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How to manage infectious complications with bispecific and CAR T therapy

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Disclosures

Consultancy: Amgen, Janssen, GSK, BMS, Abbvie, Astrazeneca, Pfizer, K-36
Therapeutics, Genentech

Research Funding: 2Seventy bio, Pfizer

Membership on an entity's Board of Directors or advisory committees: Immuneel,
Caribou biosciences

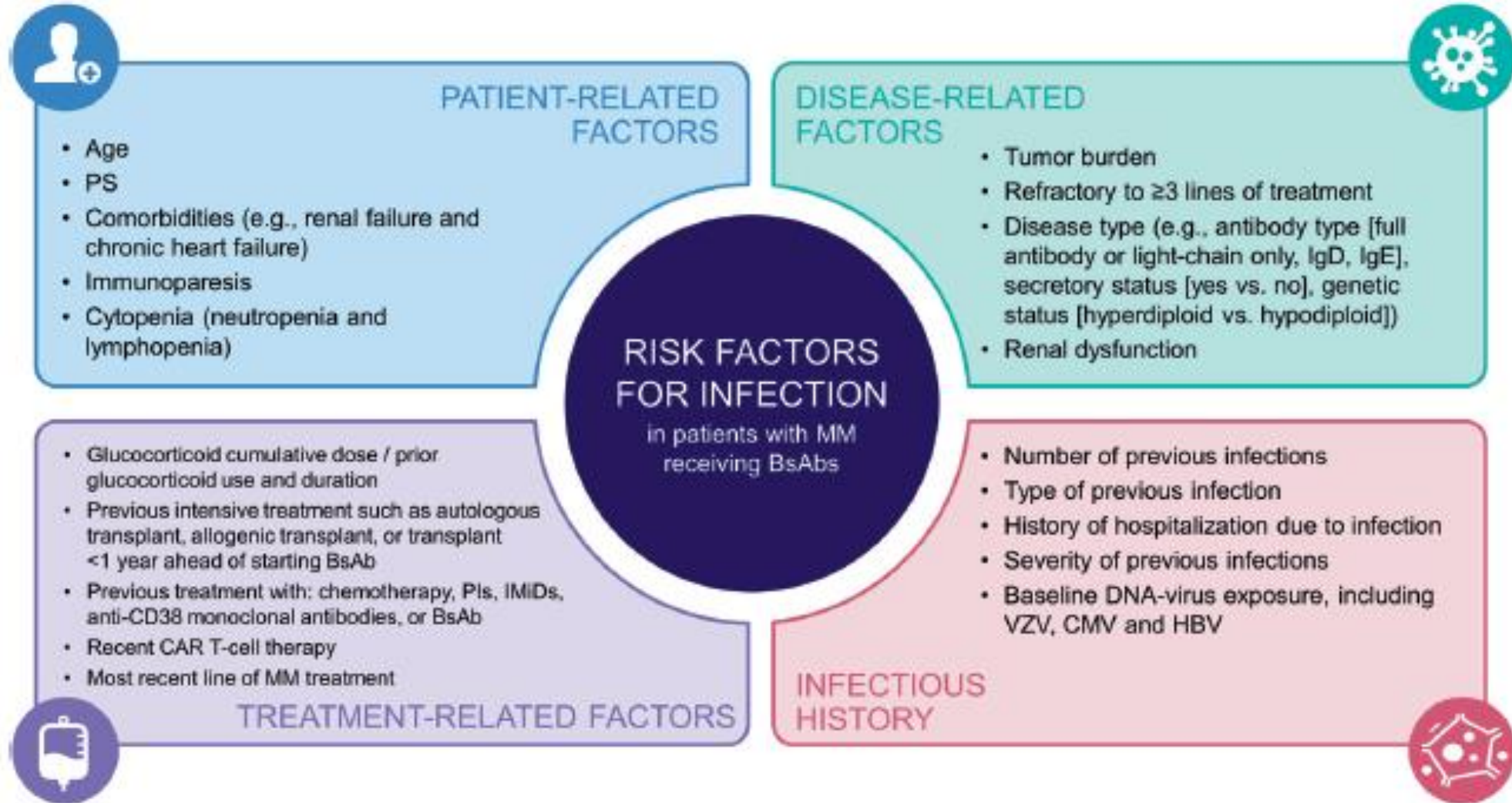
Toxicities of Interest of TCRs

- Cytopenias
- Infections
- Hypogammaglobulinemia with BCMA target

CARs versus Bispecifics

- Predictable
- Short term

Infection Prophylaxis



Cytopenias with CAR T Cells

- Lymphodepleting chemotherapy (Flu/Cy) +/- CAR T-cells often lead to prolonged neutropenia
- Thrombocytopenia (esp.) and anemia at baseline; made worse by CAR T and TCE

| CAR T-cell Product | Time until blood count recovery |
|---------------------------|---------------------------------|
| Idecabtagene vicleucel | Median 2 months (1-6 months) |
| Ciltacabtagene autoleucel | 60-70% recovered by day 30 |

| Cytopenia | Management |
|-------------------------|--|
| Neutropenia | <ul style="list-style-type: none"> - Levofloxacin as ppx - Fluconazole as ppx - TMP-SMX as ppx - G-CSF (ideally \geq 14 days out) |
| Anemia | <ul style="list-style-type: none"> - Ensure iron, B12, folate stores replete - pRBCs PRN |
| Thrombocytopenia | <ul style="list-style-type: none"> - Platelet transfusions PRN - TPO agonists if prolonged |
| Prolonged | - Stem cell boost? |

KarMMa 3

Higher rates of cytopenias in the ide-cel arm

| | ide-cel (N = 225) | | | Standard Regimens (N = 126) | | |
|----------------------|----------------------|---------------|-------------|--------------------------------|---------------|-------------|
| | Any Grade (%) | Grade 3/4 (%) | Grade 5 (%) | Any Grade (%) | Grade 3/4 (%) | Grade 5 (%) |
| Cytopenia | 91.6 | 89.8 | 0 | 72.2 | 60.3 | 0 |
| Neutropenia | 85.8 | 84.0 | 0 | 45.2 | 40.5 | 0 |
| Anemia | 67.1 | 50.7 | 0 | 35.7 | 18.3 | 0 |
| Thrombocytopenia | 56.0 | 44.0 | 0 | 29.4 | 17.5 | 0 |
| Lymphopenia | 32.0 | 31.1 | 0 | 19.8 | 18.3 | 0 |
| Febrile neutropenia | 8.9 | 8.9 | 0 | 2.4 | 1.6 | 0 |
| Infections | 61.3 | 24.4 | 4.4 | 54.0 | 18.3 | 2.4 |
| Pathogen unspecified | 40.9 | 13.3 | 2.2 | 33.3 | 9.5 | 0 |
| Viral | 22.2 | 8.0 | 0.9 | 21.4 | 6.3 | 0.8 |
| Bacterial | 18.7 | 6.2 | 0.4 | 15.9 | 8.7 | 0.8 |
| Fungal | 6.7 | 2.2 | 0.9 | 5.6 | 0.8 | 0 |

KarMMa 3: Overall safety profile of ide-cel remains consistent

| Treated population, n (%) | ide-cel (N = 225) | Standard Regimens (N = 126) |
|------------------------------|------------------------------|--|
| Any-grade AE | 225 (100) | 124 (98) |
| Serious AE | 105 (47) | 52 (41) |
| ITT population, n (%) | ide-cel (N = 254) | Standard Regimens (N = 132) |
| Overall deaths | 106 (42) | 58 (44) |
| Cause of death | | |
| Disease progression | 64 (25) | 37 (28) |
| AEs | 17 (7) | 8 (6) |
| Other causes | 23 (9) | 12 (9) |
| SPMs ^a | 2 (1) | 1 (1) |

Similar rates of deaths due to AEs in the ide-cel and Standard Regimens arms

No new safety signals

^a Deaths due to SPMs in the ide-cel arm were leukemia (n = 1) and pancreatic adenocarcinoma (n = 1); death due to SPMs in the Standard Regimens arm was malignant neoplasm of unknown primary site (n = 1).

