



NEWS RELEASE

Omeros Announces Results From Nearly Three-Year Follow-up of Patients in Phase 2 IgA Nephropathy Trial

2021-11-05

-- Data Show Improvement and Stabilization in Renal Function --

- Unprecedented median proteinuria reduction of 64.4 percent seen in the narsoplimab Phase 2 clinical trial predicts a 41.6-year delay in need for dialysis compared to standard of care
- Narsoplimab is the first candidate targeting IgA nephropathy to demonstrate long-term improvement or sustained stabilization in eGFR
- 58 percent of patients received only one narsoplimab treatment course (12 weekly doses) or less annually, with 25 percent of patients showing improvement in eGFR despite having significant, longstanding IgA nephropathy with high-risk comorbidities
- Narsoplimab-treated patients showed response irrespective of stage of their advanced disease state
- Narsoplimab was well tolerated with no treatment-related serious adverse events
- Long-term data from the narsoplimab Phase 2 clinical trial were presented yesterday at the Annual Meeting of the American Society of Nephrology by Richard Lafayette, M.D., Stanford University Professor of Medicine-Nephrology and Director of the Stanford Glomerular Disease Center

SEATTLE--(BUSINESS WIRE)--Nov. 5, 2021-- Omeros Corporation (Nasdaq: OMER) today announced results of long-term follow-up from the Phase 2 clinical trial evaluating its MASP-2 inhibitor narsoplimab in patients with IgA nephropathy. Treatment with narsoplimab in this trial was associated with an unprecedented median reduction in proteinuria of 64.4 percent. Now, long-term follow-up (out to 35 months) of these patients shows a markedly slowed rate of decline of estimated glomerular filtration rate (eGFR). Using the same analytical approach adopted by other companies* to determine the impact of proteinuria reduction on long-term risk of need for dialysis, a 64.4 percent reduction in proteinuria is predicted to delay progression to renal dialysis by 41.6 years compared to standard of care. While other companies have reported up to 1-year follow-up data on eGFR, this is the first time that sustained stabilization, let alone improvement, of eGFR through long-term follow-up has been reported for any novel therapeutic in development for IgA nephropathy. ARTEMIS-IGAN, the Phase 3 clinical trial of narsoplimab in IgA nephropathy, is ongoing.

“The long-term data are highly supportive of a key role for lectin pathway inhibition in the future management of patients with IgAN, and I am very much looking forward to seeing the results of the ongoing ARTEMIS-IGAN Phase 3 clinical trial,” said Jonathan Barratt, PhD, FRCP, the Mayer Professor of Renal Medicine at the University of Leicester and Honorary Consultant Nephrologist at Leicester General Hospital. “Most striking about these data is that the responses seen in patients with advanced kidney failure and severe proteinuria who had IgAN for over a decade are similar to those patients with early, less advanced disease, and this I believe speaks to the ability of narsoplimab to inhibit lectin pathway activation in different segments of the nephron. In early disease, glomerular complement activation predominates while, in more established disease, it is lectin pathway activation in the tubulointerstitial compartment, mediated through collectin-11, that drives disease progression. Narsoplimab appears to be effective at targeting both of these pathogenic pathways, which has implications for the treatment of not just IgAN but of any proteinuric kidney disease. Narsoplimab has shown a substantially greater reduction in proteinuria – and a substantially longer projected delay to need for dialysis – than any other drug in development for the treatment of renal disease.”

The Phase 2 clinical trial (NCT02682407) consisted of two sequential studies. Substudy 1 was a single-arm, open-label design with 12 weekly intravenous (IV) infusions of narsoplimab in patients who, at time of enrollment, were on corticosteroids that were tapered during the study; the four IgA nephropathy patients from substudy 1 were able to enter a dosing extension period. In substudy 2, which included nine evaluable patients, corticosteroid-free patients were randomized 1:1 to receive once-weekly IV narsoplimab or vehicle infusions for 12 weeks, after which they could continue in an open-label extension at the investigator’s discretion. A total of 12 patients (four from substudy 1 and eight from substudy 2) participated in the dosing extension phase. These 12 patients were followed for up to nearly three years (median 22 months), with the last assessment at 19 months or later for 75 percent of the study patients and at two years or later for 50 percent of them.

