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POSTER ABSTRACTS

905.OUTCOMES RESEARCH-LYMPHOID MALIGNANCIES

Real-World Treatment Outcomes of Teclistamab Under an Outpatient Model for Step-up Dosing Administration

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Background
Teclistamab, the first-in-class B-cell maturation antigen (BCMA) x CD3 bispecific therapy was recently approved by the FDA for the treatment of triple-class exposed relapsed or refractory multiple myeloma (MM) after ≥ 4 prior lines of therapy. Because of the risk of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), the step-up dosing (SUD) of teclistamab is commonly administered in an inpatient setting among early users. Mayo Clinic has a well-established hospital-based outpatient program for novel immunotherapies. Since the FDA approval, teclistamab SUD has been administered as part of this program. Each dose of the SUD is administered in an outpatient setting, and the patient is given a remote monitoring kit to regularly measure vital signs and stay connected with the command center for signs and symptoms of CRS and ICANS throughout the entire SUD period. This study aimed to evaluate early safety outcomes and healthcare resource utilization during SUD in real-world (RW) patients who initiated teclistamab under the outpatient administration model across 3 Mayo Clinic locations (Rochester, MN, Phoenix/Scottsdale, AZ, Jacksonville, FL).

Methods
This was a retrospective study using Mayo Clinic's electronic medical records from October 26, 2022 to June 12, 2023. Eligible patients were adults diagnosed with MM who had initiated commercial teclistamab at any of the 3 Mayo Clinic locations. Patient characteristics, rates and severity of CRS and ICANS, as well as healthcare resource utilization during SUD were described. Time between teclistamab administration and patient check-out was reported for SUD and treatment doses, respectively.

Results
At the time of data cutoff, 39 patients received at least 1 teclistamab dose across the 3 locations (median age 67.2 years; male: 74%; White: 87%; non-Hispanic: 92%), including 36 patients who initiated teclistamab SUD directly in an outpatient setting. A total of 8 (21%) patients had MM with high-risk cytogenetics and 14 (36%) had prior exposure to other BCMA-targeted therapies. Prevalent comorbidities prior to receiving teclistamab included anemia (77%), hypertension (56%), lytic bone lesions (51%), neutropenia (49%), and hypogammaglobulinemia (41%). Renal impairment or failure was observed in 31% of the patients (Table 1).
Almost all patients received acetaminophen (95%), diphenhydramine (95%), and dexamethasone (92%) as pre-medications on the same day as teclistamab administrations during SUD. Of the teclistamab doses with clinic time data, the majority (62%) of doses during SUD required 30 minutes to 1 hour of clinic time for monitoring between administration and check-out. After SUD, the clinic time for weekly treatment doses decreased to less than 30 minutes for most (79%) doses (Figure 1). In patients

who completed SUD by data cutoff (n = 37), most patients (70%) received the SUD on a 3-day dose interval (i.e., day 1, 4, 7). The mean time between the first and third doses was 6.3 days.

Among the 37 patients with complete SUD, 12 (32%) developed CRS. The highest CRS grade was grade 1 for 10 patients; 1 patient had a grade 2 CRS, and 1 patient had a grade 4 CRS. The patient with grade 4 CRS concurrently decompensated during a dialysis session and all symptoms were considered for CRS grading. A total of 6 patients had recurrent CRS, including 1 patient with 3 events during SUD. All patients who developed CRS during SUD (n=12) were admitted to the hospital for treatment, with a total of 19 admissions across all patients and a median length of stay of 1.7 days per admission. Among patients who were admitted for CRS (n=12), the majority were treated with acetaminophen (92%), diphenhydramine (83%) and dexamethasone (83%); tocilizumab was given to the 2 patients with CRS grade 2 or higher. Only 1 ICANS event (grade 2) was observed in 1 patient during SUD, after dose 3, and the patient was admitted to the hospital for treatment.

Conclusion

This study evaluated early RW safety outcomes of teclistamab under an outpatient administration model and found the CRS rate and severity to be comparable with other RW evidence generated from various data sources. Outcomes related to teclistamab SUD from Mayo Clinic supported the safety and feasibility of outpatient administration model as a potential option to reduce healthcare resource utilization and improve treatment experiences.

