Bispecific Antibodies

Ashley Bogus, PharmD, BCOP
Clinical Pharmacy Specialist, Oncology
Nebraska Medicine

University of Nebraska Medical Center

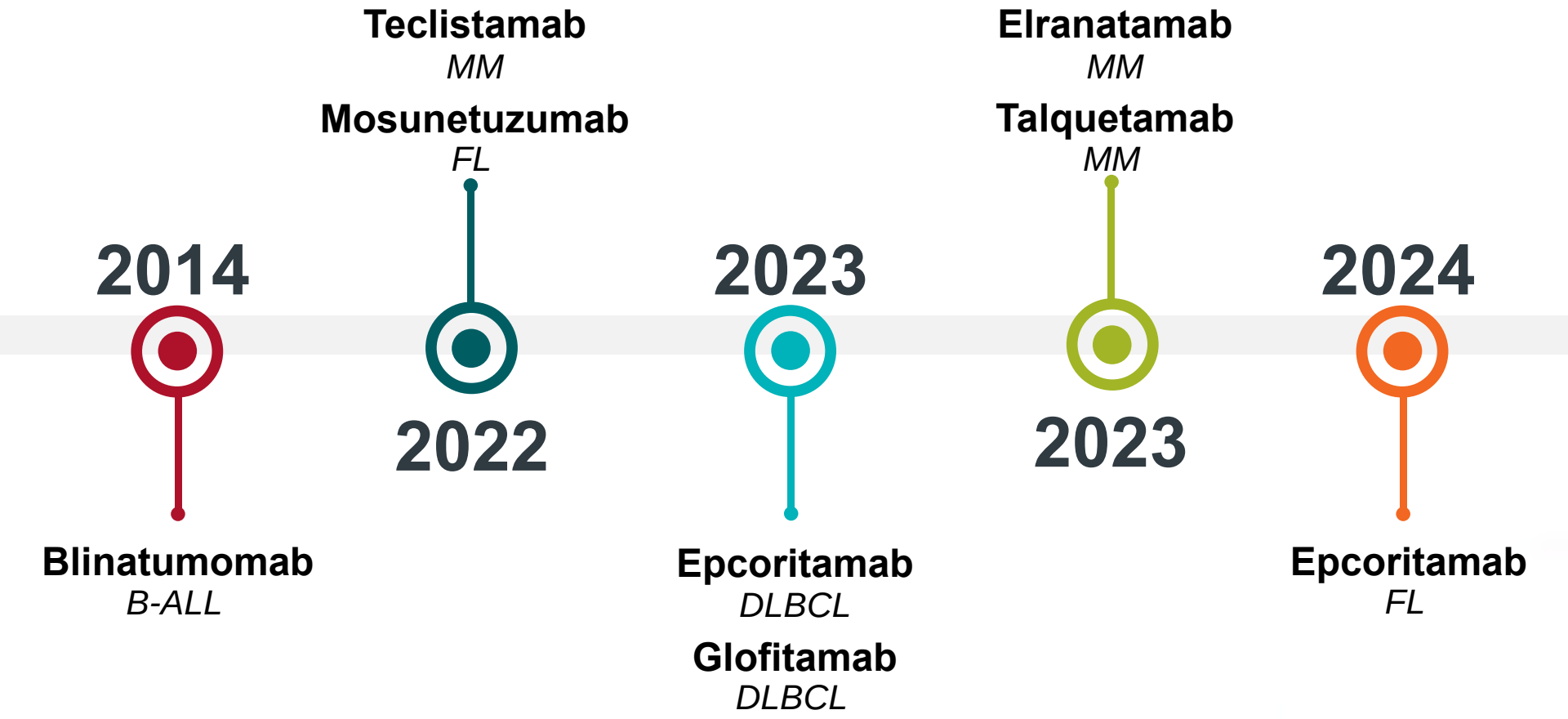
Disclosures

I have no financial relationship with any pharmaceutical companies, biomedical device manufacturers or distributors, or others whose products or services may be considered related to the content of my presentation.

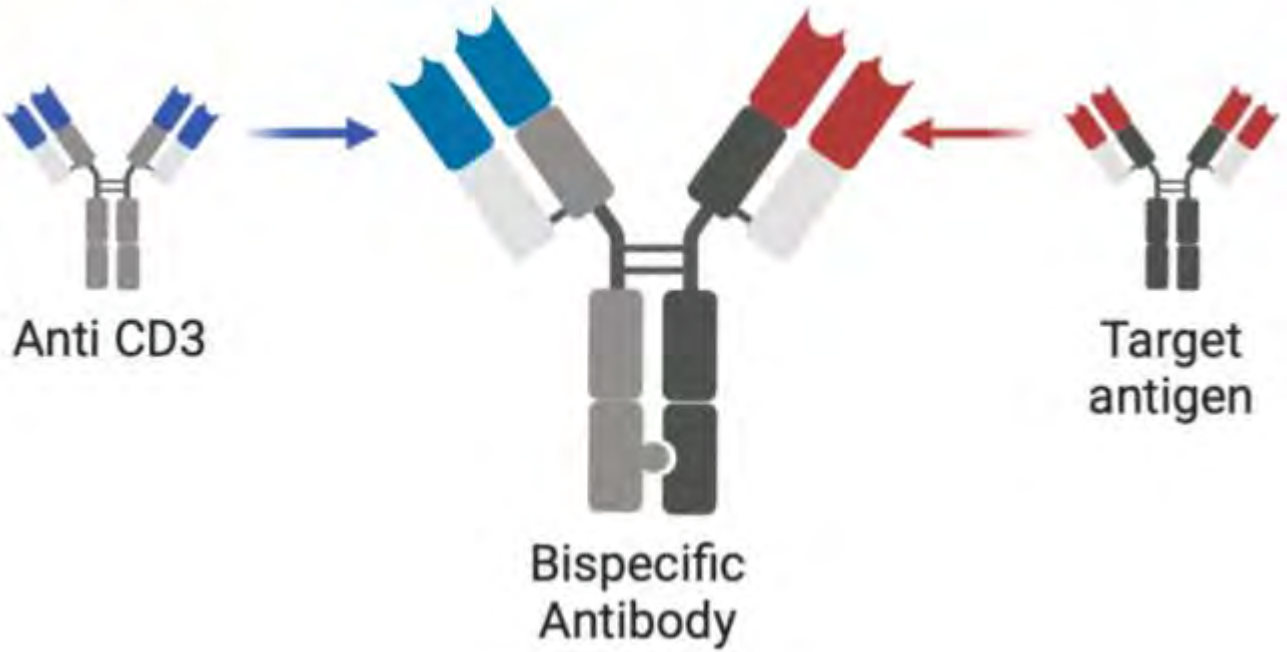
Objectives

1. Review Bispecific Antibodies (BsAbs) used in hematologic malignancies.
2. Illustrate appropriate monitoring & management of BsAbs.
3. Explore strategies for overcoming barriers associated with BsAbs.

Approvals in Hematologic Malignancies

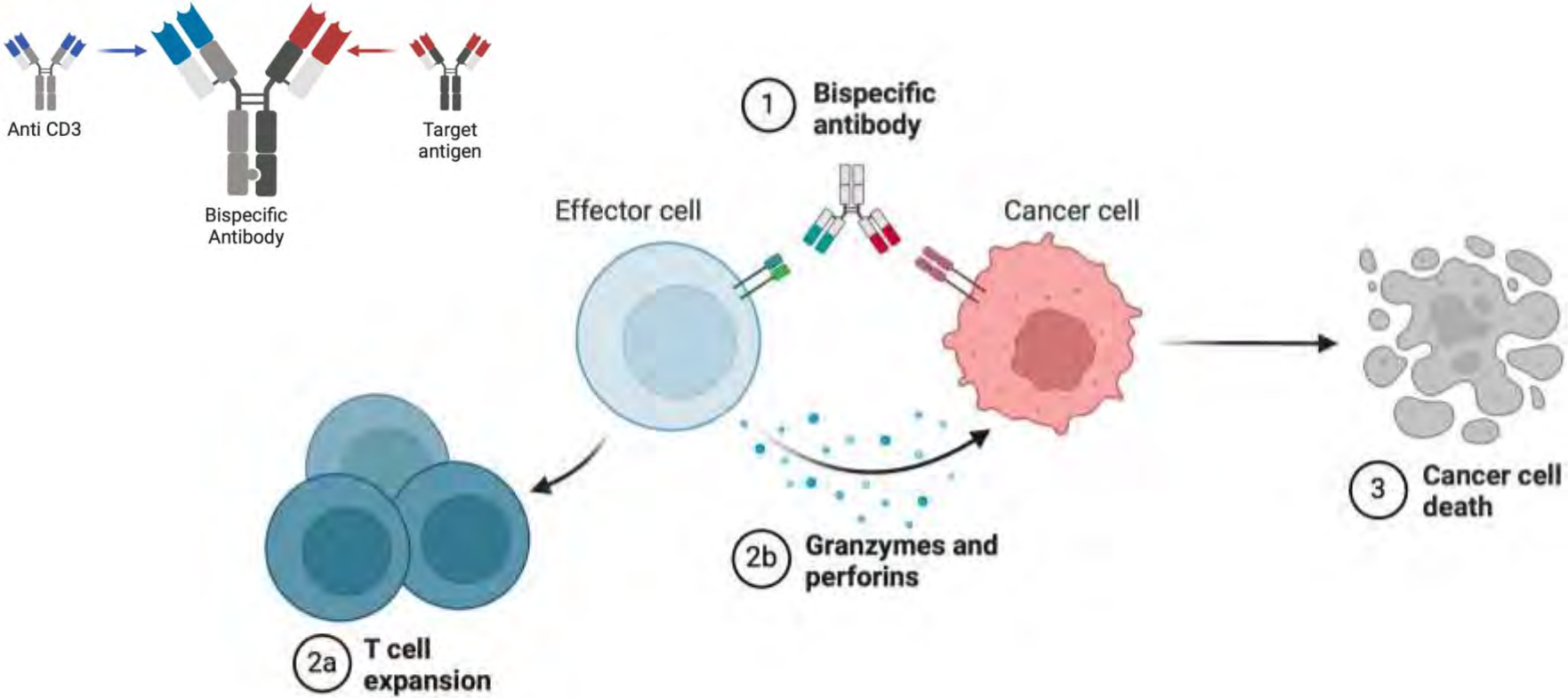


What is a bispecific antibody?



