con il patrocinio di

AIL Caserta Valentina Picazio

SIE Società Italiana di Ematologia

La rivoluzione terapeutica nel **linfoma** e nel **mieloma**

Napoli, Hotel Royal Contintental • 14–15 Maggio 2026

II SESSIONE

Moderatori:

R. Della Pepa, P. Musto

Gestione outpatient del paziente candidato a bispecifici: è già una realtà?

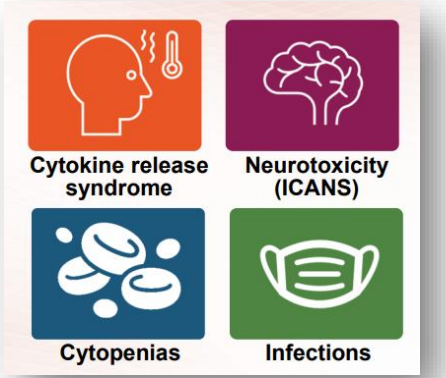
B. Rossini

Istituto Oncologico «G.Paolo II» Bari

Disclosures

Consulting and Advisory Board	Amgen, J&J, GSK, Sanofi, Menarini, Eusa Pharma, Takeda, Pfizer
Honoraria	J&J, GSK, Sanofi, Oncopeptides
Sponsorship events	Amgen, J&J, Sanofi, BMS, Menarini, Takeda

Bispecific Antibody Therapy Expected toxicities



CRS
- The main symptom is fever
- Severe cases: hypotension and hypoxia
- Treatment: tocilizumab, steroids
- Consider prophylactic strategies when CAR-T infusion or bsAb ramp-up occurs in the outpatient setting

ICANS
- Confusion, delirium, dysgraphia, word-finding difficulties
- Severe cases: seizures
- Treatment: steroids
- For severe cases, may use lymphotoxic agents such as cyclophosphamide, or consider anakinra or IT chemotherapy

NINT
- Nerve palsies, Guillain-Barré syndrome, Parkinsonism
- Mainly seen with cilta-cel
- No standard treatment
  - Consider steroids, IVIG
  - Severe cases: consider IT chemotherapy or cyclophosphamide

IEC-HS
- Hyperinflammatory syndrome
- Hyperferritinemia, hepatic dysfunction, coagulopathy, cytopenias
- Treatment: anakinra +/- steroids. For severe cases: ruxolitinib, low dose etoposide, emapalumab

Infections
- Most common cause of non-relapse mortality
- Prophylaxis is crucial:
  - VZV/HSV (acyclovir or valacyclovir)
  - PJP: 1st line TMP/SMX, alternative: atovaquone, dapsone, pentamidine
  - Anti-bacterial/fungal prophylaxis when ANC < 0.5 x 10^9/L
  - HBV: entecavir (chronic carriers)
  - Primary IVIG prophylaxis
  - Revaccinations post CAR-T[44]: DTap, HAV, HBV, VZV, RSV, Influenza, Pneumococcus, Covid-19

Cytopenias
- Most common AE with CAR-T and bsAb
- Grading per CTCAE version 5.0 or ICAHT
- Management includes:
  - G-CSF for neutropenia
  - TPO agonists for thrombocytopenia
  - Blood product transfusions
  - Stem cell boosts
  - If persistent: bone marrow biopsy to assess for therapy-related myeloid neoplasms

Skin, Nail, Mouth (GPRC5D-only) ★
- On-target/off-tumor toxicities
- Dry mouth, stomatitis, dysgeusia
- Weight loss
- Nail changes, dry skin, rashes
- Management includes:
  - Topical emollients: ammonium lactate, petroleum-based ointments
  - Topical or systemic steroids
  - Vitamin E oil or urea-based nail formulations
  - Oral antihistamines and biotin

