Omeros Corporation

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Analyst information
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Narsoplimab and Regulatory Status

- Narsoplimab is a fully human IgG4 antibody against MASP-2, the effector enzyme of the lectin pathway of complement
- Completed pivotal clinical program in hematopoietic stem cell transplant-associated-TMA (HSCT-TMA). Rolling BLA for HSCT-TMA will be submitted soon.
- Enrolling 2 additional Phase 3 clinical programs - IgA nephropathy (IgAN) and atypical hemolytic uremic syndrome (aHUS)
- ~250 patients and healthy volunteers have been dosed with narsoplimab
- No significant safety concerns have been observed
- FDA has granted narsoplimab Breakthrough Therapy designation in both HSCT-TMA and IgAN
- Broad therapeutic areas for lectin pathway inhibition:
  - Endothelial injury syndromes
  - Proteinuric diseases
  - Ischemia-reperfusion injury
  - Dysregulation of inflammation (e.g., CNS)
Narsoplimab is a Potential Therapeutic for a Broad Range of Disorders, Including HSCT-TMA and COVID-19

**Lectin Pathway Disorders**
- **COVID-19**
- **HSCT and TMA-related EIS**
  - aGVHD
  - CLS
  - DAH
  - IPS
  - SOS/VOD
  - HELLP/CAPS
- **Oncology**
  - Colorectal Cancer
  - Cervical Cancer
  - ESCC
- **Acute transplant & surgery-related conditions**
- **Chronic nephrology/proteinuria diseases**
  - IgAN
  - MGN
  - Lupus nephritis

**CLASSICAL PATHWAY**
- C1q
- C1r/C1s
- C4
- C2
- C3
- C3a
- C3b
- C5
- C5a
- C5b
- C5b-9
- Terminal Pathway (C5b-9)

**LECTIN PATHWAY**
- MBL, ficolins, collectins
- C4 convertase
- C4 bypass
- Factor XII
- Factor XIIa
- Prothrombin
- Thrombin
- MASP-3

**ALTERNATIVE PATHWAY**
- C3 convertase
- MAC

**Inflammation, platelet activation, leukocyte recruitment, endothelial cell activation**

**Cell lysis**

**Tissue injury**

**Inflammation, platelet activation, leukocyte recruitment, endothelial cell activation**

**Lectin Pathway Disorders**
- **COVID-19**
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  - IgAN
  - MGN
  - Lupus nephritis
Endothelial Injury Plays a Major Role in Pathogenesis of a Wide Range of Diseases

<table>
<thead>
<tr>
<th>Endothelial injury plays a role in the pathogenesis of:</th>
<th>Stroke</th>
<th>Viral infections (e.g. COVID-19)</th>
<th>Chronic kidney disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Venous thrombosis</td>
</tr>
<tr>
<td></td>
<td>Peripheral vascular disease</td>
<td>Stem cell transplant-related complications (e.g., TMA, aGVHD, VOD, DAH, IPS, CLS)</td>
<td>Diabetic</td>
</tr>
<tr>
<td></td>
<td>Cancer</td>
<td></td>
<td>Heart disease</td>
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</table>

Injury to endothelial cells occurs in many ways: physically, chemically, and immunologically

Damage to the vascular endothelium results in a procoagulant state and complement pathway activation

- Lectin pathway is a pattern-recognition system
- Lectin pathway is activated by carbohydrate patterns on microbes and surfaces of damaged cells
Role of Endothelial Injury in COVID-19 Published Across Numerous Peer-reviewed Journals
Endothelial Injury with Complement Activation is Central to Pathophysiology of HSCT-TMA and COVID-19

- Once endothelial injury occurs, pathophysiology of HSCT-TMA and COVID-19 are similar
- Endothelial injury activates the lectin pathway of complement
- In HSCT-TMA, endothelial injury is caused by conditioning regimen, immunosuppressants, GVHD and infection
- In COVID-19, endothelial injury is caused by direct viral infection
- MASP-2, the lectin pathway’s effector enzyme, binds the nucleocapsid protein of SARS-CoV-2 and activates the lectin pathway, leading to amplification of underlying cellular injury and inducing cytokine response (e.g., IL-6)
- Viral load has no correlation in COVID-19 patients to clinical status or disease severity

Components of COVID-19:
- Complement activation
- Inflammation
- Coagulation

Narsoplimab inhibits all 3
### Parallels Between COVID-19 and HSCT-TMA

<table>
<thead>
<tr>
<th>Comparator</th>
<th>COVID-19</th>
<th>HSCT-TMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lectin-Pathway Activation from Endothelial Damage</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cause of Endothelial Injury</td>
<td>Viral</td>
<td>Conditioning regimen, Immunosuppressants, GVHD, infection</td>
</tr>
<tr>
<td>MASP-2 Activation</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Multi-Organ TMA</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

- Approximately 50 patients have been dosed with narsoplimab across the two EIS
- Marked improvement seen in narsoplimab-treated patients in these studies
Compassionate Use of Narsoplimab for COVID-19 Patients in Bergamo, Italy

- 6 patients treated with narsoplimab, each included for presence of ARDS requiring mechanical ventilation (4 on CPAP, 2 intubated)
- Dosing IV twice weekly for 2 to 4 weeks
- All patients fully recovered, survived and were discharged
- 2 patients with massive bilateral pulmonary thromboses that resolved after narsoplimab treatment
- Temporal patterns of laboratory markers (CEC, IL-6, IL-8, CRP, LDH, AST and D-dimer) were consistent with the observed clinical improvement; in particular, CEC counts appear to be a reliable tool to evaluate endothelial damage and treatment response
- All patients received routine supportive care (prophylactic enoxaparin, azithromycin, hydroxychloroquine, darunavir/cobicistat) and, during the study, steroids (patient #1 did not receive steroids and patients 2 and 3 likely received no benefit from steroids given timing of initiation)
- Two control groups with similar entry criteria and baseline characteristics were selected for retrospective comparison showing substantial mortality rates of 32 percent and 53 percent
- Manuscript published in peer-reviewed Imunobiology
## Data from the COVID-19 Study in Italy