Trabolsi A et al. *J Immunol*. 2019;2023(3):585-592; Image created with BioRender.

Mechanism of Action



Trabolsi A et al. *J Immunol*. 2019;203(3):585-592; Image created with BioRender.
Klein C et al. *Nat Rev Drug Discov*. 2024;23(4):301-319; Image created with BioRender.

BsAbs in Lymphoma & Myeloma

- **TECLISTAMAB**
  Multiple Myeloma
- **TALQUETAMAB**
  Multiple Myeloma
- **ELRANATAMAB**
  Multiple Myeloma

- **MOSUNETUZUMAB**
  Follicular Lymphoma
- **GLOFITAMAB**
  DLBCL
- **EPCORITAMAB**
  Follicular Lymphoma, DLBCL

BsAbs in Lymphoma

- **MOSUNETUZUMAB**
  Follicular Lymphoma
- **GLOFITAMAB**
  DLBCL
- **EPCORITAMAB**
  Follicular Lymphoma, DLBCL

Mosunetuzumab

Target

CD3 x CD20

Approval

R/R Follicular Lymphoma after 2+ lines

Route

Intravenous

Hospital Admission

Not required

Cycle Length

21 days
(CR: 8 cycles
PR/SD: 17 cycles)

Dosing

- C1: Days 1, 8, 15
- C2+: Day 1

CR=Complete Response; PR=Partial Response; R/R=Relapsed or Refractory SD=Stable Disease

Lunsumio. Prescribing Information. Genentech, Inc. Accessed January 16, 2025.

Glofitamab

Target

CD3 x CD20
(1:2)

Approval

R/R DLBCL
after 2+ lines

Route

Intravenous

Hospital Admission

- C1D8: required
- C1D15: CRS w/ previous dose
- Grade ≥2 CRS

Cycle Length

21 days

(12 cycles)

Dosing

- C1: Days 1 (Obinutuzumab only), 8, 15,
- C2+: Day 1

CRS=Cytokine Release Syndrome; DLBCL=Diffuse Large B-cell Lymphoma; R/R=Relapsed or Refractory.

Columvi. Prescribing Information. Genentech, Inc. Accessed January 16, 2025.

Epcoritamab

Target

CD3 x CD20

Approval

R/R DLBCL or Follicular Lymphoma after 2+ lines

Route

Subcutaneous

Hospital Admission

- C1D15: required (DLBCL only)

Cycle Length

28 days

(Until progression)

Dosing*

- C1-3: Days 1, 8, 15, 22
- C4-9: Days 1, 15
- C10+: Day 1

DLBCL=Diffuse Large B-cell Lymphoma; R/R=Relapsed or Refractory.

*Dose strengths vary between DLBCL and Follicular Lymphoma indications

Epkinly. Prescribing Information. AbbVie Inc. Accessed January 16, 2025.

BsAbs in Lymphoma & Myeloma

- **TECLISTAMAB**
  Multiple Myeloma
- **TALQUETAMAB**
  Multiple Myeloma
- **ELRANATAMAB**
  Multiple Myeloma

- **MOSUNETUZUMAB**
  Follicular Lymphoma
- **EPCORITAMAB**
  DLBCL
- **EPCORITAMAB**
  Follicular Lymphoma, DLBCL

BsAbs in Myeloma

- **TECLISTAMAB**
  Multiple Myeloma
- **TALQUETAMAB**
  Multiple Myeloma
- **ELRANATAMAB**
  Multiple Myeloma

Teclistamab

Target

CD3 x BCMA

Approval

R/R MM
after 4+ lines

Route

Subcutaneous

Hospital Admission

48 hours after all step-up doses

Cycle Length

7 days

(CR ≥6 months consider biweekly)

Dosing*

- C1: Days 1, 4, 7
- C2+: D1

CR=Complete Responder; MM=Multiple Myeloma; R/R=Relapsed or Refractory.

*Dosing is weight-based utilizing *actual* body weight

Tecvayli. Prescribing Information. Janssen Biotech, Inc. Accessed January 16, 2025.

Talquetamab

Target

CD3 x GPRC5D

Approval

R/R MM
after 4+ lines

Route

Subcutaneous

Hospital Admission

48 hours after all step-up doses

Cycle Length

Weekly or Biweekly

Dosing*

<u>Weekly</u>

- C1: Days 1, 4, 7
- C2+: Day 1

<u>Biweekly</u>

- C1: Days 1, 4, 7, 10
- C2+: Day 1

*Dosing is weight-based utilizing *actual* body weight

MM=Multiple Myeloma; R/R=Relapsed or Refractory.

Talvey. Prescribing Information. Janssen Biotech, Inc. Accessed January 16, 2025.

Elranatamab

Target

CD3 x GPRC5D

Approval

R/R MM
after 4+ lines

Route

Subcutaneous

Hospital Admission

48 hours after first dose, 24 hours after second dose

Cycle Length

7 days

(At Week 25 can move to biweekly)

Dosing

- C1: Days 1, 4, 8
- C2+: D1

MM=Multiple Myeloma; R/R=Relapsed or Refractory.

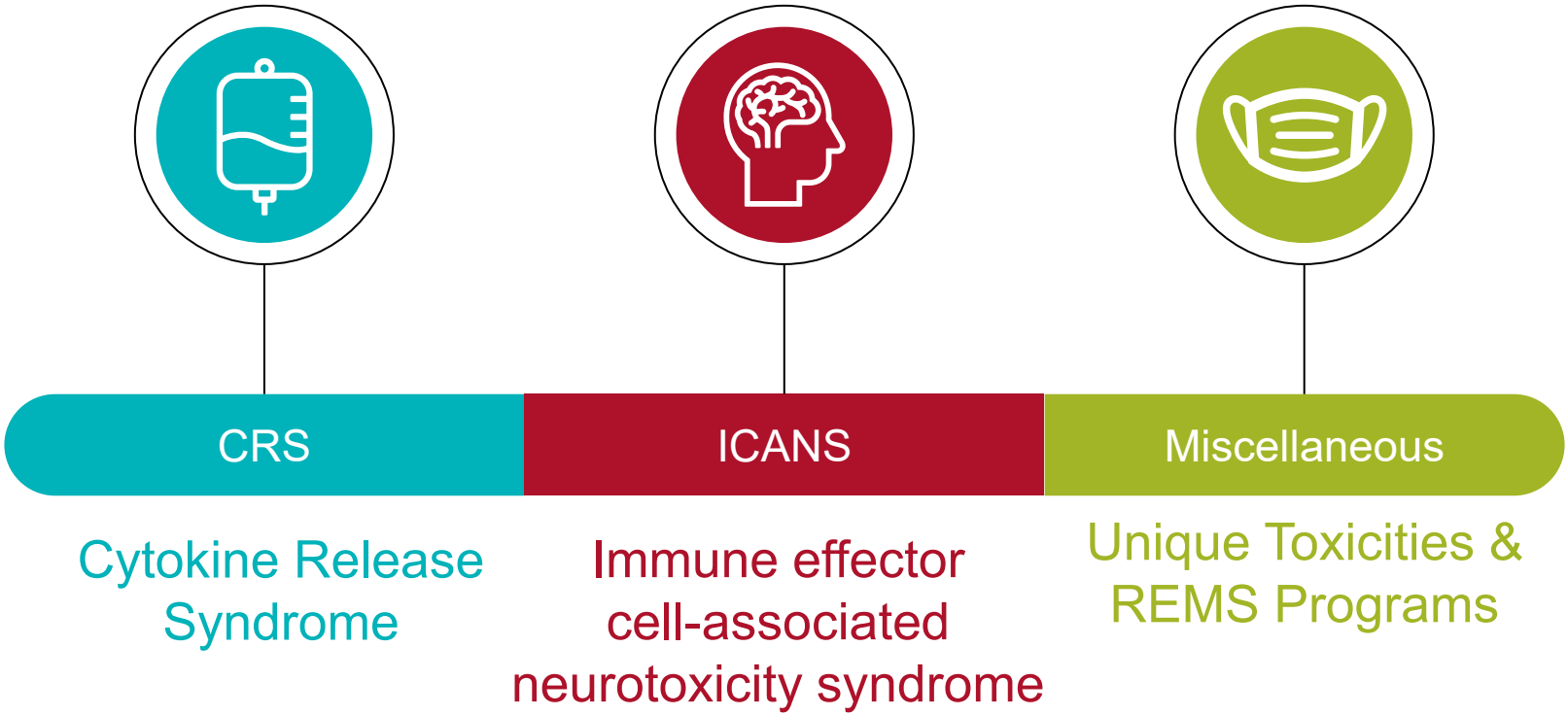
Elrexfio. Prescribing Information. Pfizer Inc. Accessed January 16, 2025.