CARTITUDE-4: TEAEs

| Select TEAE ≥15%, n (%) | Safety population | | | |
|--------------------------------------|-------------------|------------|-------------|------------|
| | Cilta-cel (n=208) | | SOC (n=208) | |
| | Any grade | Grade 3/4 | Any grade | Grade 3/4 |
| Any AE | 208 (100) | 201 (96.6) | 208 (100) | 196 (94.2) |
| Serious AE | 92 (44.2) | 67 (32.2) | 81 (38.9) | 70 (33.7) |
| Hematologic | 197 (94.7) | 196 (94.2) | 185 (88.9) | 179 (86.1) |
| Neutropenia | 187 (89.9) | 187 (89.9) | 177 (85.1) | 171 (82.2) |
| Anemia | 113 (54.3) | 74 (35.6) | 54 (26.0) | 30 (14.4) |
| Thrombocytopenia | 113 (54.3) | 86 (41.3) | 65 (31.3) | 39 (18.8) |
| Lymphopenia | 46 (22.1) | 43 (20.7) | 29 (13.9) | 25 (12.0) |
| Infections | 129 (62.0) | 56 (26.9) | 148 (71.2) | 51 (24.5) |
| Upper respiratory tract ^a | 39 (18.8) | 4 (1.9) | 54 (26.0) | 4 (1.9) |
| Lower respiratory tract ^b | 19 (9.1) | 9 (4.3) | 36 (17.3) | 8 (3.8) |
| COVID-19 ^c | 29 (13.9) | 6 (2.9) | 55 (26.4) | 12 (5.8) |

- **Hematologic TEAEs most common**
 - 85–90% neutropenia, almost all grade 3/4
 - Most high-grade cytopenias **resolved to grade ≤2 by day 30**
 - Grade 3/4 infections similar between arms
- **Second primary malignancies:**
 - Cilta-cel, 4.3% (n=9); most commonly cutaneous/noninvasive and hematologic
 - SOC, 6.7% (n=14); most commonly cutaneous/noninvasive^d
- Deaths due to TEAEs
 - Cilta-cel, n=10^e (7 due to COVID-19^f)
 - SOC, n=5^g (1 due to COVID-19)

^aIncludes preferred terms upper respiratory tract infection, nasopharyngitis, sinusitis, rhinitis, tonsillitis, pharyngitis, laryngitis, and pharyngotonsillitis. ^bIncludes preferred terms lower respiratory tract infection, pneumonia, and bronchitis. ^cTreatment-emergent COVID-19 only; includes preferred terms COVID-19, COVID-19 pneumonia, and asymptomatic COVID-19. ^dWith 1 case of peripheral T-cell lymphoma in the cilta-cel arm. ^e7 due to COVID-19, and 1 each due to neutropenic sepsis, pneumonia, and respiratory failure. ^f3 of 7 who died from COVID-19 were unvaccinated prior to cilta-cel. These COVID-19-related deaths contributed to the higher number of fatal events in the first year. ^g1 each due to COVID-19, progressive multifocal leukoencephalopathy, respiratory tract infection, septic shock, and pulmonary embolism. AE, adverse event; cilta-cel, ciltacabtagene autoleucel; TEAE, treatment-emergent adverse event; SOC, standard of care.



CARTITUDE-4: Causes of Death (Safety Population)

| TEAE ≥15%, n (%) | Safety population | |
|---|-----------------------|-------------|
| | Cilta-cel (n=208) | SOC (n=208) |
| | Any grade | Any grade |
| Deaths, n (%) | 39 (18.8) | 46 (22.1) |
| Progressive disease | 14 (6.7) | 30 (14.4) |
| Non-treatment-emergent adverse event ^a | 15 (7.2) | 11 (5.3) |
| Treatment-emergent adverse event | 10 (4.8) ^b | 5 (2.4) |
| COVID-19 pneumonia ^b | 7 (3.4) | 1 (0.5) |
| Neutropenic sepsis | 1 (0.5) | 0 |
| Pneumonia | 1 (0.5) | 0 |
| Progressive multifocal leukoencephalopathy | 0 | 1 (0.5) |
| Respiratory tract infection | 0 | 1 (0.5) |
| Septic shock | 0 | 1 (0.5) |
| Respiratory failure | 1 (0.5) ^c | 0 |
| Pulmonary embolism | 0 | 1 (0.5) |

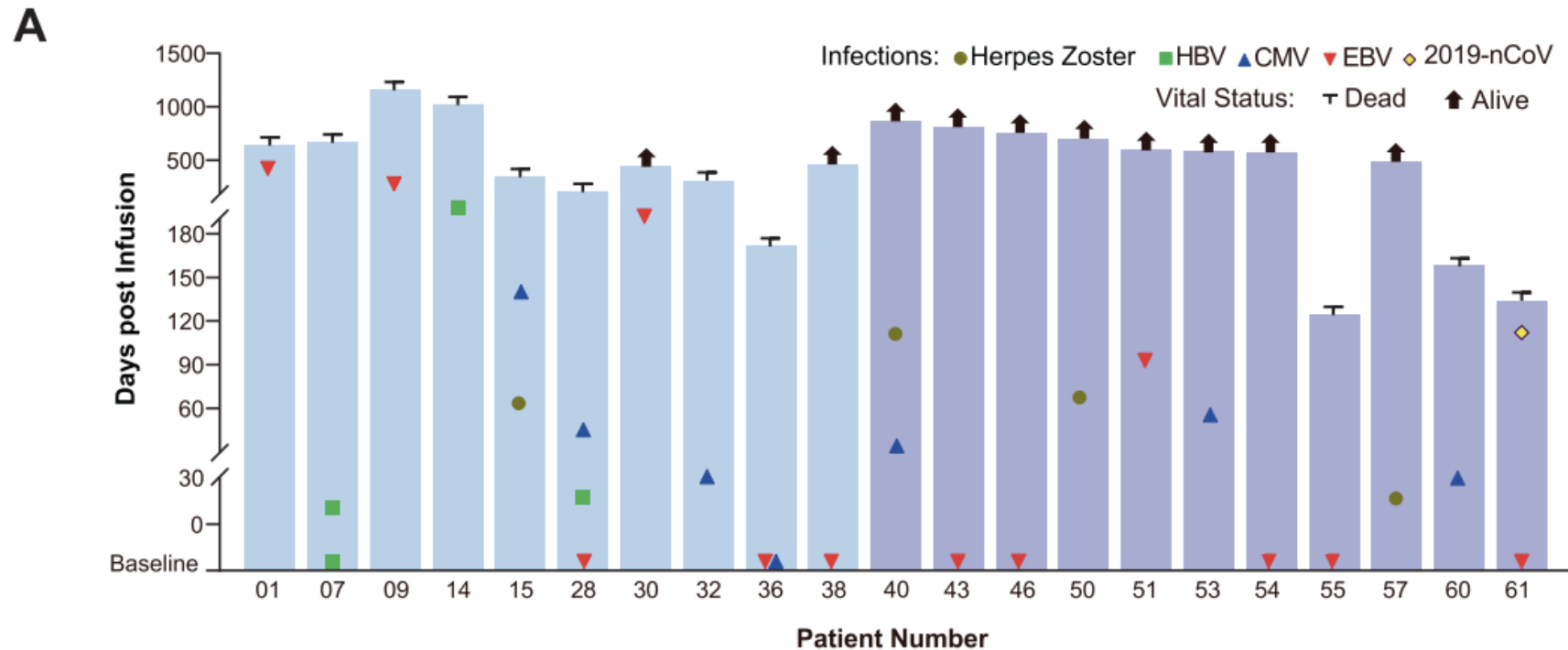
^aAdverse events in the cilta-cel arm were considered non-treatment emergent if they were not considered related to study treatment, and they occurred either >112 days after cilta-cel or after the start of subsequent therapy; for the standard care arm, adverse events were considered non-treatment emergent if they were not considered related to study treatment (DPd or PVd), and they occurred more than 30 days after the last dose of study treatment or after the start of subsequent therapy, whichever came first. ^b4 cilta-cel patients received 2 or 3 COVID-19 vaccinations prior to receiving cilta-cel, and 3 patients received no vaccines prior to cilta-cel. 2 of 7 patients received COVID-19 vaccination after cilta-cel, 1 dose each. All patients had a response of partial response or better to study treatment and did not progress prior to COVID-19 infection.