The narsoplimab trial population consisted of high-risk patients with advanced IgA nephropathy at study baseline with a median disease duration of 6.9 years (range 0.4 – 27.5). Several other risk factors, such as hypertension (83%) and obesity (58%; median body mass index 32.5 kg/m², range 24.4 – 44.3) were present in a large majority of the cases along with excessive baseline proteinuria (median urine protein excretion [UPE] of 4.2 g/24 hours; range 1.5 – 11.9) and renal failure (baseline median eGFR of 40.7 mL/min/1.73m²; range 25.4 – 75.9).

Narsoplimab appeared effective irrespective of the stage of the study patients' advanced disease state and, using the same analytical approach adopted by other companies*, is predicted to provide an unprecedented delay in progression to renal dialysis.

- A median reduction in proteinuria of 64.4 percent was previously observed across the 2 substudies in the narsoplimab Phase 2 trial.
- The magnitude of median proteinuria reduction seen with narsoplimab is predicted to delay progression to renal dialysis by 41.6 years compared to standard of care.

Through the nearly three-year extended follow-up:

- Study patients received a median of one course of 12 weekly doses of narsoplimab per year (range 0.7 to 2.5 courses), with 58 percent of patients receiving one course or less per year.
- eGFR rate of decline was slowed by 3.4 mL/min/year compared to a literature control cohort with IgA nephropathy** matched for proteinuria excretion and eGFR levels.
- eGFR showed improvement in 25 percent of the patients despite having significant IgA nephropathy with sclerotic lesions present in the glomeruli and with significant risk factors such as longstanding disease up to 18 years, obesity with BMI up to 38.1kg/m², and long history of hypertension.
- Narsoplimab was well tolerated with no treatment-related serious adverse events.

"The long-term data from the Phase 2 clinical trial in IgA nephropathy confirm the previously published interim analysis results and provide an excellent foundation for our ongoing Phase 3 clinical trial in IgA nephropathy ARTEMIS-IGAN," said Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "MASP-2 inhibition with narsoplimab is associated with significant proteinuria reduction and, most importantly, improvement and stabilization of eGFR, even in high-risk patients with advanced IgA nephropathy. We look forward to reading out the results from our ongoing Phase 3 clinical trial."

Long-term data from the narsoplimab Phase 2 clinical trial were **presented** yesterday at the Annual Meeting of the American Society of Nephrology (ASN) by Richard Lafayette, M.D., Stanford University Professor of Medicine-Nephrology and Director of the Stanford Glomerular Disease Center. The data are also being prepared for submission to a peer-reviewed journal.

A second presentation directed to the benefits of narsoplimab in IgA-related disease – Reduction of Urinary Levels of Lectin Pathway Complement Components in an IgA Vasculitis Patient after MASP-2 Inhibition with Narsoplimab – was also part of yesterday's program at the ASN Annual Meeting.

*Carroll K. et al., Estimating Delay in Time to ESKD for Treatment Effects on Proteinuria in IgA Nephropathy and FSGS. ERA-EDTA 2021, Oral Presentation; and Calliditas Therapeutics AB, April 2019, Investor Day Webinar.

**Leicester Renal Unit IgA Nephropathy Registry

About Narsoplimab

Narsoplimab, also known as "OMS721," is an investigational human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), a novel pro-inflammatory protein target and the effector enzyme of the lectin pathway of complement. 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. Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2.

A biologics license application (BLA) is pending before the U.S. FDA for use of narsoplimab in the treatment of HSCT-TMA, and the drug is in Phase 3 clinical programs for immunoglobulin A (IgA) nephropathy and atypical hemolytic uremic syndrome (aHUS). Narsoplimab is also being evaluated for the treatment of COVID-19 as part of the I-SPY-COVID-19 platform trial sponsored by Quantum Leap Healthcare Collaborative. FDA has granted narsoplimab breakthrough therapy designations for HSCT-TMA and for IgA nephropathy; orphan drug status for the prevention (inhibition) of complement-mediated thrombotic microangiopathies, for the treatment of HSCT-TMA and for the treatment of IgA nephropathy; and fast track designation for the treatment of patients with aHUS. The European Medicines Agency has granted orphan drug designation to narsoplimab for treatment in HSCT and for treatment of primary IgA nephropathy.

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 is the subject of a biologics license application pending before FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Narsoplimab is also in multiple late-

stage clinical development programs 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. 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 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, risks associated with product commercialization and commercial operations, unproven preclinical and clinical development activities, the impact of COVID-19 on our business, regulatory processes and oversight, challenges associated with manufacture or supply of our investigational or commercial products, delays in completion of ongoing or planned clinical trials, 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 (SEC) 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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