BsAbs in Lymphoma and Myeloma

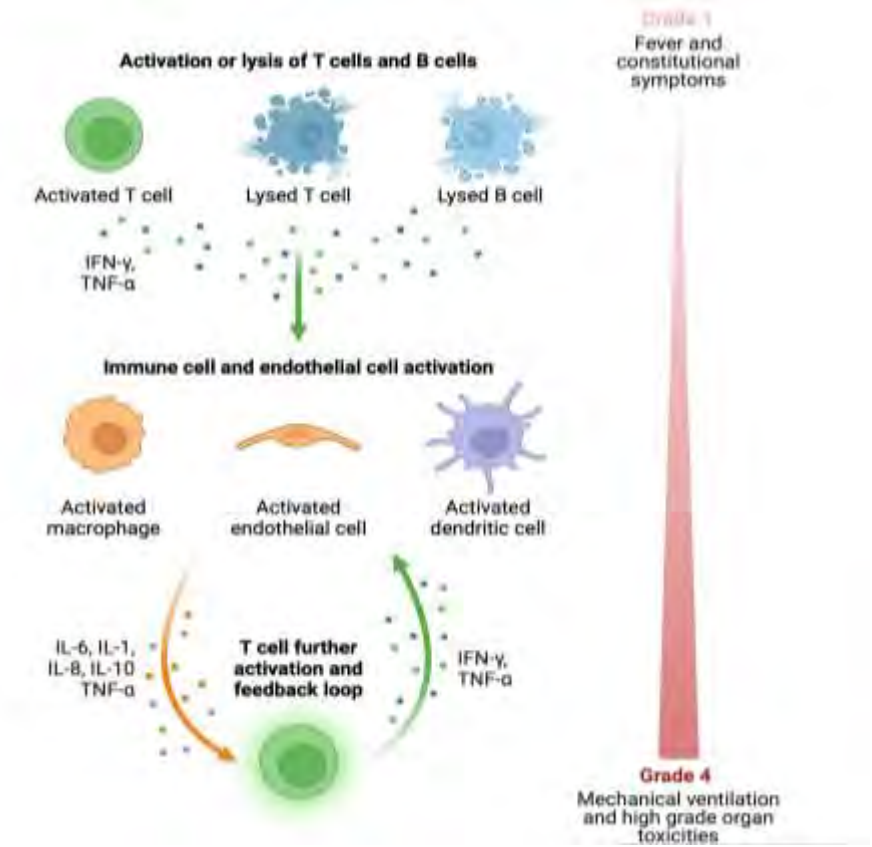
- **TECLISTAMAB**
  Multiple Myeloma
- **TALQUETAMAB**
  Multiple Myeloma
- **ELRANATAMAB**
  Multiple Myeloma

- **MOSUNETUZUMAB**
  Follicular Lymphoma
- **GLOFITAMAB**
  DLBCL
- **EPCORITAMAB**
  Follicular Lymphoma, DLBCL

BsAbs Toxicity Profile



Cytokine Release Syndrome



Key Symptoms

- Fever
- Hypotension
- Hypoxia

Other Symptoms

- Tachycardia, arrhythmias
- Myalgia, arthralgia, fatigue
- Headache, confusion, delirium
- Nausea, vomiting
- Many more

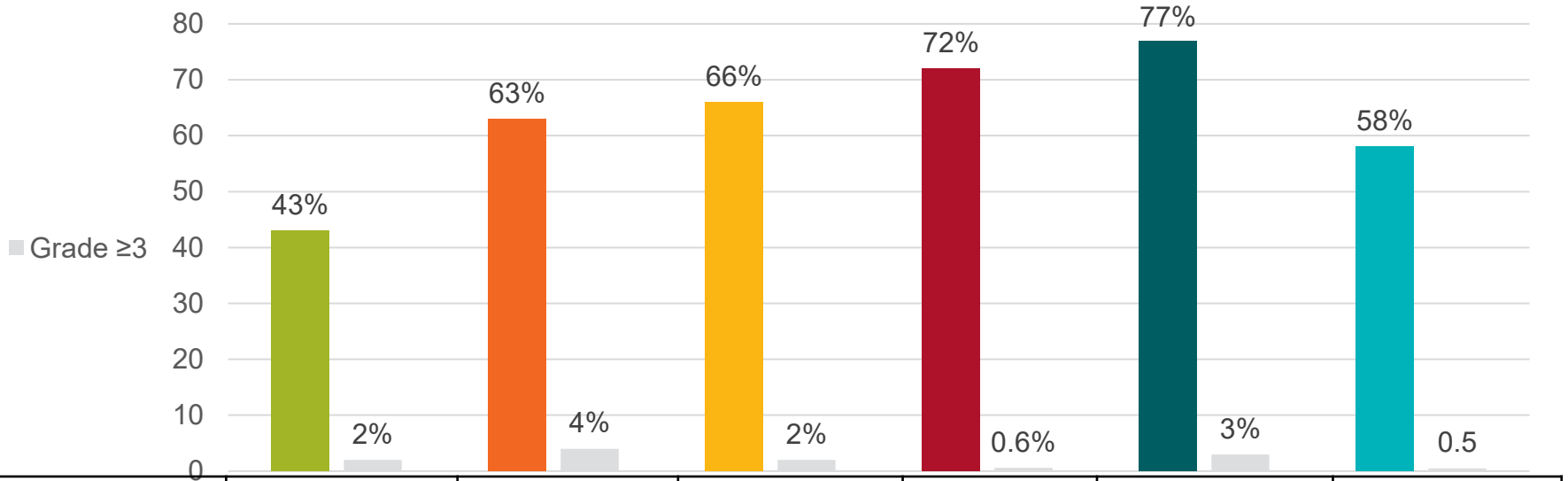
Shimabukuro-Vornhagen A et al. *J Immunother Cancer.* 2018;6(1):56.
Morris EC et al. *Nat Rev Immunol*. 2022;22(2):85-96.
. Image created with BioRender.

ASTCT Consensus on CRS Grading

Parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever	T ≥ 38º C	T ≥ 38º C	T ≥ 38º C	T ≥ 38º C
with				
Hypotension	None	Not requiring vasopressors	Requiring a vasopressor ± vasopressin	Requiring multiple vasopressors
and/or				
Hypoxia	None	Requiring low-flow nasal cannula or blow-by	Requiring high-flow nasal cannula, face mask, nonrebreather, or Venturi mask	Requiring positive pressure (e.g., CPAP, BiPAP, mechanical ventilation)

Lee DW et al. *Biol Blood Marrow Transplant*. 2019;25(4):625-638.

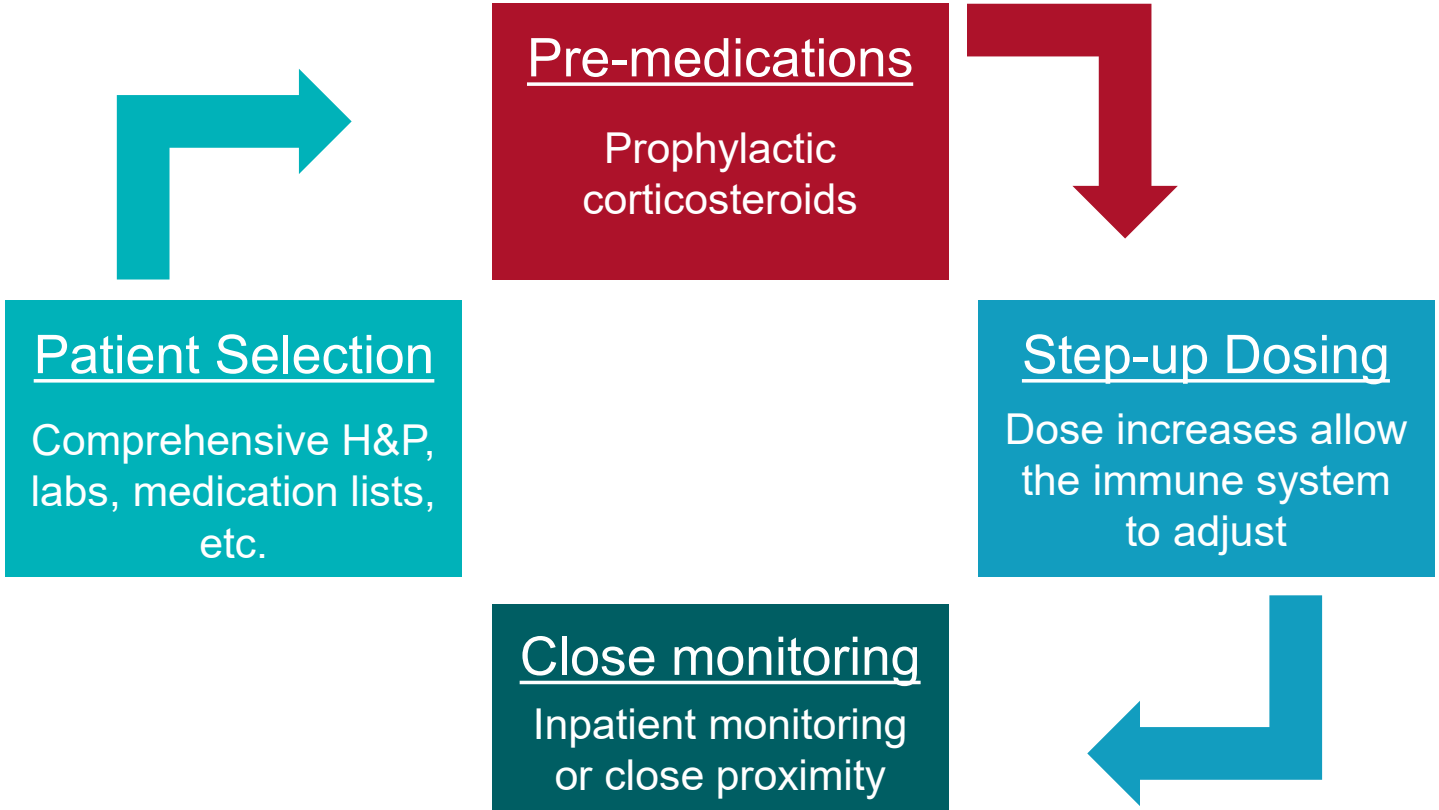
CRS Rates



	Mosunetuzumab	Glofitamab	Epcoritamab	Teclistamab	Talquetamab	Elranatamab
Trial	GO29781	NP30179	EPCORE NHL1	MajesTEC-1	MonumenTAL-1	MagnetisMM-3
Any Grade	43	63	66	72	77	58
Grade ≥3	2	4	2	0.6	3	0.5
Median Onset, h	5-27	13.5	20	48	27	48

Budde LE et al. *Lancet Oncol*. 2022;23(8):1055-1065. Chari A et al. *N Engl J Med.* 2022;387(24):2232-2244. Dickinson MJ et al. *N Engl J Med.* 2022;387(24):2220-2231. Lesokhin AM et al. *Nat Med.* 2023;29(9):2259-2267. Linton KM et al. *Lancet Haematol*. 2024;11(8):e593-e605. Moreau P et al. *N Engl J Med.* 2022; 387(6):495-505. .