### Demographics and Treatment Summary

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Median (range) or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>57 years (47-63)</td>
</tr>
<tr>
<td><strong>Male sex</strong></td>
<td>5 (83%)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>86 Kg (82-100 Kg)</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
<td>Diabetes (n=1); Hypertension (n=1); Dyslipidemia (n=2); Obese/Overweight (n=6)</td>
</tr>
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</table>

### Treatment Summary

<table>
<thead>
<tr>
<th>Timing of narsoplimab treatment from start of CPAP oxygen support</th>
<th>n (%) or Median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within 24 hours</strong></td>
<td>4 (67%)</td>
</tr>
<tr>
<td><strong>Within 48 hours</strong></td>
<td>2 (33%)</td>
</tr>
<tr>
<td><strong>Time from hospital admission to treatment</strong></td>
<td>2 days (1-4)</td>
</tr>
<tr>
<td><strong>Duration of follow-up (to date) after first dose</strong></td>
<td>27 days (16-90)</td>
</tr>
</tbody>
</table>
Data from the COVID-19 Study in Italy

Evidence of Endothelial Damage (CEC Counts) in COVID-19

5 normal (uninfected) and 33 infected patients without

Friedman test, \( p = 0.004 \)

IL-6 / IL-8 Levels Improved in 6 Patients Treated with Narsoplimab

Friedman test, \( p = 0.006 \)

6 infected patients treated with Narsoplimab
Data from Narsoplimab-treated COVID-19 Patients

**C-Reactive Protein**
Improved in all 6 Patients

Spearman correlation = -0.83, p < 0.0001

**Lactate Dehydrogenase**
Improved in all 6 Patients

Spearman correlation = -0.37, p = 0.005

**Aspartate Aminotransferase (AST)**
Improved in all 6 Patients

Spearman correlation = -0.55, p = 0.0001

**D-Dimer**
Improved in all Assessed Patients
Clinical Outcomes of COVID-19 Patients Treated with Narsoplimab

- The bar colors indicate the different oxygen support (CPAP = yellow; mechanical ventilation with intubation = red; non-rebreather oxygen mask/Venturi mask = green; low-flow oxygen by nasal cannula = light green; room air = blue)
- Narsoplimab doses are marked by blue arrows
- Black circle indicates the beginning of steroid treatment
- CPAP = continuous positive airway pressure; NRM = non-rebreather oxygen mask; VM = Venturi mask; TEP = pulmonary thromboembolism
At 5-6 Month Follow-Up, All 6 Patients Without Clinical or Laboratory Evidence of Sequelae

<table>
<thead>
<tr>
<th>Laboratory Findings</th>
<th>Baseline</th>
<th>Last Evaluation (5-6 Mos. Post-Discharge)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White cell count - per mm$^3$, median (range)</td>
<td>8335 (6420-10,120)</td>
<td>7320 (3200-8770)</td>
</tr>
<tr>
<td>&gt; 10,000 per mm$^3$ - no. (%)</td>
<td>2 (33)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>&lt; 4000 per mm$^3$ - no. (%)</td>
<td>0 (0)</td>
<td>1 (17)</td>
</tr>
<tr>
<td>Lymphocyte count - per mm$^3$, median (range)</td>
<td>875 (410-1290)</td>
<td>2815 (810-3780)</td>
</tr>
<tr>
<td>Platelet count - x 10$^3$ per mm$^3$, median (range)</td>
<td>282 (199 -390)</td>
<td>238 (170-354)</td>
</tr>
<tr>
<td>Hemoglobin - g/dL, median (range)</td>
<td>13.4 (13.2-14.1)</td>
<td>14.8 (13.4-15.8)</td>
</tr>
<tr>
<td>Distribution of other findings (laboratory reference ranges)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-reactive protein (0.0-1.0 mg/dL)</td>
<td>14 (9.5-31.3)</td>
<td>0.15 (0-0.5)</td>
</tr>
<tr>
<td>Lactate dehydrogenase (120/246 U/L)</td>
<td>518.5 (238-841)</td>
<td>212 (119-249)</td>
</tr>
<tr>
<td>Aspartate aminotransferase (13-40 U/L)</td>
<td>78.5 (51-141)</td>
<td>18 (12-29)</td>
</tr>
<tr>
<td>Alanine aminotransferase (7-40 U/L)</td>
<td>73 (37-183)</td>
<td>22.5 (20-67)</td>
</tr>
<tr>
<td>Creatinine (0.3-1.3 mg/dL)</td>
<td>0.85 (0.38-1.33)</td>
<td>0.94 (0.51-1.07)</td>
</tr>
<tr>
<td>D-dimer (&lt; 500 ng/mL)</td>
<td>0 (0)</td>
<td>3 (50)</td>
</tr>
<tr>
<td>&gt; 190 - no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 190 - median (range)</td>
<td>1250.5 (943-1454)</td>
<td>324 (202-390)</td>
</tr>
</tbody>
</table>

- Clinical status at last evaluation of all 6 patients - no evidence of post-COVID sequelae
Bergamo Patient #7 Undergoing Narsoplimab Treatment

- 74-year-old man
- High-risk: diabetic, obese, long history of smoking/COPD, prostate cancer
- Rapidly deteriorating pulmonary status: nasal cannula → mask → CPAP → intubation
- Began treatment with narsoplimab following intubation; extubated around the 2nd dose

* Gray arrows denote dosing; Red lines denote normal value threshold