^cOccurred before infusion of cilta-cel.



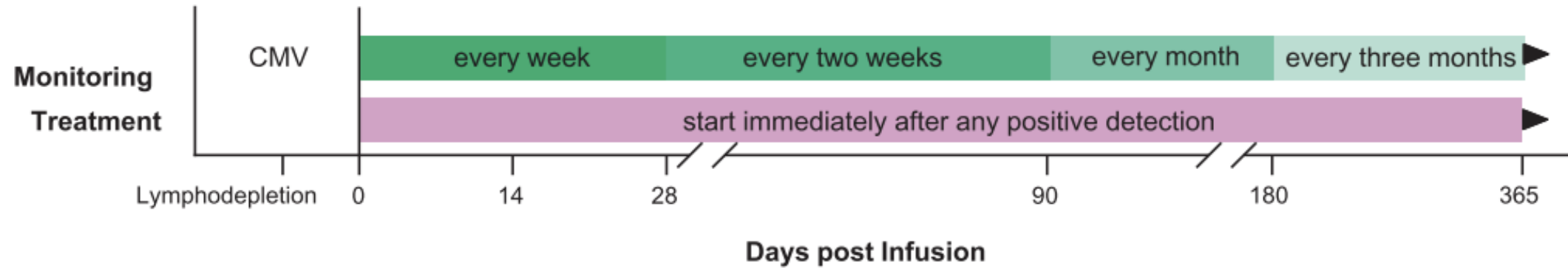
Infectious Complications: CMV

CMV Reactivation



***6/61 (10%) had CMV reactivation post CAR T-therapy**

Infectious Complications: CMV (3)



Low level CMV by PCR: Valganciclovir ppx dose

High level/rapid rise in CMV: Valganciclovir treatment dose

****WATCH FOR MYELSUPPRESSION:** Maribavir or letermovir may work in select situations without cytopenias

Bispecific Antibodies for MM: Infections

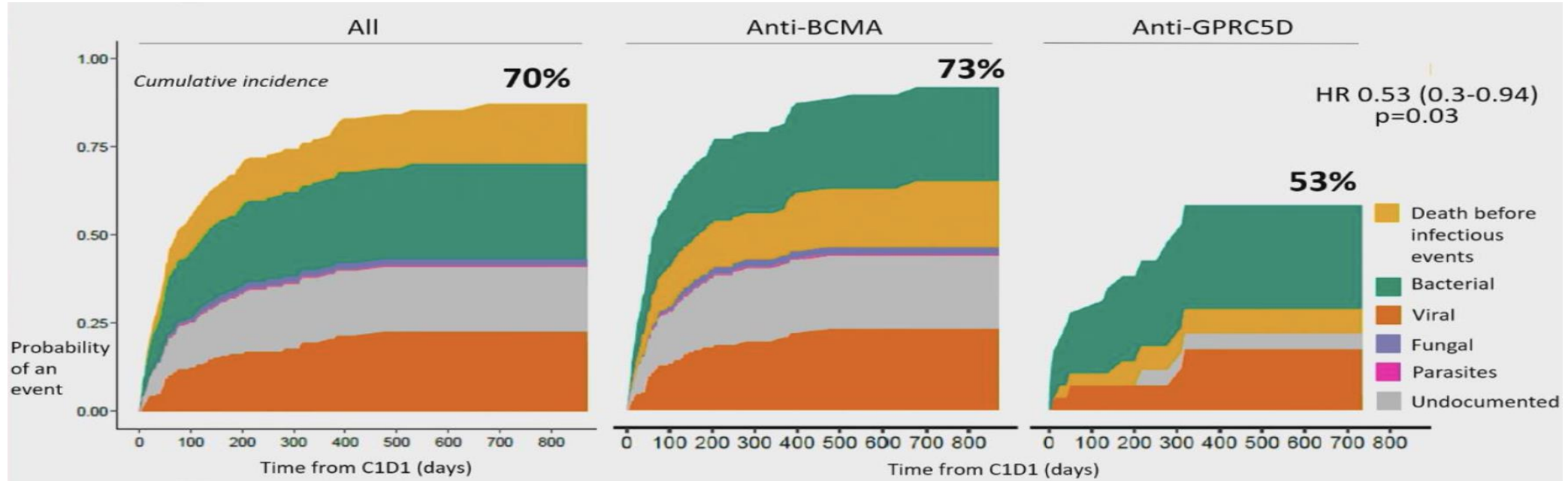
- Increased risk of bacterial infections, viral infections, and opportunistic infections
- Infections occur due to combined effects of:
 - Neutropenia
 - Hypogammaglobulinemia
 - T-cell exhaustion
 - Other factors:
 - Myeloma-related immunodeficiency (deficits in humoral and cellular immunity)
 - Extent of prior immunosuppressive treatment

Phase I/II trials of BCMA-targeting BsAbs as monotherapy in heavily pretreated multiple myeloma patients

| BsAb | Patients (n) | BsAb structure | Design | ORR/ CR (%) | PFS (months) | CRS (all grades, ≥grade 3; %) | NTX (all grade; %) | Approved dosing schedule |
|--------------------------------|----------------------|--|--|----------------|-----------------|-------------------------------|-----------------------|---|
| Teclistamab (TECVAYLI™) | 165 treated at RP2D | Fully human, IgG4-based | SQ , two step-up doses, then once per week; option for doses q2weeks if ≥CR for ≥6 months | 63%, 39% | 11 months | 72%, 1% | 14% (ICANS 3%) | 1.5 mg/kg SQ, weekly after step-up doses (0.06 and 0.3 mg/kg). Biweekly dosing approved. |
| Elranatmab (ELREXFIO™) | 123 treated at RP2D | Humanized, IgG2a backbone | SQ , two step-up doses, then weekly (q2 weeks if patient received ≥6 cycles and had ≥PR) | 61%, 28% | 17.2 months | 58%, 0% | ICANS 3% | 76 mg fixed dose, SQ weekly after two step-up doses (12 and 32 mg). Biweekly after 6 cycles. |
| Talquetamab (TALVEY™) | 232 (102 IV, 130 SQ) | GPRC5D (IgG4 with proline, alanine, alanine scaffold designed to minimize Fc-receptor binding) | SQ , two step-up doses, then weekly; OR 3 step-up doses and then q2 weeks | 64-70%, 22-23% | 7.8-10.2 months | 77-80%, 0-3% | 5-10% (all grade 1-2) | 0.8 mg/kg SQ, biweekly after 3 step-up doses (0.01, 0.06 and 0.4 mg/kg) 0.4 mg/kg SQ, weekly after 2 step-up doses (0.01 and 0.06 mg/kg) |

Moreau. NEJM. 2022;387:495. Raje. ASH 2022. Abstr 158. Lesokhin. ASCO 2022. Abstr 8006. Voorhees. ASH 2022. Abstr 1919. Bumma. ASH 2022. Abstr 4555. Wong SW ASH 2022. van de Donk, NWCJ, et al. Lancet. July 2023

Bispecific Antibodies for MM and Infections



| BsAb | Follow-up (months) | Infections (%) | Infections of \geq grade 3 (%) |
|-------------------------------|--------------------|----------------|----------------------------------|
| Teclistamab (MajesTEC-1) | 14.1 | 76% | 49% |
| Elranatamab (MagnetisMM-3) | 10.4 | 67% | 35% |
| Talquetamab (MonumenTAL-1) | 14.9 and 8.6* | 57% and 50%* | 17% and 12%* |

*Frequency of infections for both RP2Ds is reported (400 μ g/kg SQ weekly and 800 μ g/kg SQ q2weeks).