Prevention



Crombie JL, et al. *Blood*. 2024;143(16):1565-1575.
Falchi L et al. *Blood*. 2023;142(supp 1):3130.

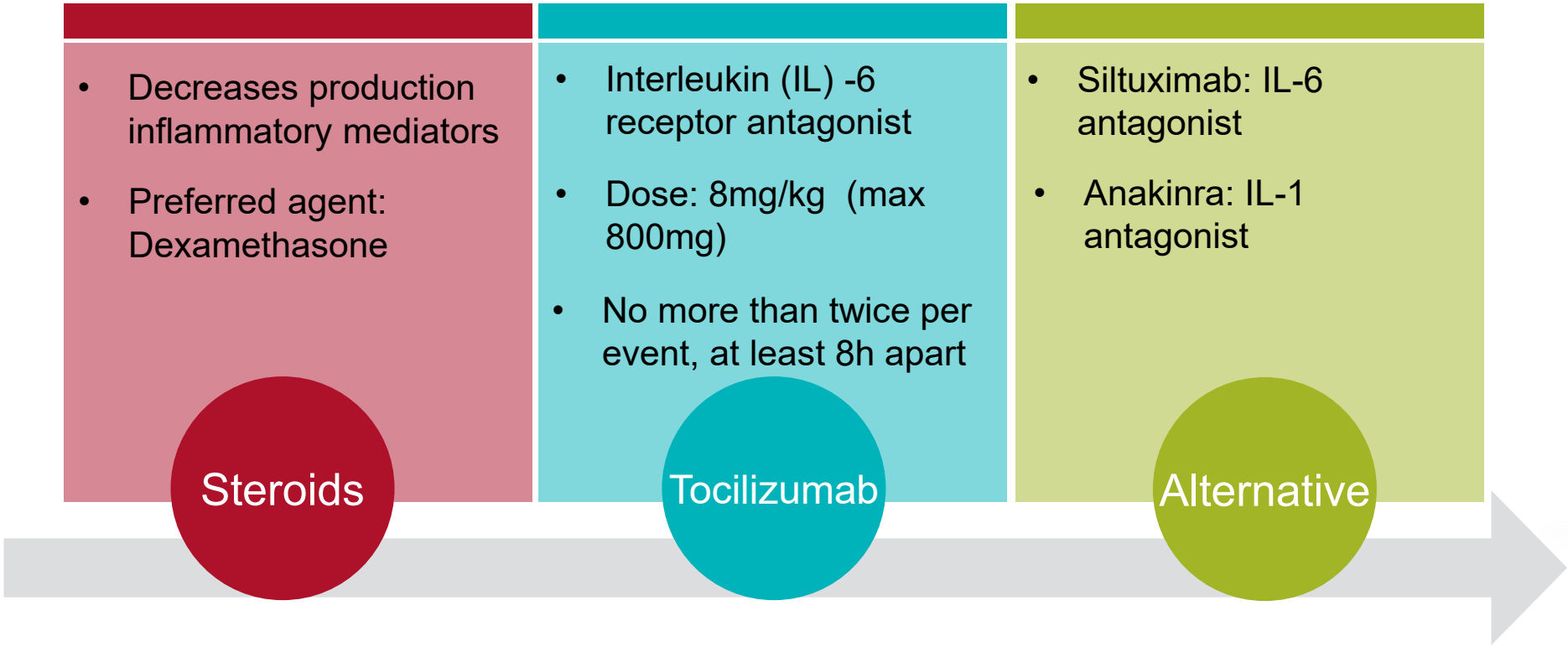
CRS Management

CRS Grade	Management
1 **OP or IP**	• APAP 650-1000mg (can repeat if recurrent fever ≥6-8h later) • Oral hydration • Consider dexamethasone 10mg x1 if refractory/recurrent fever (<6-8h) • Consider tocilizumab if protracted fever (>48h despite steroids)
2 **IP**	• APAP 650-1000mg every 6-8h as needed • IV fluids and supplemental oxygen as needed • Dexamethasone 10mg every 12 hours • Consider tocilizumab if persistent symptoms (despite IV fluids and steroids)
3 **IP or ICU**	• APAP 1000mg every 6-8h when safe • Dexamethasone 10mg IV every 6 hours until ≤ Grade 1, then taper • Tocilizumab, consider alternatives (anakinra, siltuximab) if persistent symptoms • Evaluate for sepsis and consider antibiotics
4 **ICU**	• APAP 1000mg every 6-8h when safe • Dexamethasone 20mg IV every 6 hours until ≤ Grade 1, then taper • Tocilizumab, consider alternatives (anakinra, siltuximab) if persistent symptoms

APAP = acetaminophen; ICU = intensive care unit; IP = inpatient; OP = outpatient

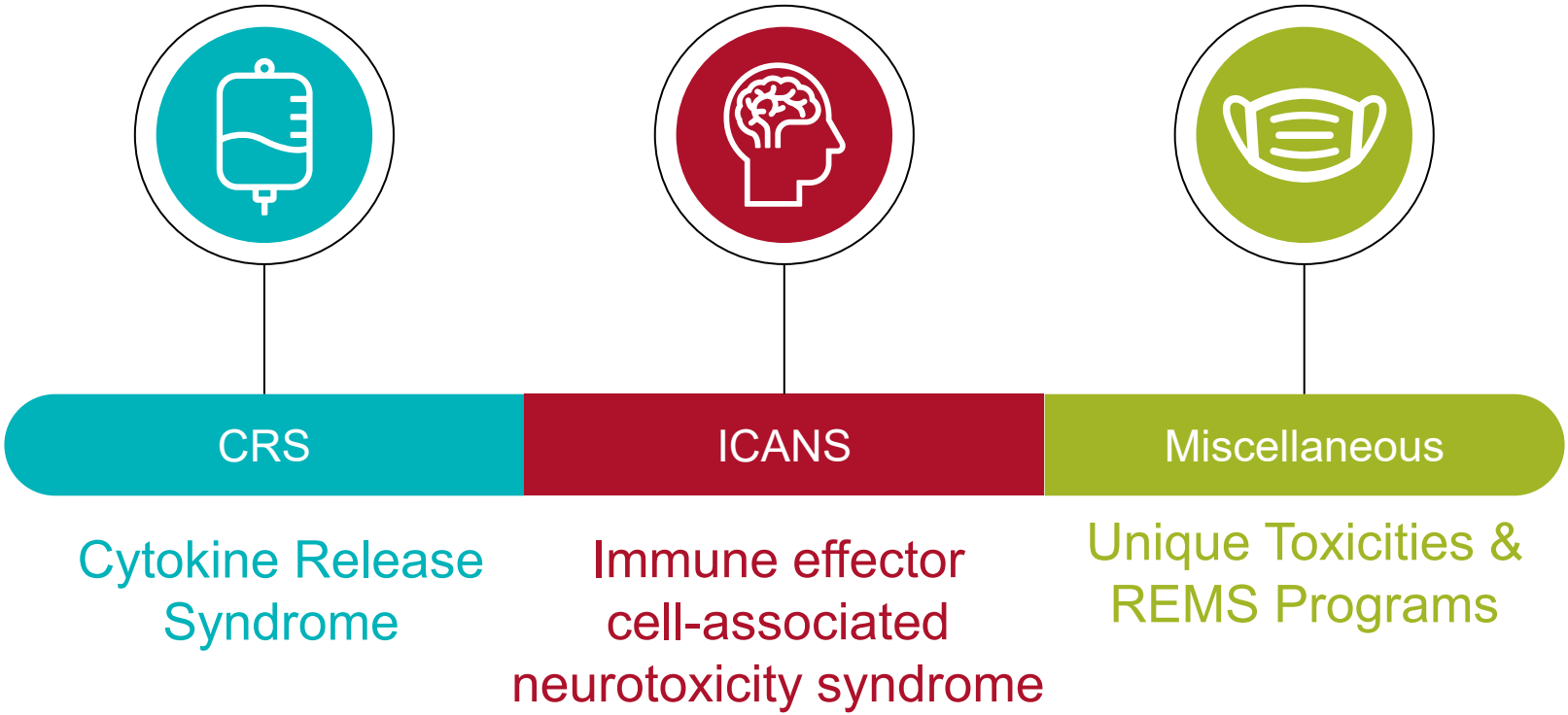
Crombie JL, et al. *Blood*. 2024;143(16):1565-1575.