CRS and ICANS elicited by BsAB were generally low-grade

	Teclistamab		Elranatamab	Talquetamab			Linvoseltamab	Cevostamab
Antigen target	BCMA		BCMA	GPRC5D			BCMA	FcRH5
Trial	MajesTec-1		MagnetisMM-3	MonumenTal-1			LINKER-MM1	CAMMA
Phase	I/II		I/II	I/II			I/II	I
Sample size (N)	Cohort A *N*=165	Cohort C *N*=40	123	0.4 QW *N*=143	0.8 Q2W *N*=154	Prior TCR *N*=78	200mg TDL *N*=117	160mg TDL *N*=167
Age, median (range), years	64 (33–84)	63.5 (32–82)	68 (36–89)	67 (58–72)	67 (58–74)	61 (55–68)	70 (37–91)	66 (40–90)
Median LOT (range)	5 (2–14)	6 (3–14)	5	5 (4–6)	4.5 (4–6)	6 (5–8)	5 (2–16)	6 (2–18)
High-risk cyto (%)	26	33	25	31	30	37	39	38
EMD (%)	17	30	32	23	27	32	16	28
Triple-refractory (%)	78	85	97	75	71	85	82	96
Penta-refractory (%)	30	35	42	31	25	44	28	74
Prior BCMA Rx (%)	0	100	0	15	11	96	0	57.5
ORR (≥CR), (%)	63 (46)	52.5 (30)	61 (35)	74 (33)	69 (40)	67 (41)	71 (50)	43 (13)
Median PFS (mo)	11.4	4.5	17.2	7.5	11.2	7.7	NR	NA
Median DOR (mo)	8.4	14.8	NR	9.5	17.5	NA	29.4	10.4
Median OS (mo)	22.2	15.5	24.6	NR	NR	NR	NR	NA
Any CRS (gr ≥3), (%)	72 (1)	65 (0)	56 (0)	77 (2)	74 (1)	72 (1)	46 (1)	74 (2)
Any ICANS (gr ≥3), (%)	3 (0)	10 (2.5)	3 (0)	11 (2)	10 (4)	23 (0)	8 (3)	13 (1)
Any infections (gr ≥3), (%)	76 (45)	70 (42.5)	70 (40)	59 (20)	68 (18)	76 (26)	74 (36)	54 (19)

BCMA, B-cell maturation antigen; ≥CR, complete response or better; CRS, cytokine release syndrome; Cyto, cytogenetics; DOR, duration of response; EMD, extramedullary disease; GPRC5P, G protein-coupled receptor class C group 5 member D; gr, grade; ICANS, immune effector cell-associated neurotoxicity syndrome; LOT, lines of therapy; NR, not reached; mo, months; NA, not available; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; QW, weekly; Q2W, every two weeks; Rx, treatment; TCR, T-cell redirecting therapy; TDL, target dose level.

Danai Dima et al. Hematology 2025 – ASH Educational Program

Original Reports | Quality in Cancer Care

Real-World Safety and Health Care Resource Utilization of Teclistamab Under an Outpatient Model for Step-Up Dosing Administration

Tyler B. Sandahl, PharmD[1]; Scott A. Soefje, PharmD[1]; Rafael Fonseca, MD[2]; Sikander Ailawadhi, MD[3]; Ricardo Parrondo, MD[3]; Dee Lin, PharmD[4]; Bingcao Wu, PhD[4]; Ediz S. Calay, PhD[5]; Eli Silvert, BS[5]; Nina Kim, PharmD[4]; Corinne Carpenter, PhD[5]; Tyler E. Wagner, PhD[5]; Jessica Fowler, PhD[4]; Laura Hester, PhD[6]; Nivedita Rangarajan, MS[5]; Karthik Murugadoss, BS[5]; Alexander Marshall, PharmD[7]; Patrick Stoy, PhD[4]; Dina Gifkins, PhD[6]; Yi Lin, MD, PhD[1]; and Shaji Kumar, MD[1]