Infections in MajesTEC-1

- Majority of grade ≥ 3 infections were COVID-19 and respiratory infections
 - Study enrollment overlapped with peak of the COVID-19 pandemic*
 - 13/165 (7.9%) patients received a COVID-19 vaccine prior to the first teclistamab dose
 - 18/165 (10.9%) patients died due to COVID-19

| Patients, n (%) | N=165 | | |
|-----------------------------------|------------|-----------|-----------|
| | Any Grade | Grade 3/4 | Grade 5 |
| Any infection | 132 (80.0) | 91 (55.2) | 21 (12.7) |
| Respiratory infections | 95 (57.6) | 32 (19.4) | 2 (1.2) |
| COVID-19 infection | 48 (29.1) | 35 (21.2) | 18 (10.9) |
| Key viral infections ^a | 20 (12.1) | 7 (4.2) | 1 (0.6) |
| GI infections | 15 (9.1) | 2 (1.2) | 0 |
| Fungal infections ^b | 9 (5.5) | 0 | 0 |
| PJP | 7 (4.2) | 7 (4.2) | 0 |
| HBV reactivation | 1 (0.6) | 1 (0.6) | 0 |

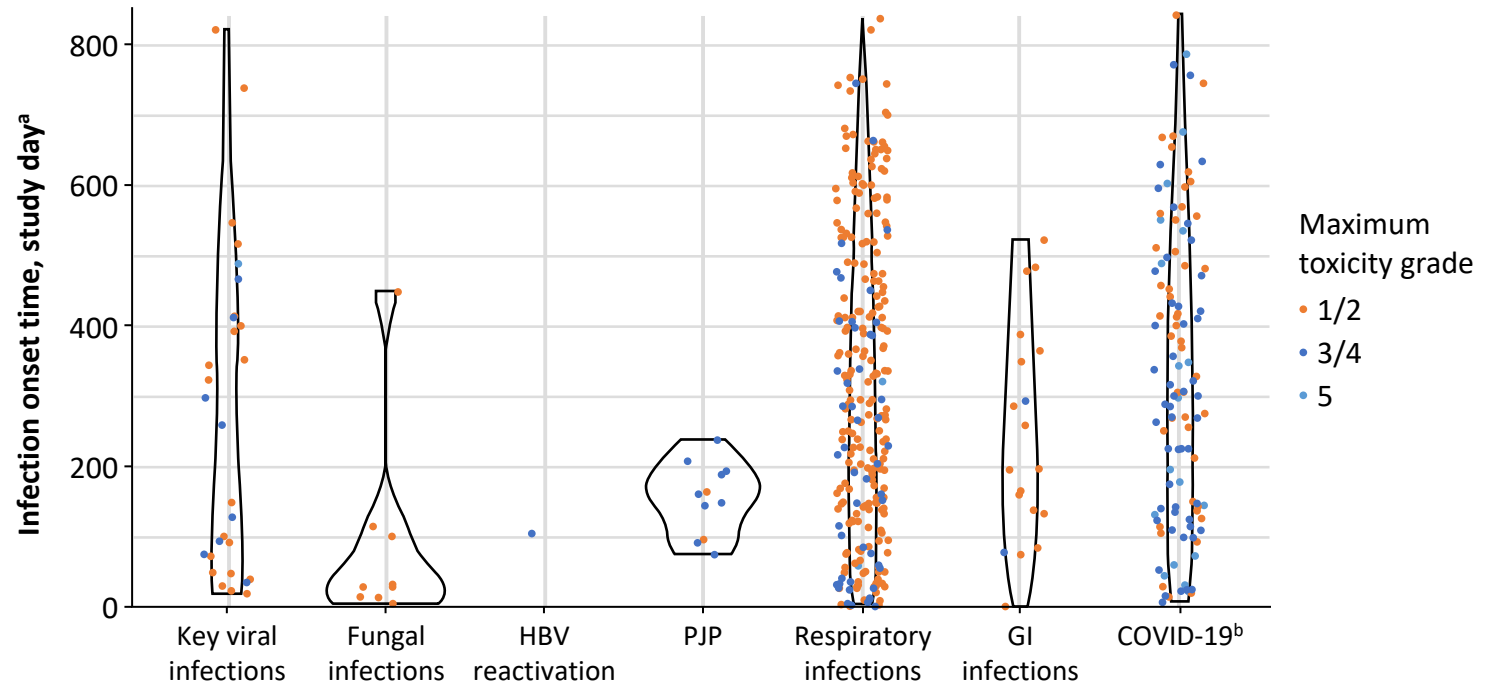
^a Excluding COVID19 ^b Excluding PJP

Significant proportion of infections on trial were COVID19; likely less of an issue currently with majority of population vaccinated and/or have had prior COVID19 infections

*Trial enrolled between March 2020 and August 2021

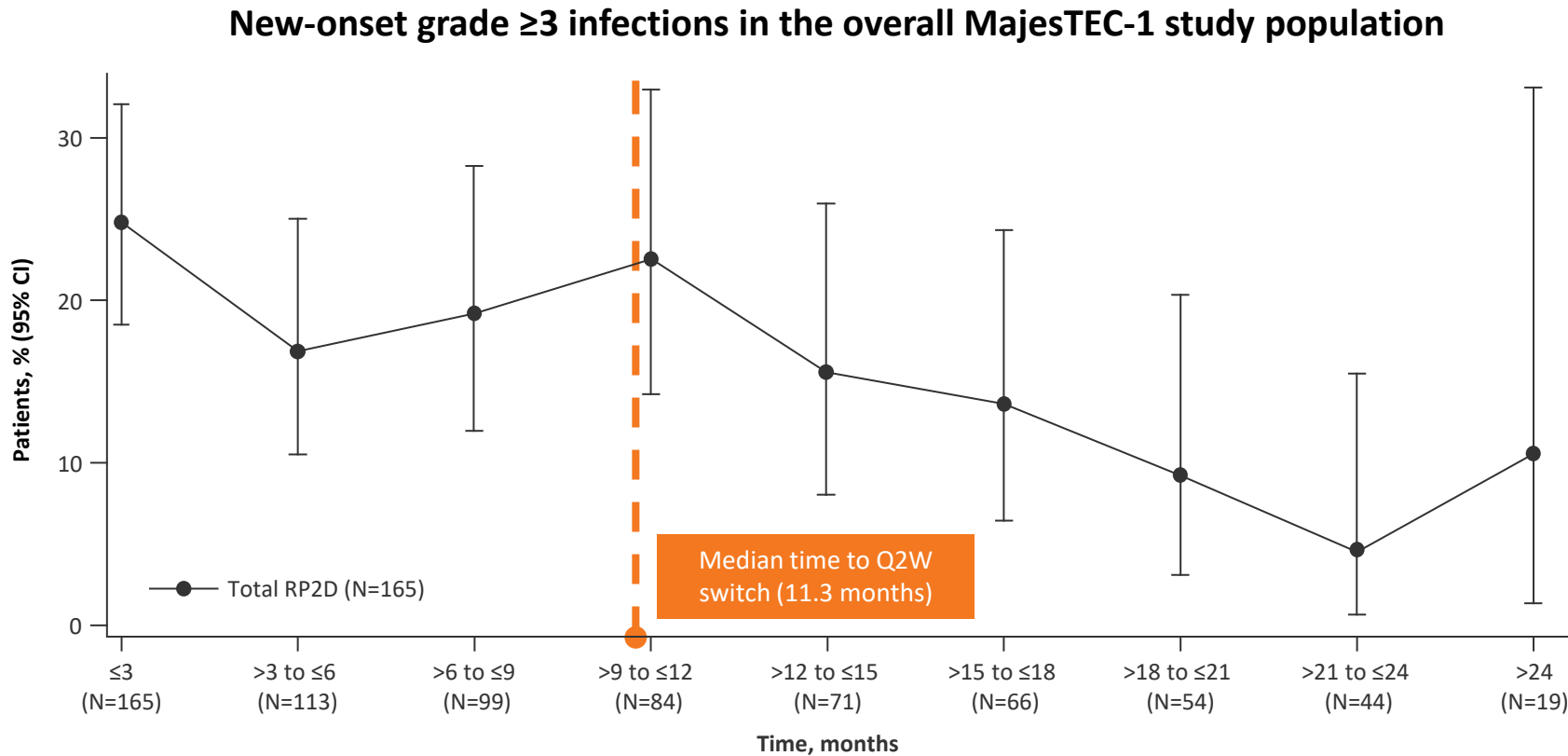
Timing and Maximum Toxicity Grade of Clinically Relevant Infections During Teclistamab Treatment Was Variable