Medications for CRS Management

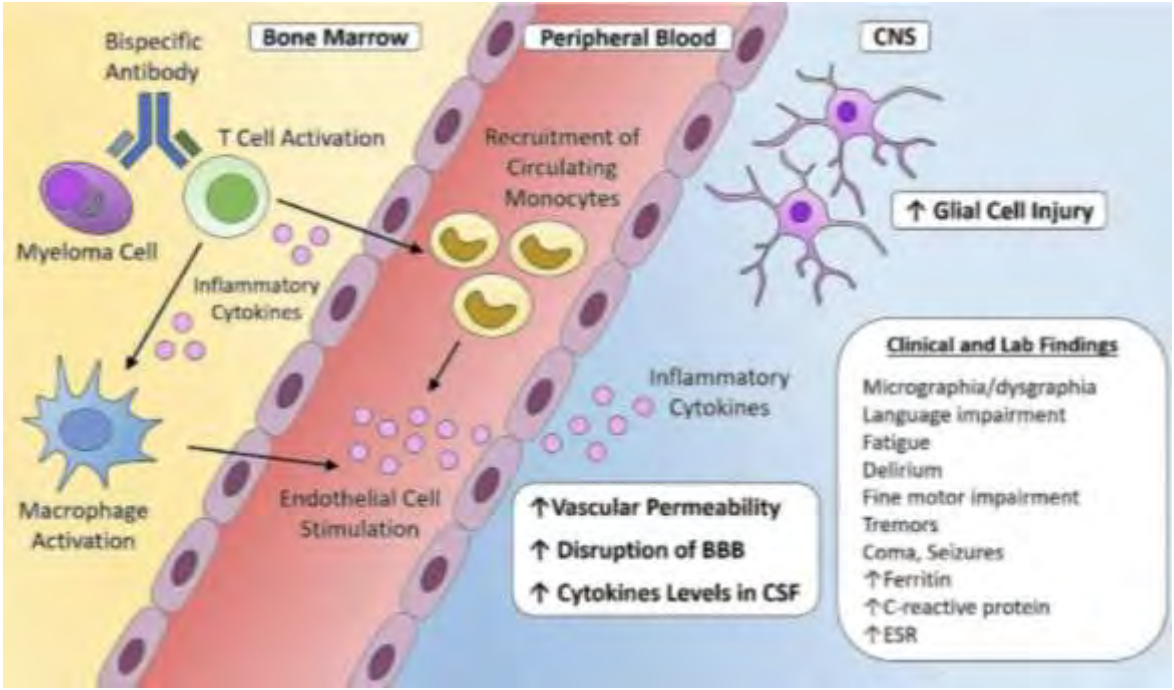


Crombie JL, et al. *Blood*. 2024;143(16):1565-1575.

BsAbs Toxicity Profile



ICANS



Orientation (4 points)

- Oriented to year, month, city, and hospital

Naming (3 points)

- Ability to name 3 objects

Follows Commands (1 point)

- Follows simple commands

Writing (1 point)

- Writes a standard sentence

Attention (1 point)

- Can count backwards from 100 by 10

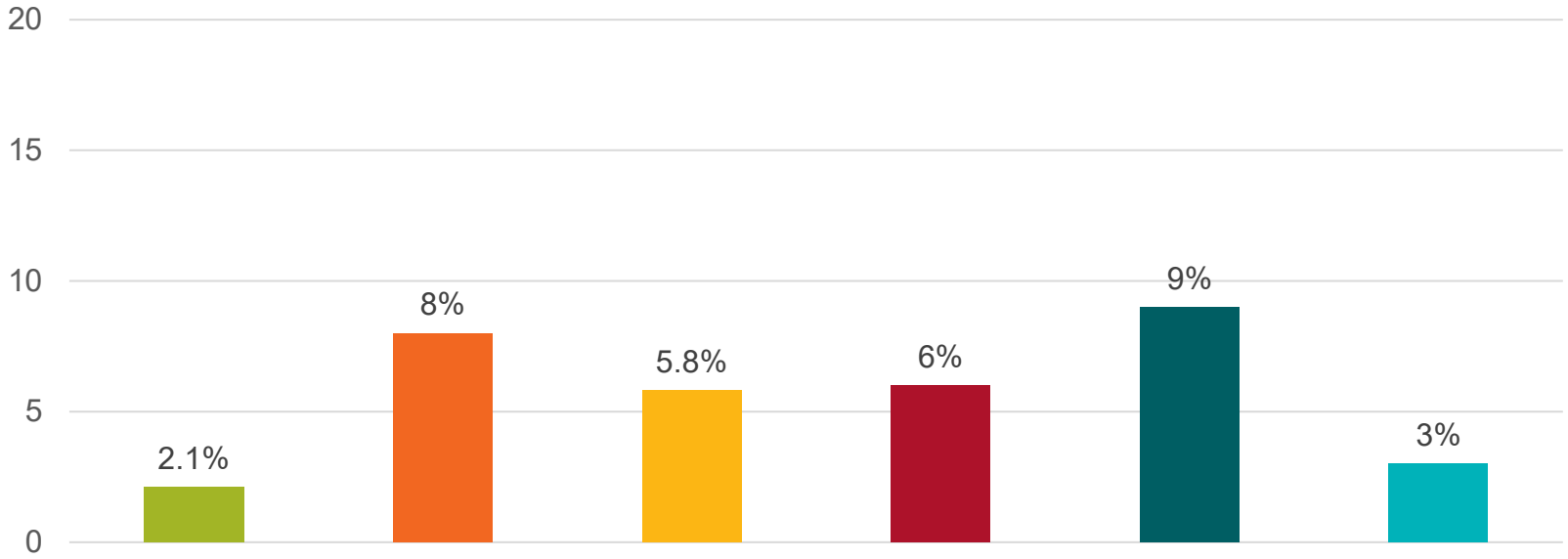
Lee DW et al. *Biol Blood Marrow Transplant*. 2019;25(4):625-638.
Pan D, Richter J. *Curr Hematol Malig Rep*. 2024;19(6):237-245.

ASTCT Consensus on ICANS Grading

Parameter	Grade 1	Grade 2	Grade 3	Grade 4
ICE Score	7-9	3-6	0-2	Unarousable & unable to perform
Depressed levels of consciousness	Awakens spontaneously	Awakens to voice	Awakens only to tactile stimulus	Unarousable or requires vigorous or repetitive tactile stimuli to arouse; stupor or coma
Seizure	N/a	N/a	Any clinical seizure focal or generalized that resolves rapidly or nonconvulsive seizures on EEG that resolve with intervention	Life-threatening prolonged seizure (>5 min); or repetitive clinical or electrical seizures without return to baseline in between
Motor findings	N/a	N/a	N/a	Deep focal motor weakness, such as hemiparesis or paraparesis
Elevated ICP / Cerebral edema	N/a	N/a	Focal/local edema on neuroimaging	Decerebrate or decorticate posturing, cranial nerve VI palsy, papilledema, Cushing's triad or signs of diffuse cerebral edema on neuroimaging

Lee DW et al. *Biol Blood Marrow Transplant*. 2019;25(4):625-638.

ICANS Rates



	Mosunetuzumab	Glofitamab	Epcoritamab	Teclistamab	Talquetamab	Elranatamab
Trial	GO29781	NP30179	EPCORE NHL1	MajesTEC-1	MonumenTAL-1	MagnetisMM-3
ICANS	2.1%	8%	5.8%	6%	9%	3.3%

Budde LE et al. *Lancet Oncol*. 2022;23(8):1055-1065. Chari A et al. *N Engl J Med.* 2022;387(24):2232-2244. Dickinson MJ et al. *N Engl J Med.* 2022;387(24):2220-2231. Lesokhin AM et al. *Nat Med.* 2023;29(9):2259-2267. Linton KM et al. *Lancet Haematol*. 2024;11(8):e593-e605. Moreau P et al. *N Engl J Med*. 2022; 387(6):495-505. .