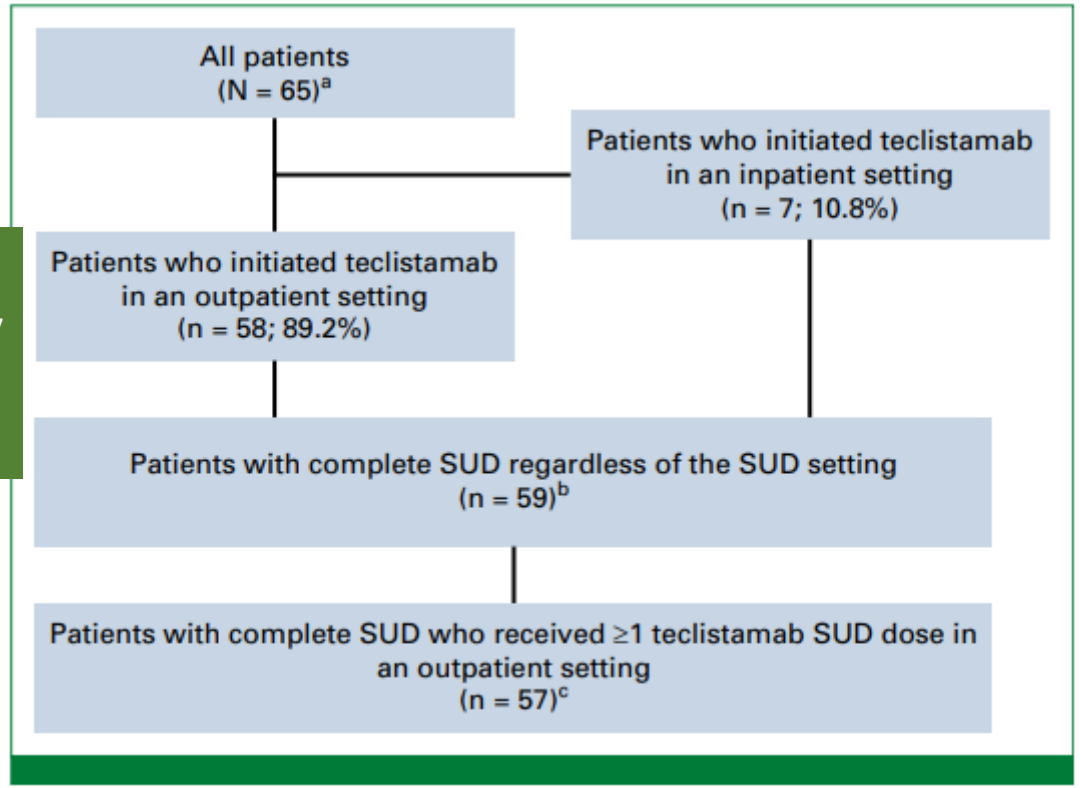
DOI https://doi.org/10.1200/OP-24-00489

Over 80% of patients treated at the Mayo Clinic received teclistamab in an outpatient setting within 12 months of the drug's initial approval (oct 2022)

Mayo Clinic has pioneered an outpatient model

Hospital-Based Outpatient (HBO) program for immunotherapies

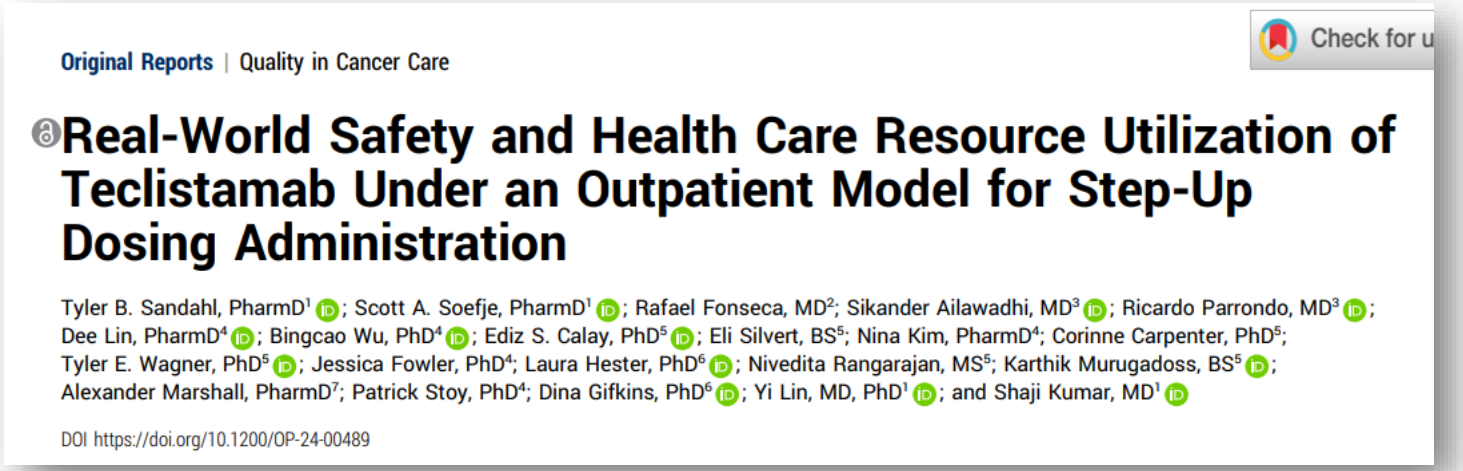
Largest published experience of fully outpatient SUD with teclistamab



To receive outpatient SUD:

- patients are required to stay within 30 minutes of the clinic
- have access to 24-hour caregiver support
- monitored for 30 minutes in the clinic
- remotely monitoring with technology package to use at home (bluetooth devices for blood pressure cuff and monitor, pulse oximeter, and thermometer

Tyler B. Sandahl et al. *JCO Oncology Practice.* Nov 2024



Original Reports | Quality in Cancer Care

Check for u

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DOI https://doi.org/10.1200/OP-24-00489

Patients treated with teclistamab in a real-world setting were older and had high disease burden compared with MajesTEC-1

All patients received premedications on the same day as teclistamab SUD administration
Although six patients received tocilizumab as supportive care during SUD, none received tocilizumab prophylactically

Previous exposure to other BCMA-targeted therapeutics did not appear to affect CRS rates
CRS rate was 31.6% lower than the MajesTEC-1 trial 72.1%
ICANS rate (3.5%) was similar to MajesTEC-1 (3%)

These differences likely reflect:
variations in how CRS events were captured and reported
CRS prophylaxis strategies between health institutions

Tyler B. Sandahl et al. *JCO Oncology Practice.* Nov 2024

Editorials

Check for updates

Impatient for Outpatient: Operationalizing Bispecific Antibodies for Multiple Myeloma in the Ambulatory Setting

Daniel J. Olivieri, MD, MPA[1] and Rahul Banerjee, MD[1,2]

DOI https://doi.org/10.1200/OP-24-00921

Why are we so impatient as a field for outpatient-based bsAb SUD algorithms?