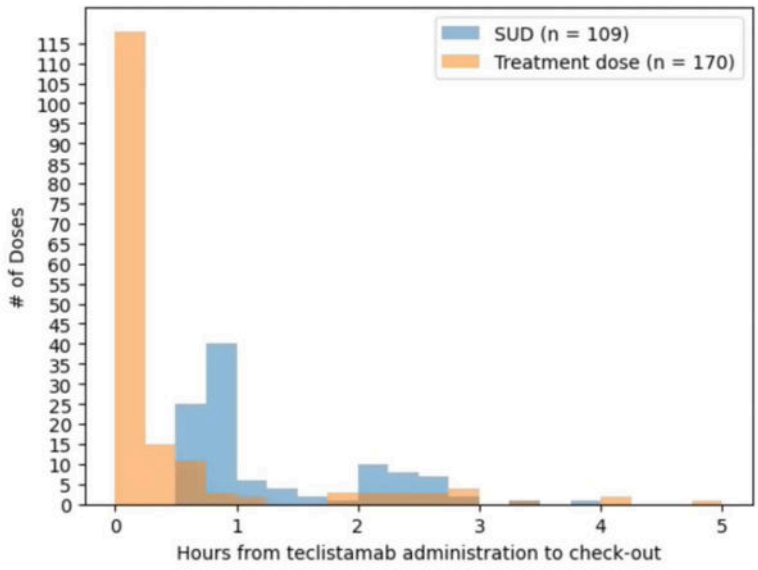
Disclosures Sandahl: *Janssen:* Consultancy, Membership on an entity's Board of Directors or advisory committees. **Calay:** *GeneDx:* Current equity holder in publicly-traded company, Ended employment in the past 24 months. **Fonseca:** *Janssen:* Consultancy; *Takeda:* Consultancy; *Adaptive Biotechnologies:* Membership on an entity's Board of Directors or advisory committees; *Caris Life Sciences:* Membership on an entity's Board of Directors or advisory committees; *AbbVie:* Consultancy; *Adaptive Biotechnologies:* Consultancy; *Binding Site:* Consultancy; *Aztrazenica:* Consultancy; *FISH:* Patents & Royalties: FISH; *Millenium:* Consultancy; *AZBio:* Membership on an entity's Board of Directors or advisory committees; *Sanofi:* Consultancy; *AMGEN:* Consultancy; *BMS (Celgene):* Consultancy; *Bayer:* Consultancy; *Antegene:* Membership on an entity's Board of Directors or advisory committees; *Regeneron:* Consultancy; *Oncotracker:* Membership on an entity's Board of Directors or advisory committees; *Pharmacyclics:* Consultancy; *Pfizer:* Consultancy; *Merck:* Consultancy; *Kite:* Consultancy; *Juno:* Consultancy. **Ailawadhi:** *AbbVie, Amgen, Ascentage, BMS, Cellectar, GSK, Janssen, Pharmacyclics, Sanofi:* Research Funding; *Beigene, BMS, Cellectar, GSK, Janssen, Pfizer, Regeneron, Sanofi, Takeda:* Consultancy. **Lin:** *Janssen Scientific Affairs, LLC.:* Current Employment, Current equity holder in publicly-traded company. **Wu:** *Janssen Scientific Affairs, LLC:* Current Employment, Current equity holder in publicly-traded company. **Silvert:** *nference:* Consultancy, Current Employment, Current holder of *stock options* in a privately-held company. **Kim:** *Janssen:* Current Employment. **Carpenter:** *nference Inc.:* Ended employment in the past 24 months. **Wagner:** *Anumana, Inc.:* Current Employment, Current equity holder in private company, Current holder of *stock options* in a privately-held company, Patents & Royalties. **Fowler:** *Janssen:* Current Employment. **Hester:** *Janssen R&D, LLC:* Current Employment, Current equity holder in publicly-traded company. **Marshall:** *Johnson & Johnson:* Current Employment, Current equity holder in publicly-traded company. **Stoy:** *Janssen Biotech, Inc:* Current Employment, Current equity holder in publicly-traded company; *GlaxoSmithKline:* Current equity holder in publicly-traded company. **Gifkins:** *Janssen R&D, LLC:* Current Employment, Current equity holder in publicly-traded company.

Table 1. Patient Demographic and Clinical Characteristics Before Initiating Teclistamab

	Total
Patients who received teclistamab	39 (100.0%)
Patients with a complete step-up dosing (SUD) period, n (%)	37.0 (94.9%)
Patients with ≥1 treatment dose after SUD period, n (%)	34.0 (87.2%)
Mean number of doses received per patient as of data cutoff (SD)	7.5 (4.3)
Site of administration, n (%)	
Rochester, MN	26 (66.7%)
Phoenix/Scottsdale, AZ	8 (20.5%)
Jacksonville, FL	5 (12.8%)
Patient demographic characteristics	
Median age at the first teclistamab dose, years (range)	67.2 (38.7-84.2)
Male, n (%)	29 (74.4%)
Race, n (%)	
White	34 (87.2%)
Black or African American	2 (5.1%)
Other	3 (7.7%)
Ethnicity, n (%)	
Non-Hispanic	36 (92.3%)
Patient clinical characteristics	
MM with high-risk cytogenetics, n (%)	8 (20.5%)
Prior BCMA exposure, n (%)	14 (35.9%)
Comorbidities of interest during 6 months before initiating teclistamab, n (%)	
Anemia	30 (76.9%)
Hypertension	22 (56.4%)
Lytic bone lesions	20 (51.3%)
Neutropenia	19 (48.7%)
Hypogammaglobulinemia	16 (41.0%)
Renal impairment/failure*	12 (30.8%)
Hypercalcemia	7 (18.0%)
Extramedullary Plasmacytomas Disease	3 (7.7%)

*Renal impairment/failure includes all stage chronic kidney disease, dialysis, end stage renal disease, kidney transplant and kidney failure

Figure 1. Time between teclistamab administration and check-out during step-up dosing (SUD) and for treatment doses



Note: SUD includes the two initial step-up doses and the first full treatment dose (first 3 doses); treatment dose refers to full treatment doses after completing SUD (dose 4 and beyond)

Figure 1

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