ICANS Management

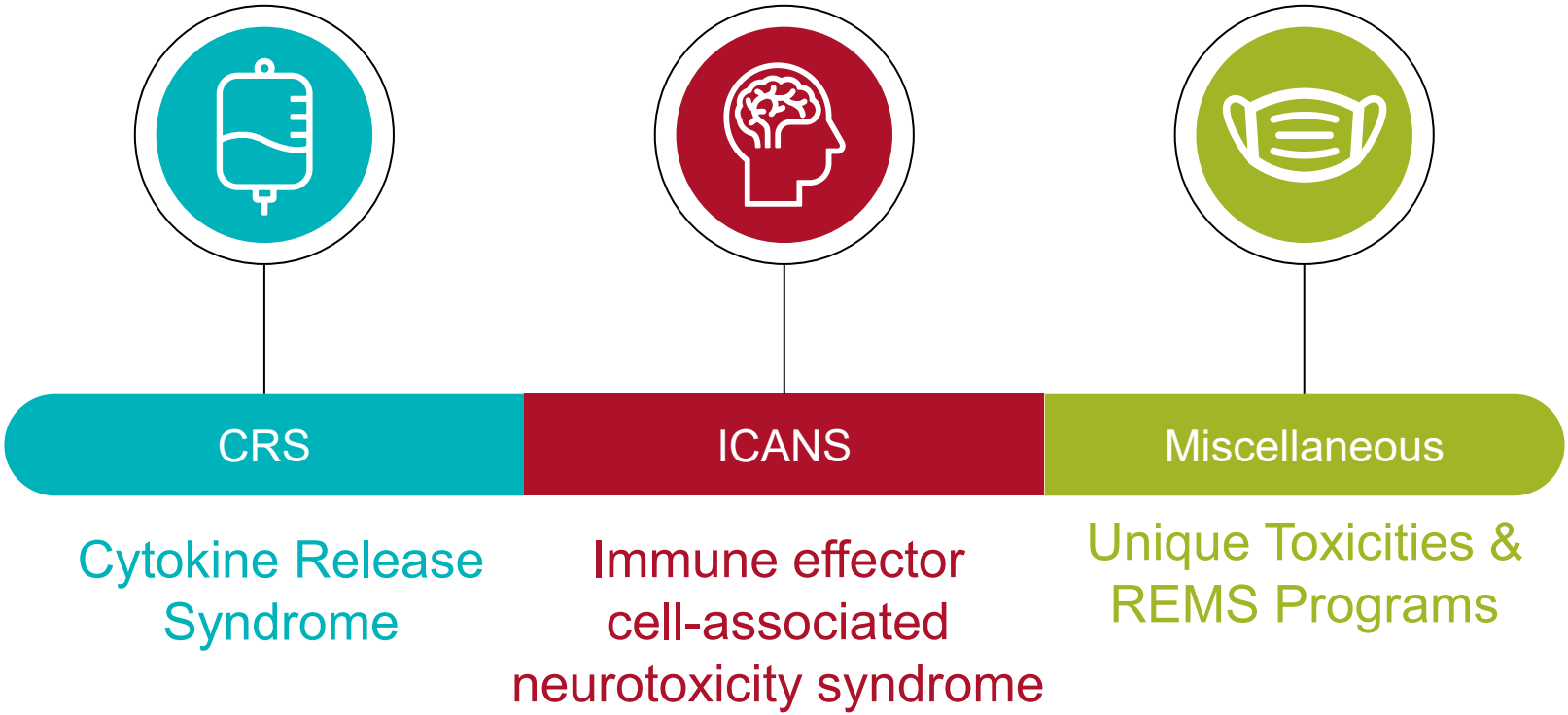
CRS Grade	Management
1 **OP or IP**	• Consider Dexamethasone 10mg x1 • Pending clinical scenario/social situation can consider observation or close monitoring in outpatient setting
2 **IP**	• Dexamethasone 10mg every 12h, then taper once ≤ Grade 1
3 or 4 **ICU**	• Dexamethasone 10mg IV every 6h, then taper once ≤ Grade 1 • Use antiepileptics for seizure management as needed • Consider anakinra 1000mg every 12h if persistent symptoms beyond 24h • Neurology consults

REMS Program

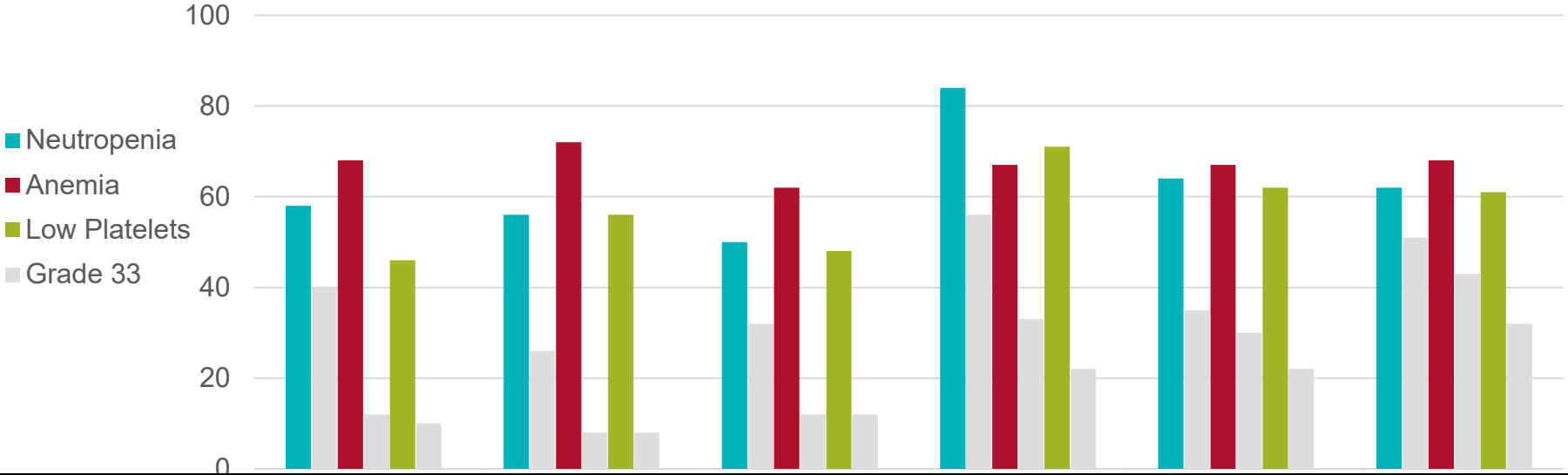
Talquetamab, Teclistamab, and Elranatamab

- Prescribers must be certified with the program and complete education
- Patients must be counseled about CRS and neurotoxicity risk, including ICANS. If applicable, provide wallet card.
- Dispensers must be certified and verify prescribers and certified

BsAbs Toxicity Profile



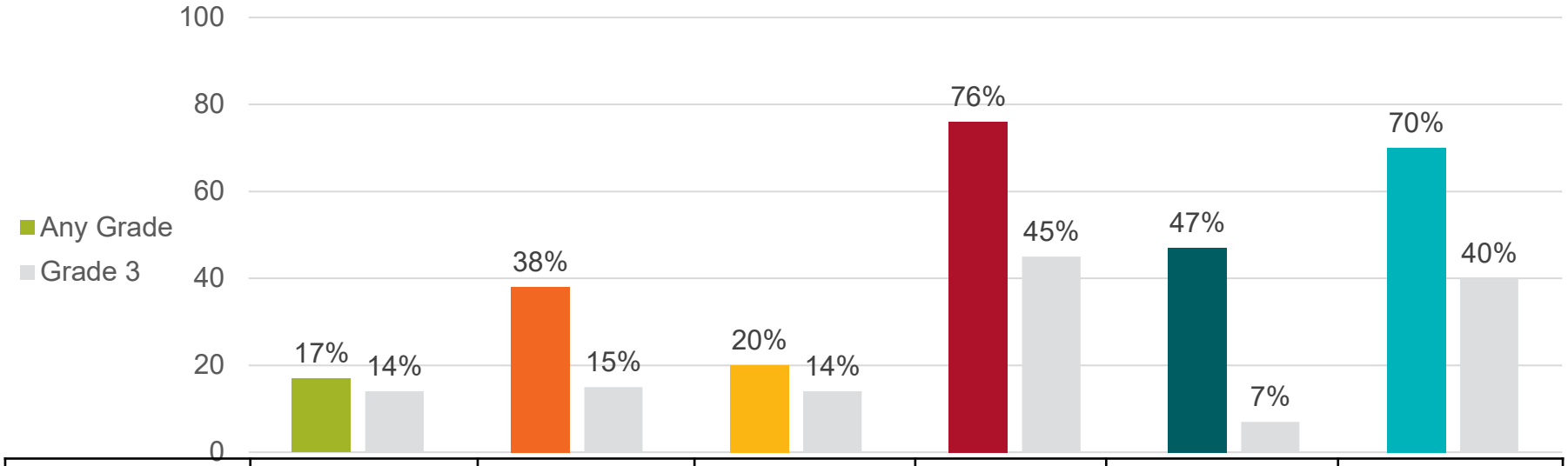
Cytopenias



	Mosunetuzumab	Glofitamab	Epcoritamab	Teclistamab	Talquetamab	Elranatamab
Trial	GO29781	NP30179	EPCORE NHL1	MajesTEC-1	MonumenTAL-1	MagnetisMM-3
Neutropenia (G3)	58% (40%)	56% (26%)	50% (32%)	84% (56%)	64% (35%)	62% (51%)
Anemia (G3)	68% (12%)	72% (8%)	62% (12%)	67% (33%)	67% (30%)	68% (43%)
Low Platelets (G3)	46% (10%)	56% (8%)	48% (12%)	71% (22%)	62% (22%)	61% (32%)

Budde LE et al. *Lancet Oncol*. 2022;23(8):1055-1065. Chari A et al. *N Engl J Med.* 2022;387(24):2232-2244. Dickinson MJ et al. *N Engl J Med.* 2022;387(24):2220-2231. Lesokhin AM et al. *Nat Med.* 2023;29(9):2259-2267. Linton KM et al. *Lancet Haematol*. 2024;11(8):e593-e605. Moreau P et al. *N Engl J Med*. 2022; 387(6):495-505. .

Infections



	Mosunetuzumab	Glofitamab	Epcoritamab	Teclistamab	Talquetamab (Weekly)	Elranatamab
Trial	GO29781	NP30179	EPCORE NHL1	MajesTEC-1	MonumenTAL-1	MagnetisMM-3
Any Grade	17%	38%	20%	76%	47%	69.9%
Grade ≥3	14%	15%	14%	45%	7%	39.8%

Budde LE et al. *Lancet Oncol*. 2022;23(8):1055-1065. Chari A et al. *N Engl J Med.* 2022;387(24):2232-2244. Dickinson MJ et al. *N Engl J Med.* 2022;387(24):2220-2231. Lesokhin AM et al. *Nat Med.* 2023;29(9):2259-2267. Linton KM et al. *Lancet Haematol*. 2024;11(8):e593-e605. Moreau P et al. *N Engl J Med.* 2022; 387(6):495-505. .

