assessed at 31 weeks to 54 weeks post-baseline)
- 5 of the 8 patients have achieved greater than 50 percent proteinuria reductions (median reduction of 65 percent), with 2 of those 5 having received their last OMS721 administration 5 months earlier
- Across the first (4 patients) and second cohorts, a total of 9 of 12 patients achieved greater than 50 percent reductions in proteinuria (median reduction of 65 percent)
- OMS721 continues to be well tolerated and no safety concerns have been observed

“The data from the Phase 2 study continue to show a consistent and significant drug effect, the magnitude of which is unparalleled,” stated Richard Lafayette, MD, Professor of Medicine (Nephrology) and Director of the Glomerular Disease Center, Stanford University Medical Center and chair of the OMS721 IgAN Academic Leadership Committee. “Nephrologists are focused on long-term kidney survival, and the observed effects of OMS721 on both proteinuria and eGFR are what we would hope to see in an IgAN treatment. The OMS721 Academic Leadership Committee believes the data on OMS721 in IgAN are sufficiently groundbreaking and robust to warrant publication in a major scientific journal and plans to submit the Phase 2 data for publication in the first half of this year, together with other publications directed to OMS721 in renal disease throughout 2019. From the perspective of the ALC, the extended data from the Phase 2 cohort study strongly support the potential efficacy of OMS721 in IgA nephropathy, even in patients at the very highest risk of progression to kidney failure. The data, together with the

recently finalized registration plan, are further consistent with our expectations that the OMS721 Phase 3 ARTEMIS-IgAN trial will be successful, and we look forward to making the drug available to our patients.”

In addition to IgAN, OMS721 is in Phase 3 clinical programs for hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) and atypical hemolytic uremic syndrome. OMS721 holds breakthrough therapy designations from FDA for IgAN and for HSCT-TMA and, to the company’s knowledge, no other drug has breakthrough therapy designation for either of these indications.

“The additional understandings reached with FDA are important, and we appreciate the Agency’s ongoing engagement around our breakthrough designation for OMS721 in IgA nephropathy,” stated Gregory A. Demopoulos, MD, chairman and chief executive officer of Omeros. “We’re confident in the effects seen with OMS721 and in our registration approach for the drug in IgA nephropathy, and we expect that it will likely follow stem-cell transplant TMA as the second approved indication for OMS721.”

About Omeros’ MASP Programs

Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2, a novel pro-inflammatory protein target involved in activation of the complement system, which is an important component of the immune system. The complement system plays a role in the inflammatory response and becomes activated as a result of tissue damage or microbial infection. MASP-2 is the effector enzyme of the lectin pathway, one of the principal complement activation pathways. Importantly, inhibition of MASP-2 does not appear to interfere with the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection, and its abnormal function is associated with a wide range of autoimmune disorders. MASP-2 is generated by the liver and is then released into circulation. Gene-targeted MASP-2-deficient mice and humans with MASP-2 gene polymorphisms that affect MASP-2 serum levels and MASP-2 functional activity are generally healthy with no obvious adverse phenotype.

Phase 3 clinical programs are in progress for OMS721 in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), in immunoglobulin A (IgA) nephropathy, and in atypical hemolytic uremic syndrome (aHUS). Also, two Phase 2 trials are ongoing. One is continuing to enroll IgA nephropathy patients and has already generated positive data in patients with IgA nephropathy and with lupus nephritis; the other continues to enroll patients with HSCT-TMA and has previously reported positive data in patients with HSCT-TMA and in patients with aHUS. OMS721 can be administered both intravenously and subcutaneously, and Omeros expects to commercialize each formulation of OMS721 for different therapeutic indications. In parallel, Omeros is developing small-molecule inhibitors of MASP-2. Based on requests from treating physicians, Omeros has established a compassionate-use program for OMS721, which is active in both the U.S. and Europe. The FDA has granted OMS721 breakthrough therapy designation for IgA nephropathy and for HSCT-TMA, orphan drug status for the prevention (inhibition) of

complement-mediated thrombotic microangiopathies, for the treatment of IgA nephropathy, for the treatment of HSCT-TMA, and fast track designation for the treatment of patients with aHUS. The European Medicines Agency has granted orphan drug designation to OMS721 for treatment of primary IgA nephropathy and for treatment in HSCT.

Omeros also has identified MASP-3 as responsible for the conversion of pro-factor D to factor D and as a critical activator of the human complement system's alternative pathway. The alternative pathway is linked to a wide range of immune-related disorders. In addition to its lectin pathway inhibitors, the company is advancing its development of antibodies and small-molecule inhibitors against MASP-3 to block activation of the alternative pathway. Omeros has initiated the manufacturing scale-up process of its MASP-3 antibodies in preparation for clinical trials.

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 and disorders of the central nervous system. The company's drug product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is marketed 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," "future", "goal," "intend," "likely", "look forward to," "may," "on track", "path", "plan," "potential," "predict," "project," "prospects," "should," "slated," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including statements regarding the anticipated basis and prospects for approval of OMS721, 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, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 2018. 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.

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