- Respiratory infections occurred throughout the study (mostly grade 1/2)
- COVID-19 infections of all grades were observed throughout the study
- Most viral infections occurred during the first 12 months
- GI infections were seen throughout the study
- Most fungal and PJP infections were observed early



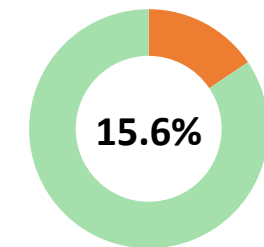
Continued monitoring throughout treatment is recommended, although improvements are expected with increased awareness and vigilance, new expert management guidelines, and additional strategies

New-Onset Grade ≥ 3 Infections Decreased Over Time in MajesTEC-1, With Fewer Infections in Patients Switching to Q2W

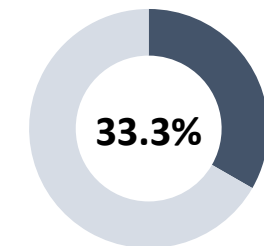


New-onset grade ≥ 3 infections at 1–1.5 years¹

Patients switching to Q2W dosing by 1 year



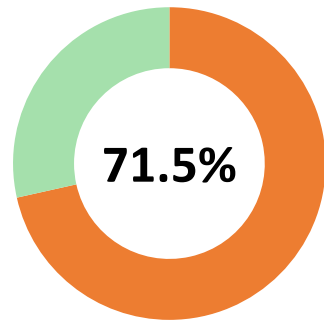
Patients remaining on QW dosing at 1 year



Hypogammaglobulinemia Was Managed With IgG Replacement Although Institutional Protocols and Access Varied

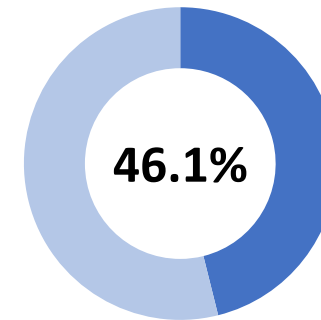
Overall incidence

≥1 hypogammaglobulinemia
AE or post-baseline
IgG value <400 mg/dL

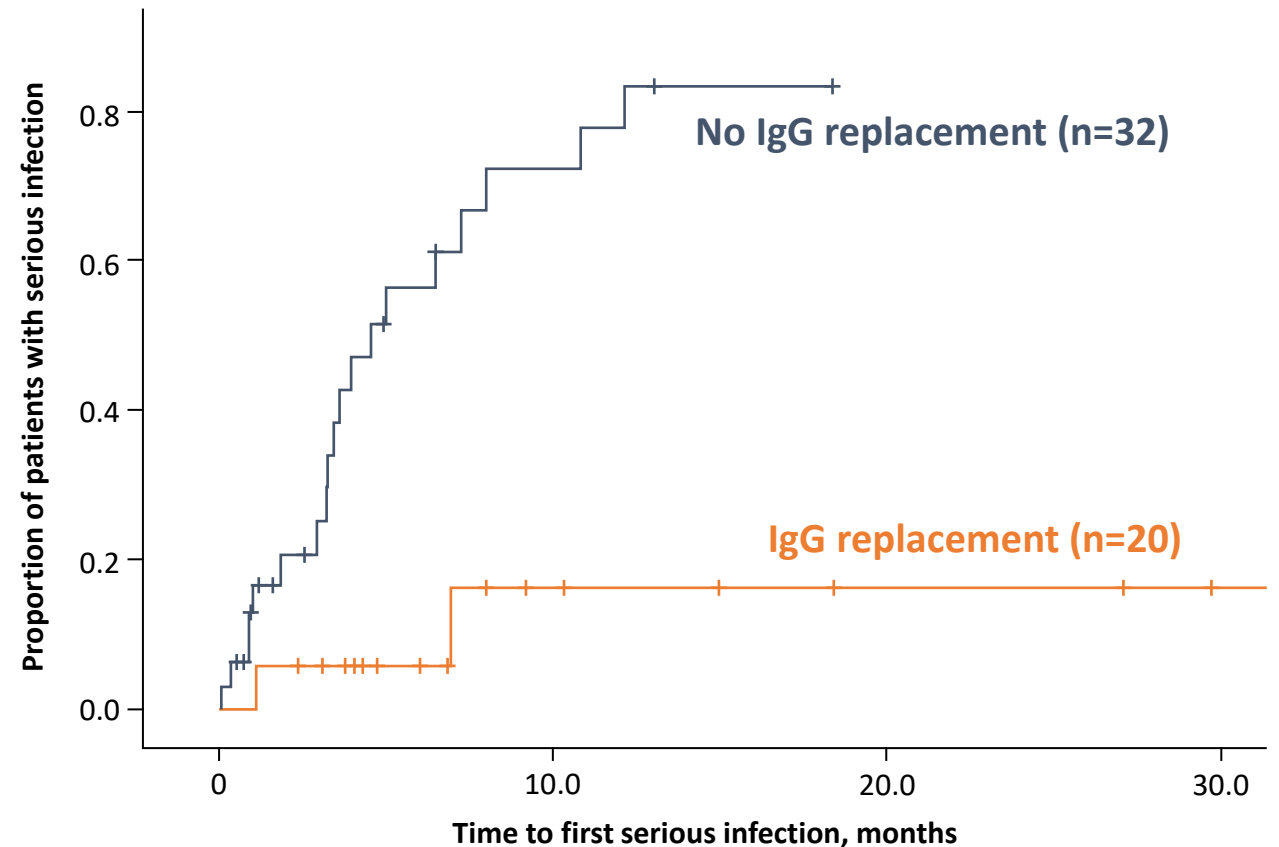


IgG replacement

≥1 dose of
IgG replacement

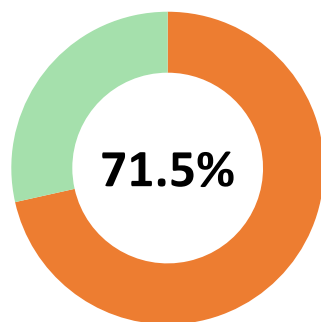


- In a retrospective analysis of 52 patients at Amsterdam UMC:
 - Low baseline polyclonal IgG levels further decreased after starting teclistamab¹
 - Monthly IgG replacement significantly reduced the risk of grade ≥ 3 infections
 - Mostly lower respiratory tract infections caused by gram-negative bacteria
- Consistent with another study of BCMA-targeted bispecific antibodies, showing 80% reduction in grade ≥ 3 infections with IgG replacement²



Any grade neutropenia

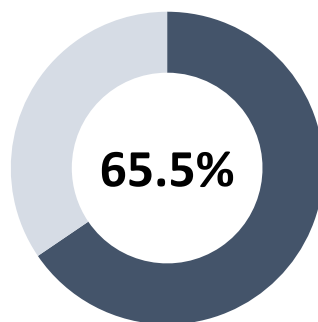
Overall
incidence



Median duration:
1.2 months

Grade 3/4 neutropenia

Overall
incidence



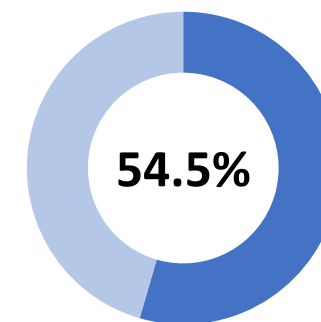
Median duration:
0.8 months^a

Median time
to onset^a



G-CSF use

Prophylaxis and
management



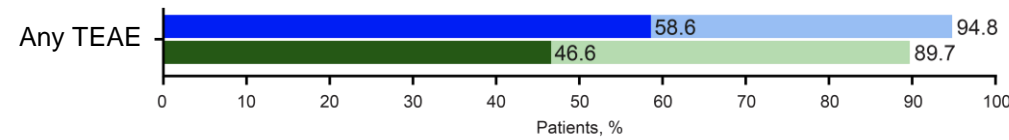
MagnetisMM-3 Study: AEs of special interest: Infections

- Infections were reported in 69.9% (grade 3/4, 39.8%; grade 5, 6.5%) of patients
- Among patients with quantitative Ig data (n=72), 98.6% had immune paresis at baseline
- Overall, 43.1% of patients received IgG replacement during the study