Unique Toxicities with GPRC5D

62%

Skin

Rash, erythema, maculo-papular rash, erythematous rash

50%

Nails

Changes in nail colors, texture, or growth

80%

Gastrointestinal

Altered taste, dry mouth, dysphagia

Chari A et al. *N Engl J Med.* 2022;387(24):2232-2244.
Talvey. Prescribing Information. Janssen Biotech, Inc. Accessed January 16, 2025.

Managing GPRC5D Toxicities

Figure 1: Management strategies for symptoms (oral, skin, and nail) from the expert panel

Oral symptoms:

Dysgeusia

- Prophylactic use of dexamethasone and nystatin mouth rinses 3×/day, starting at SUD and before symptom onset
- Prophylactic use of zinc and vitamin B complex to delay oral toxicities
- Ice pack/wrap around cheeks 3×/day to reduce circulation
- Altering diet to address taste alterations and nutrition consultation if weight loss occurs

Dry mouth

- Biotène, saliva alternatives, lozenges, sour citrus, sour candy, and sugar-free candy or gum

Other considerations

- Decreasing dose frequency from Q2W to Q4W[a] (dose reduction was not found to help)

Skin symptoms:

- Moisturizers and antihistamines for dryness and itchiness, respectively
- Creams, including topical steroids, ammonium lactate cream (AmLactin), and urea-based creams (2×/day) for hands and feet
- Moisturizer brands such as CeraVe, Vanicream, Eucerin, and Cetaphil
- Avoiding contact with alcohols (ie, perfumes/fragrances) that dry out skin
- A thick emollient used on the full body at least once a day, as well as topical steroids
- Avoiding hot showers and applying emollients after drying off from cool showers

Nail symptoms:

- Vitamin E cuticle oil and ammonium lactate (AmLactin) around the nails/cuticles
- Good emollients and low-dose topical steroids for peeling around the nails
- Urea-based treatments on hands and feet (2×/day)
- Wearing cotton gloves with Aquaphor in them overnight to prevent nails falling off
- Wearing soft socks and avoiding trauma to the nails
- Keeping good nail hygiene, including keeping nails short

SUD, step-up dosing; Q2W, once every 2 weeks (biweekly); Q4W, once every 4 weeks.
[a]Q4W dosing at 0.8 mg/kg for all but 1 center, which used 0.4 mg/kg.

Schinke C et al. *Curr Med Res Opin*. 2024;40(10):1705-1711.

Managing Toxicities

Cytopenias	Follow dose adjustments in prescribing information Growth factors were utilized in trials
Infections	Antimicrobial prophylaxis (PJP and HSV) Consider fungal prophylaxis if high dose steroids are utilized
GPRC5D	Consider topical or systemic treatments for symptom management, closely monitor weight, nutrition consults, dose modifications, etc.
CRS	Appropriate pre-medications, follow dosing schedule, treatment per recommendations with dexamethasone ± tocilizumab
ICANS	Appropriate monitoring, treatment per recommendations with dexamethasone

Columvi. Prescribing Information. Genentech, Inc. Accessed January 16, 2025. Elrexfio. Prescribing Information. Pfizer Inc. Accessed January 16, 2025.Epkinly. Prescribing Information. AbbVie Inc. Accessed January 16, 2025. Lunsumio. Prescribing Information. Genentech, Inc. Accessed January 16, 2025. Talvey. Prescribing Information. Janssen Biotech, Inc. Accessed January 16, 2025. Tecvayli. Prescribing Information. Janssen Biotech, Inc. Accessed January 16, 2025

Benefits of Ambulatory Administration

- Less burden on patient's time
- Decreased strain on inpatient beds
- Improved access to community settings
- Patients who never experience CRS
- Improved reimbursement

Olivieri DJ, Banerjee R. *JCO Oncol Pract*. 2024:OP2400921. Epub ahead of print.
Sandahl TB et al. JCO Oncol Pract. 2024 Dec 20:OP2400489. Epub ahead of print.
Mahmoudjafari Z et al. *J Adv Pract Oncol*. 2024:1-16. Epub ahead of print.

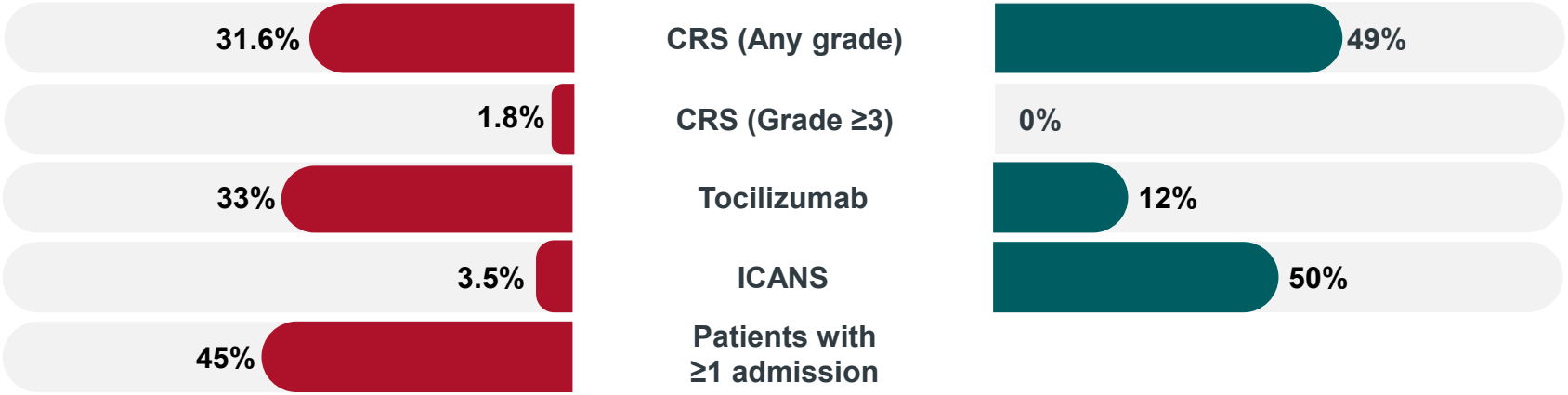
Is ambulatory administration possible?

Outpatient Mayo Clinic: Sandahl, et al

- Admin of Teclistamab step-up dosing across 3 outpatient clinics
- Stay within 30 min of facility with 24h caregiver support

EPCORE NHL-1: FL C1 OPT cohort

- Admin of Epcoritamab in 3 step up doses (did not mandate hospitalization)
- Dexamethasone prophylaxis, hydration, selectively withholding antihypertensives



Sandahl TB et al. JCO Oncol Pract. 2024 Dec 20:OP2400489. Epub ahead of print.
Vose J et al. *JCO*. 2024; 42(supp 16):7015.

	Mosunetuzumab	Glofitamab	Epcoritamab	Teclistamab	Talquetamab	Elranatamab
Target	CD3xCD20	CD3xCD20 (1:2)	CD3xCD20	CD3xBCMA	CD3xGPRC5D	CD3xBCMA
Indication	R/R FL	R/R DLBCL	R/R DLBCL or FL	R/R MM	R/R MM	R/R MM
Route	IV	IV	SubQ	SubQ	SubQ	SubQ
Hospital	No	C1D8: 24h	C1D15: 24h (DLBCL only)	48h after all step-up doses	48h after all step-up doses	48h after dose 1, 24h after dose 2
Pre-meds	• APAP: C1-2 • H1RA: C1-2 • Steroid: C1-2	• APAP: all doses • H1RA: all doses • Steroid: C1D8 & 15, C2D1, C3D1	• APAP: C1 • H1RA: C1 • Steroid: C1 (cont. 3 days)	• APAP: C1 • H1RA: C1 • Steroid: C1	• APAP: C1 • H1RA: C1 • Steroid: C1	• APAP: C1 • H1RA: C1 • Steroid: C1
Step-up dosing	• C1D1: 1mg • C1D8: 2mg • C1D15: 60mg • C2: 60mg • C3+: 30mg	• C1D1: Obin • C1D8: 2.5mg • C1D15: 10mg • C2+: 30mg	DLBCL: • C1D1: 0.16mg • C1D8: 0.8mg • C1D15: 48mg • C1D22: 48mg • C2+: 48mg FL: • C1D1: 0.16mg • C1D8: 0.8mg • C1D15: 3mg • C1D22: 48mg • C2+: 48mg	• C1D1: 0.06mg/kg • C1D4: 0.3mg/kg • C1D7: 1.5mg/kg • C2+: 1.5mg/kg	Weekly: • C1D1: 0.01mg/kg • C1D4: 0.06mg/kg • C1D7: 0.4mg/kg • C2+: 0.4mg/kg Biweekly: • C1D1: 0.01mg/kg • C1D4: 0.06mg/kg • C1D7: 0.4mg/kg • C1D10: 0.8mg/kg • C2+: 0.8mg/kg	• C1D1: 12mg • C1D4: 32mg • C1D8: 76mg • C2D1: 76mg
Cycle Length	21 days	21 days	28 days	7 days CR ≥6 mo: 14 days	7 or 14 days	Week ≤24: 7 days Week ≥25: 14 days
Duration	CR: 8 cycles PR/SD: 17 cycles	12 cycles	Until progression	Until progression	Until progression	Until progression

