Safety of Bamlanivimab Monotherapy Administered in Dialysis Centers to Hemodialysis Patients for COVID-19

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Disclosures

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Background

- Bamlanivimab (Eli Lilly) is an intravenously administered monoclonal antibody that was granted an emergency use authorization (EUA) by the US Food and Drug Administration for the treatment of mild to moderate COVID-19 on 09 Nov 2020.
- On 16 Apr 2021, the EUA was revoked over concerns of resistance among SARS-CoV-2 variants.
- Between 01 Jan and 16 April 2021, physicians at DaVita dialysis clinics were able to order bamlanivimab (700 mg) treatment during dialysis for nonhospitalized hemodialysis patients who tested positive for SARS-CoV-2 infection and met the eligibility criteria.
- Here, we report safety data among dialysis patients who received bamlanivimab as a monotherapy for COVID-19.

Methods

- Bamlanivimab was administered intravenously as a single dose over the course of 60 minutes during a regularly scheduled hemodialysis session.
- All patients were monitored for at least 1 hour after bamlanivimab administration.
- All facilities were required to have emergency medications on-site, and staff were trained to identify and treat potential reactions.
- A serious adverse event was considered if a patient developed anaphylaxis or any condition requiring use of an epinephrine injection (1:10,000 IM) or albuterol, was sent to the emergency department, or was hospitalized after bamlanivimab administration.
- An adverse event was considered if a patient developed fever, chills, hives, rash, hypotension, headache, nausea, fatigue, dizziness, angioedema, muscle pain, or throat irritation.

Results

- 264 patients with newly diagnosed SARS-COV-2 infections received a single dose of bamlanivimab at DaVita.
- Among all patients who received the drug, 46% were female and the mean age was 60 years.
- On average, patients were followed for 64 days post-infusion.
- There were 0 adverse events or serious adverse events documented in the 1-hour post-administration observation window.

Patients	264
Days postadministration, mean ± SD	63.5 ± 23.9
Age, years, mean ± SD	60.3 ± 14.4
Female sex, n (%)	121 (45.8)
Severe adverse events within 1-hour postadminstration, n (%)	0 (0.0)
Adverse events within 1-hour postadminstration, n (%)	0 (0.0)

Abbreviations: SD, standard deviation

Conclusions and Limitations

Conclusions:

Bamlanivimab was found to be safe in dialysis patients.

Limitations:

Difficult to address efficacy of bamlanivimab due to lack of control group in this study.