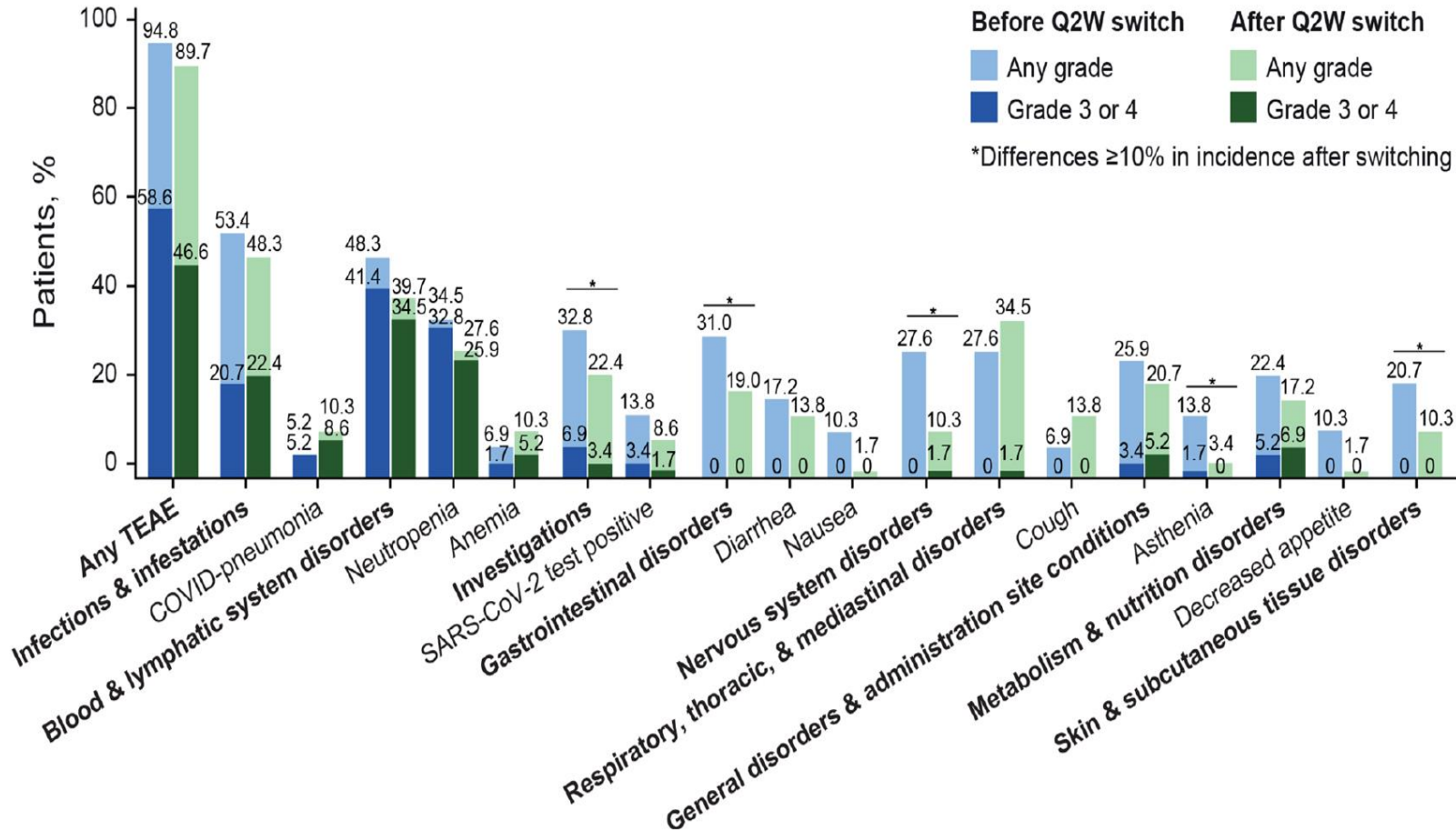
| Patients, n (%) | Cohort A (N=123) | | |
|--|----------------------|-----------|----------------------|
| | Any grade | Grade 3/4 | Grade 5 |
| Infection TEAEs in ≥5% of patients | | | |
| COVID-19–related ^a | 36 (29.3) | 19 (15.4) | 2 (1.6) |
| Upper respiratory tract infection | 20 (16.3) | 0 | 0 |
| Pneumonia | 20 (16.3) | 10 (8.1) | 0 |
| Sinusitis | 13 (10.6) | 2 (1.6) | 0 |
| Urinary tract infection | 12 (9.8) | 4 (3.3) | 0 |
| Sepsis | 8 (6.5) | 8 (6.5) | 0 |
| Bacteremia | 7 (5.7) | 2 (1.6) | 0 |
| CMV reactivation | 7 (5.7) | 2 (1.6) | 0 |
| Key infections occurring in <5% of patients ^b | | | |
| <i>Pneumocystis jirovecii</i> pneumonia | 6 (4.9) | 5 (4.1) | 0 |
| CMV infection | 4 (3.3) | 0 | 0 |
| Adenoviral hepatitis | 1 (0.8) | 0 | 1 (0.8) |
| Adenovirus infection | 1 (0.8) ^c | 0 | 1 (0.8) ^c |
| Hepatitis B reactivation | 1 (0.8) | 0 | 0 |
| Pneumonia adenoviral | 1 (0.8) ^c | 0 | 1 (0.8) ^c |
| Pneumonia cytomegaloviral | 1 (0.8) | 1 (0.8) | 0 |
| Pneumonia pseudomonal | 1 (0.8) | 0 | 1 (0.8) |

^a Includes preferred terms in COVID-19 (narrow) standardized MedDRA queries; ^b Key infection TEAEs includes preferred terms: CMV infection reactivation, *Pneumocystis jirovecii* pneumonia, CMV infection, Adenoviral hepatitis, Adenovirus infection, Hepatitis B reactivation, Pneumonia adenoviral, Pneumonia CMV, Pneumonia pseudomonal; ^c Preferred Terms both reported in the same patient. Immune paresis was defined as ≥2 uninvolved Ig <lower limit of normal.

Elranatamab - Safety with Q2W dosing



Before Q2W switch After Q2W switch
 Any grade Any grade
 Grade 3 or 4 Grade 3 or 4



Before Q2W switch After Q2W switch
 Any grade Any grade
 Grade 3 or 4 Grade 3 or 4
 *Differences ≥10% in incidence after switching