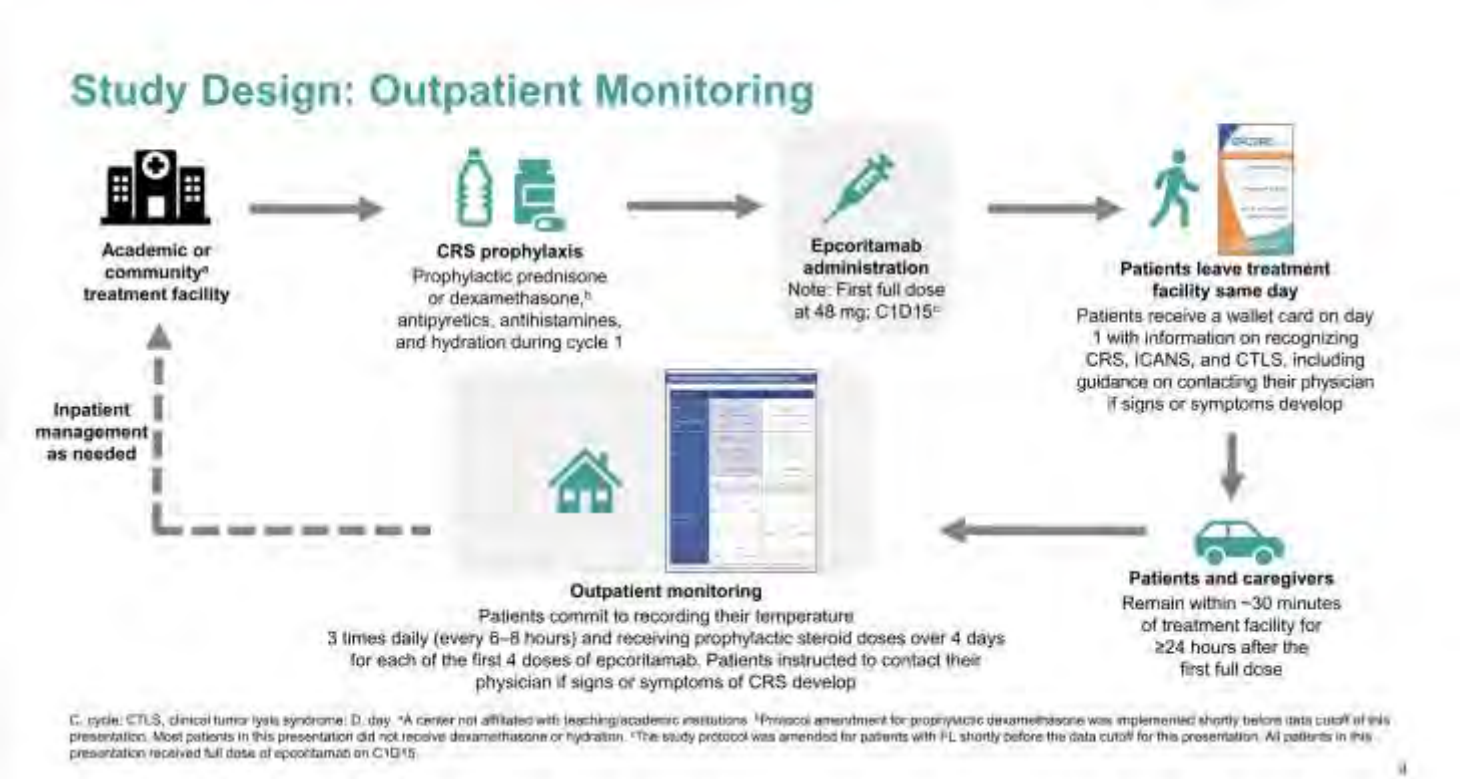
	Mosunetuzumab	Glofitamab	Epcoritamab	Teclistamab	Talquetamab	Elranatamab
CRS Rates	G1: 26% G2: 17% G3: 1% G4: 1%	G1: 47% G2: 12% G3: 3% G4: 1%	G1: 40% G2: 25% G3: 2% G4: 0%	G1: 50% G2: 21% G3: 0.6% G4: 0	G1: 57% G2: 17% G3: 3% G4: 0%	G1: 44% G2: 14% G3: 0.5% G4: 0%
Median Onset (Range)	D1: 5 hours D8: 20 hours D15: 27 hours	13.5 hours	LBCL: 24 hours FL: 59 hours	48 hours	27 hours (0.1 – 167)	2 days (1 – 9)
Med. Duration (Range)	3 days (1 – 29)	30 hours (0.5 – 317)	2 days (1 – 27)	2 days	17 hours (0 – 622)	2 days (1 – 19)
ICANS Rates	G1-2: 2.1% G3-4: 0%	G1-2: 5% G3-4: 3%	G1-2: 6% G3-4: 0%	G1-2: 6% G3-4: 0%	Any Grade: 9%	G1-2: 3.3% G3-4: 0%
Infections	Any Grade: 17% Grade ≥3: 14% Fatal: 0.9%	Any Grade: 35% Grade ≥3: 10% Fatal: 4.8%	Any Grade: • LBCL: 15% • FL: 40% Fatal: • DLBCL: 1.3% • FL: 6%	Any Grade: 30% Grade ≥3: 35% Fatal: 4.2%	Any Grade: • Weekly: 47% • Biweekly: 34% Grade ≥3: 7%	Any Grade: 70% Grade ≥3: 40% Fatal: 6.5%
Grade ≥3 Cytopenia	Lymphopenia (98%), Neutropenia (40%)	Lymphopenia (83%), Neutropenia (26%)	Lymphopenia (77%), Neutropenia (32%)	Neutropenia (64%), Anemia (37%), Lymphopenia (33%)	Lymphopenia (80%), Leukopenia (35%) Neutropenia (35%), Anemia (30%)	Lymphopenia (84%), Neutropenia (51%), Anemia (43%), Leukopenia (40%), Thrombocytopenia (32%)
REMS	No	No	No	Yes	Yes	Yes
Trial	GO29781	NP30179	EPCORE NHL-1	MajesTEC-1	MonumenTAL-1	MagnetisMM-3

Bispecific Antibodies

Ashley Bogus, PharmD, BCOP
Clinical Pharmacy Specialist, Oncology
Nebraska Medicine

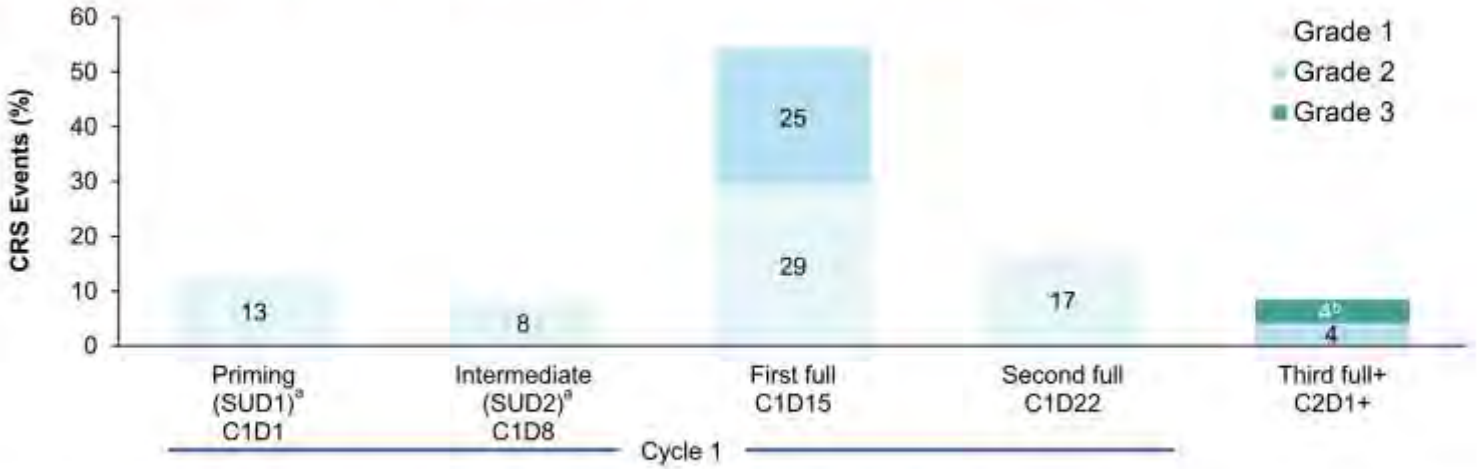
University of Nebraska Medical Center

EPCORE NHL-6


Study Design: Outpatient Monitoring
Academic or community[a] treatment facility
CRS prophylaxis
Prophylactic prednisone or dexamethasone,[b] antipyretics, antihistamines, and hydration during cycle 1
Epcoritamab administration
Note: First full dose at 48 mg; C1D15[c]
Patients leave treatment facility same day
Patients receive a wallet card on day 1 with information on recognizing CRS, ICANS, and CTLS, including guidance on contacting their physician if signs or symptoms develop
Patients and caregivers
Remain within ~30 minutes of treatment facility for ≥24 hours after the first full dose
Outpatient monitoring
Patients commit to recording their temperature 3 times daily (every 6–8 hours) and receiving prophylactic steroid doses over 4 days for each of the first 4 doses of epcoritamab. Patients instructed to contact their physician if signs or symptoms of CRS develop
Inpatient management as needed
C, cycle; CTLS, clinical tumor lysis syndrome; D, day. [a]A center not affiliated with teaching/academic institutions. [b]Protocol amendment for prophylactic dexamethasone was implemented shortly before data cutoff of this presentation. Most patients in this presentation did not receive dexamethasone or hydration. [c]The study protocol was amended for patients with FL shortly before the data cutoff for this presentation. All patients in this presentation received full dose of epcoritamab on C1D15.

EPCORE NHL-6

CRS: Events Primarily Low Grade and All Resolved



- Predictable timing of CRS onset: most events occurred after the first full dose and were primarily confined to cycle 1
- After enrollment of 34 patients, the protocol was amended to implement prophylactic dexamethasone as the preferred steroid and hydration during cycle 1 for CRS prophylaxis