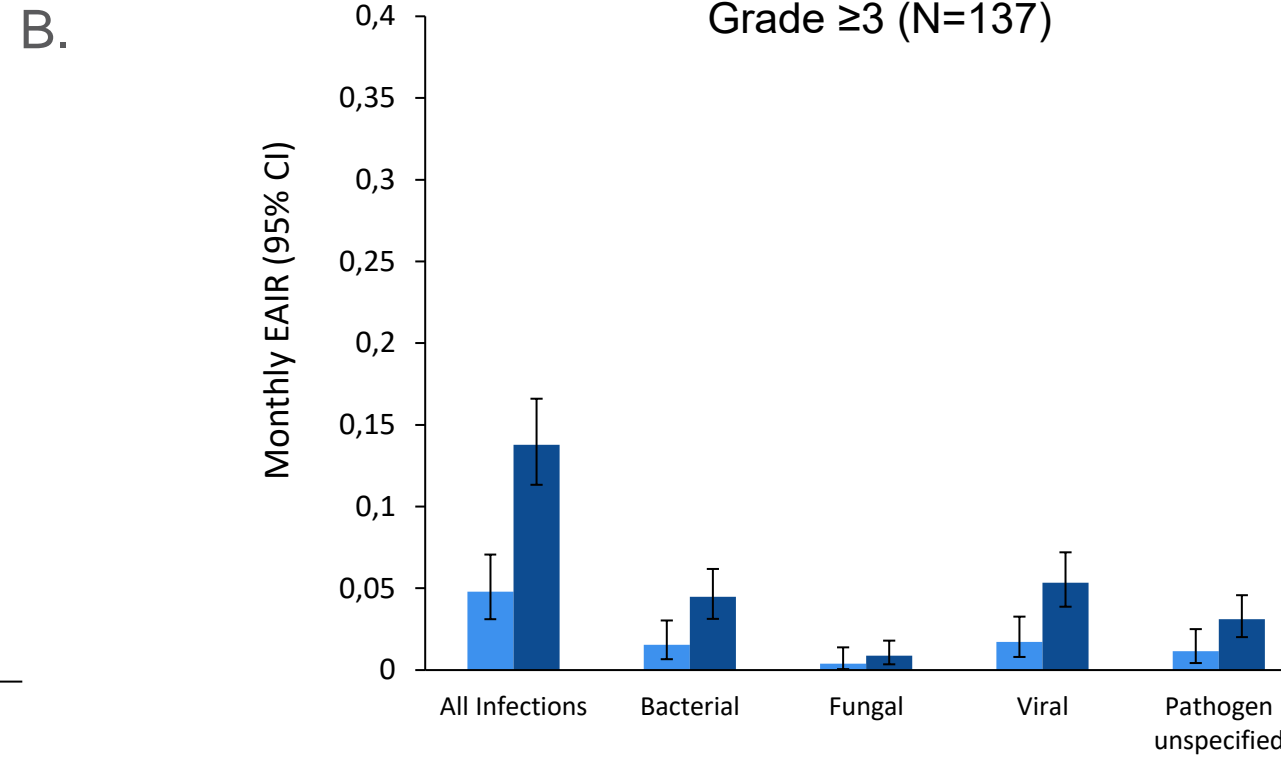
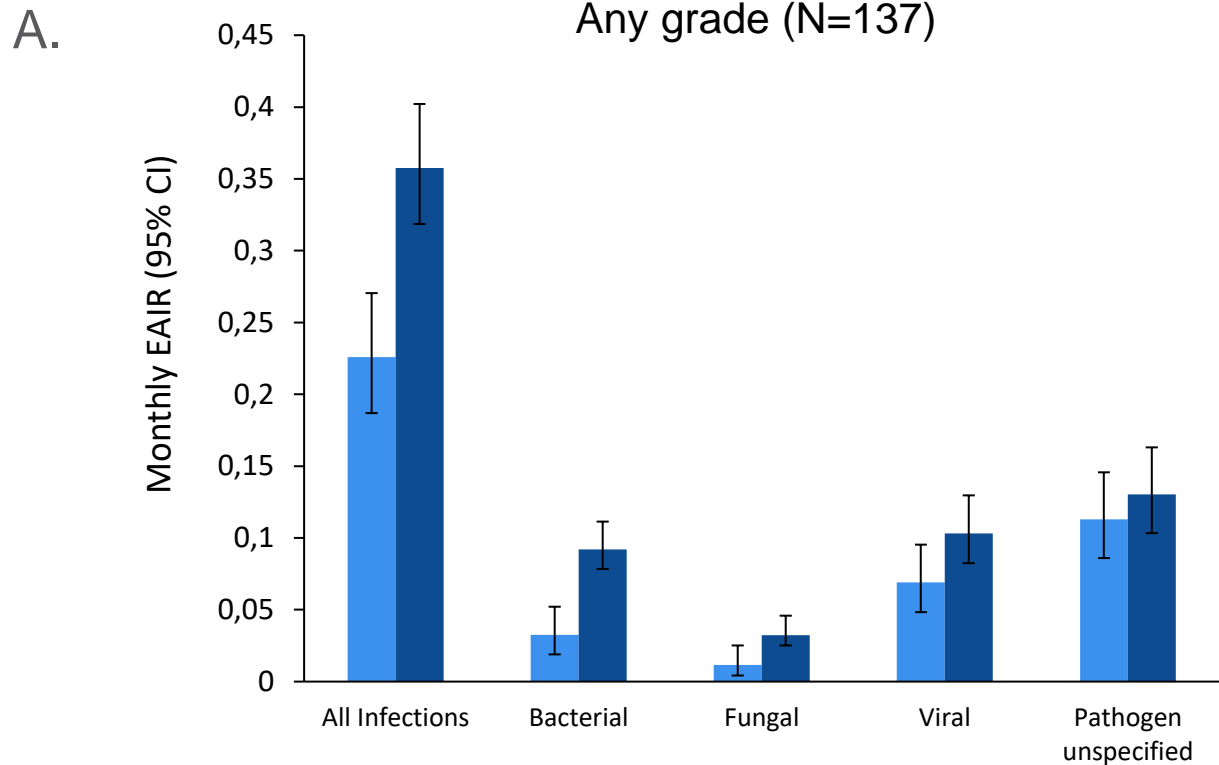
- A total of 50 patients had a response per BICR and **switched to Q2W dosing**; 40 (80%) of these patients maintained or improved their response ≥6 mo after the switch
- 66.7% (n=50/75) objective responses were ongoing
- Incidence of grade 3/4 TEAEs decreased by >10% after **switching to Q2W dosing**; 58.6% within 3 mo before switching and 46.6% in the 3 mo after switching

*Difference ≥10% in incidence after switching

TEAEs occurring in ≥20% of patients at the level of SOC and in ≥10% of patients at the level of PT in the 3 mo before or after switching to Q2W dosing are reported. New onset TEAEs for each patient were included for an equal time period before and after the switch (based on individual patient follow-up time after the switch), with a maximum time period of up to 3 mo. PT=preferred terms; Q2W=once every 2 weeks; SOC=System Organ Class; TEAE=treatment-emergent adverse event

Infections of any grade (A) and grade ≥ 3 (B) in patients with or without hypogammaglobulinemia in MagnetisMM-3

| Time, months | Without hypogammaglobulinemia (n=92) | With hypogammaglobulinemia (n=115) |
|----------------|--------------------------------------|------------------------------------|
| Median (Range) | 4.1 (0.0 to 20.5) | 6.3 (0.0 to 17.7) |



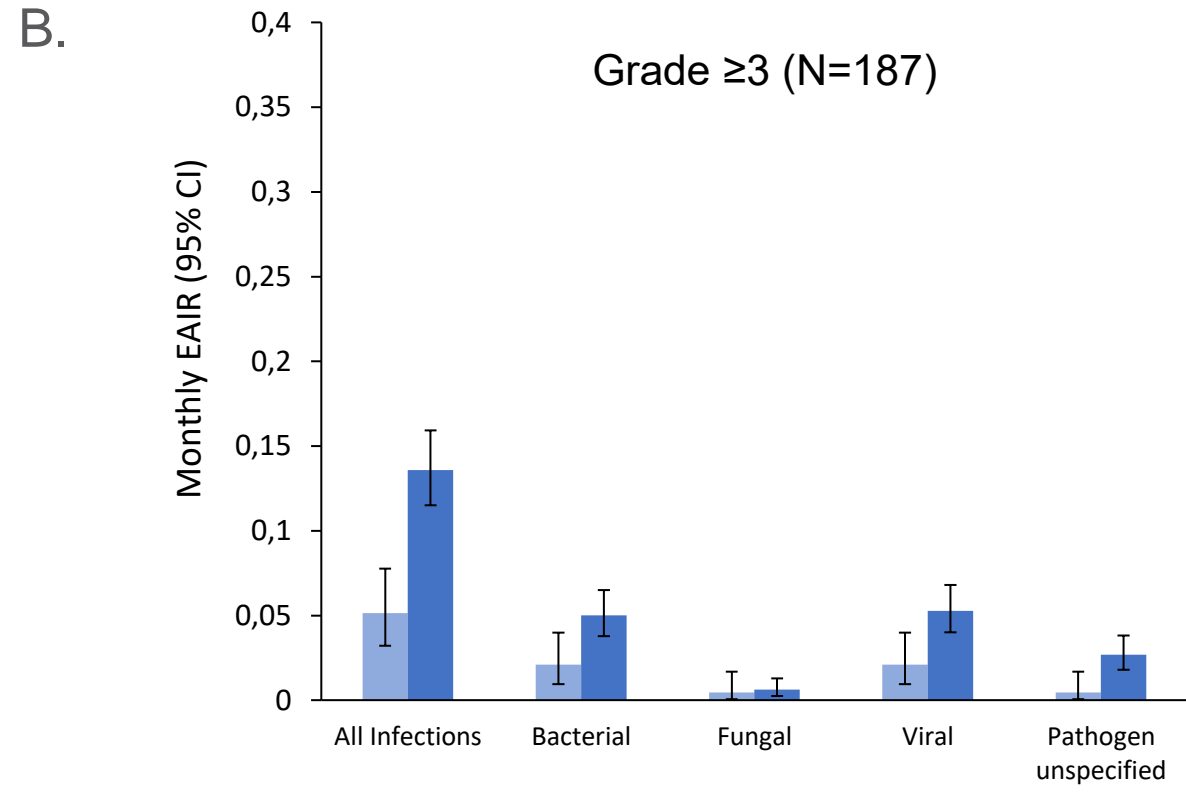
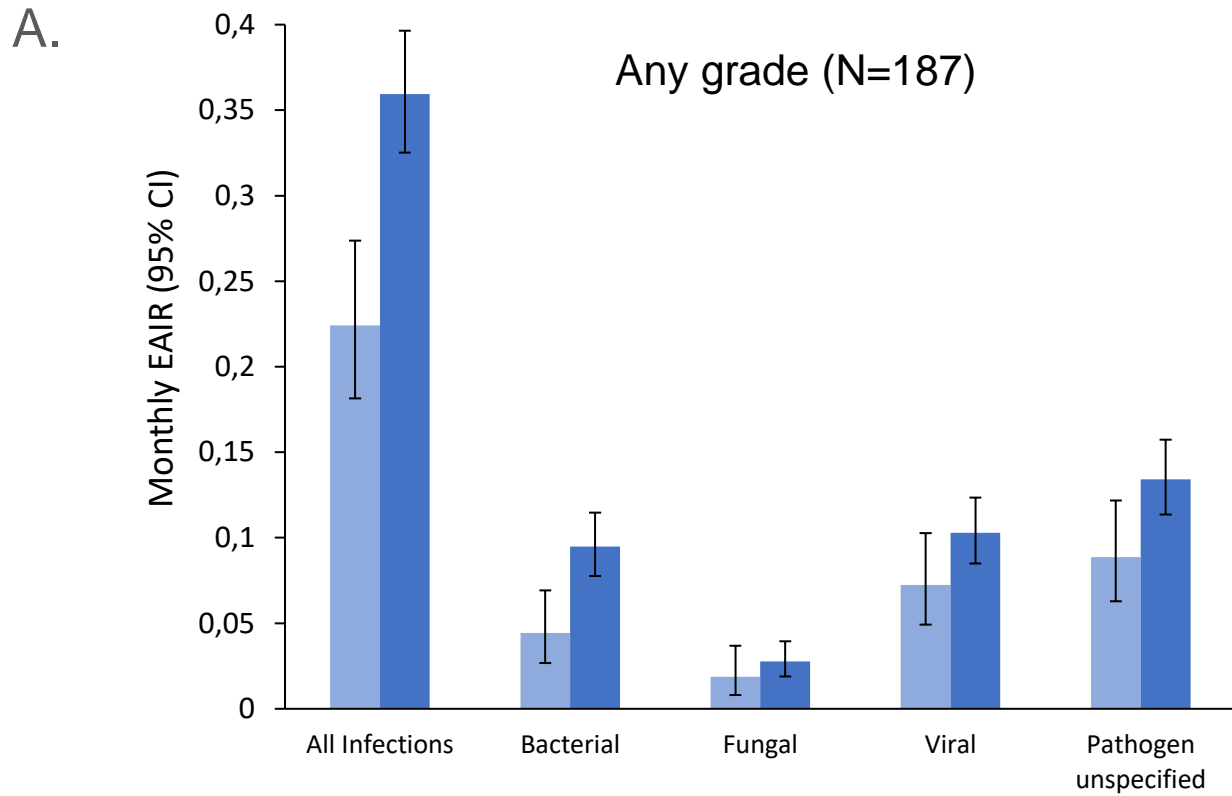
| | | | | | |
|-------------------------------------|---------|---------|---------|---------|---------|
| Rates without hypogammaglobulinemia | 0.22589 | 0.03254 | 0.01149 | 0.06892 | 0.11294 |
| Rates with hypogammaglobulinemia | 0.35759 | 0.09188 | 0.03228 | 0.10306 | 0.13037 |
| Cases without hypogammaglobulinemia | 118 | 17 | 6 | 36 | 59 |
| Cases with hypogammaglobulinemia | 288 | 74 | 26 | 83 | 105 |

| | | | | | |
|-------------------------------------|---------|---------|---------|---------|---------|
| Rates without hypogammaglobulinemia | 0.04786 | 0.01531 | 0.00383 | 0.01723 | 0.01149 |
| Rates with hypogammaglobulinemia | 0.13782 | 0.04470 | 0.00869 | 0.05339 | 0.03104 |
| Cases without hypogammaglobulinemia | 25 | 8 | 2 | 9 | 6 |
| Cases with hypogammaglobulinemia | 111 | 36 | 7 | 43 | 25 |

EAIR=exposure adjusted infection rate

Infections of any grade (A) and grade ≥ 3 (B) in patients with or without Ig replacement therapy in MagnetisMM-3

| Time, months | With immunoglobulin replacement (n=77) | Without immunoglobulin replacement (n=177) |
|----------------|--|--|
| Median (Range) | 3.0 (0.1 to 25.0) | 4.6 (0.2 to 18.60) |









| | | | | | |
|------------------------------|---------|---------|---------|---------|---------|
| Rates with Ig replacement | 0.22413 | 0.04436 | 0.01868 | 0.07238 | 0.08872 |
| Rates without Ig replacement | 0.35951 | 0.09480 | 0.02772 | 0.10284 | 0.13414 |
| Cases with Ig replacement | 96 | 19 | 8 | 31 | 38 |
| Cases without Ig replacement | 402 | 106 | 31 | 115 | 150 |

| | | | | | |
|------------------------------|---------|---------|---------|---------|---------|
| Rates with Ig replacement | 0.05136 | 0.02101 | 0.00467 | 0.02101 | 0.00467 |
| Rates without Ig replacement | 0.13593 | 0.05008 | 0.00626 | 0.05276 | 0.02683 |
| Cases with Ig replacement | 22 | 9 | 2 | 9 | 2 |
| Cases without Ig replacement | 152 | 56 | 7 | 59 | 30 |

EAIR=exposure adjusted infection rate

Overview of Consensus Recommendations from Expert Meeting

-  Administer **monthly IVIG** for the duration of **hypogammaglobulinemia** and in the absence of life-threatening infectious manifestations (level IIC)
-  Use **colony-stimulating factors** in patients with **Grade ≥ 3 neutropenia*** (level III)
-  **Screen for HBV reactivation risk** in all patients (level III)
-  Use **anti-viral prophylaxis** against **HSV** and **VZV** in all patients (level III)
-  Use **PJP prophylaxis** for all patients (level IIC)
-  Except for PJP, **do not use general anti-fungal prophylaxis** unless a patient has a previous history of fungal infections, prolonged neutropenia, or has recently received prolonged treatment with high dose corticosteroids (>2 weeks) (level IIC)

*Grade 3 neutropenia: ANC 500 to 1000/mm³; Grade 4 neutropenia: ANC <500/mm³.

ANC = absolute neutrophil count; HBV = hepatitis B virus; HSV = herpes simplex virus; IVIG = intravenous immunoglobulin; PJP = *Pneumocystis jirovecii* pneumonia; VZV = varicella zoster virus

Infectious Complications: COVID

| Situation | Management Advice |
|---|--|
| Before CAR T-cell / TCE therapy | - Ensure adequate COVID vaccination |
| Post CAR T-cell / During TCE therapy | - Revaccinate +/- Evusheld - If (+) test: Remdesivir (IV) vs Paxlovid (PO) |

*Vaccination may lead to transient elevations in light chains

Summary

- Cytopenias and infections are target and TCR specific
- Appropriate monitoring and prophylaxis is critical
- Case for fixed duration treatment with bispecifics to minimize infectious complications over time



Acknowledgements

Our Patients

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GENERAL HOSPITAL

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Thank you!

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