Clinical Background

Bispecific antibodies (e.g., BCMA- or GPRC5D-targeting) show:

- High efficacy in relapsed/refractory multiple myeloma
- Deep and durable responses

Represent a major therapeutic advancement

In MajesTEC-1, 30% of patients did not experience CRS during the SUD period

Core Challenge

Current administration often **inpatient-based** due to:

- **Cytokine Release Syndrome (CRS)**
- **Neurotoxicity (ICANS)**

Requires close monitoring and rapid intervention

Daniel J. Olivieri, and Rahul Banerjee. *JCO Oncology Practice*. Nov 2024

Operational requirements for Outpatient Implementation

Treatment Optimization
- Step-up dosing strategies
- Premedication protocols
- Toxicity mitigation approaches

Patient Selection
- Risk stratification
- Assessment of comorbidities
- Availability of caregiver/support system

Monitoring & Safety
- Early toxicity recognition protocols
- Rapid access to emergency care
- Defined escalation pathways

Institutional guidelines for outpatient delivery

Education

Patient and caregiver training:
- Recognizing CRS/ICANS symptoms
- Knowing when to seek care

Infrastructure

outpatient facilities with:
- Trained staff
- Immediate intervention capability

Coordination across multidisciplinary teams

Standardization

Clinical pathways and protocols

Mayo experience shows that the **outpatient SUD** **is feasible and reduces costs, improves access, and decreases time toxicity**
It is not for everyone, someone still requires hospitalization (high disease burden, comorbidities, logistical constraints)
The direction is clear: bispecific antibodies should become outpatient therapies, supported by structured and personalized workflows

Daniel J. Olivieri, and Rahul Banerjee. *JCO Oncology Practice*. Nov 2024

ELSEVIER

Blood 144 (2024) 932–933

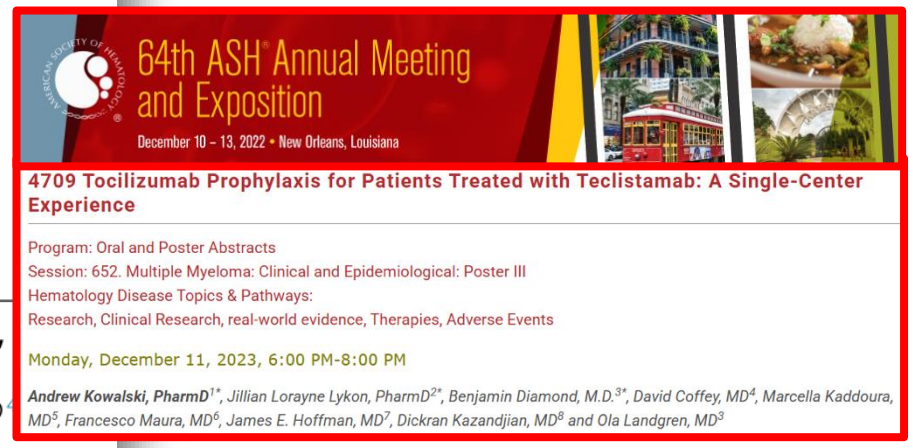
The 66th ASH Annual Meeting Abstracts

ORAL ABSTRACTS

907.OUTCOMES RESEARCH: PLASMA CELL DISORDERS

Tocilizumab Prophylaxis for Patients with Relapsed or Refractory Multiple Myeloma Treated with Teclistamab, Elranatamab or Talquetamab

Andrew Kowalski, PharmD[1], Jill Lykon, PharmD[2], Benjamin Diamond[2], David G. Coffey, MD[3], Marcella Kaddoura, MD[4], Francesco Maura, MD[5], James E. Hoffman[2], Dickran Kazandjian, MD[2], Ola Landgren[6]



🎯 **primary end point**

➢ **Tocilizumab prophylaxis** in RRMM, to reduce:

CRS

ICANS

Treated with:

➢ teclistamab

➢ elranatamab

➢ talquetamab

❖ **CRS:** 14% (almost all **grado 1**)

❖ **ICANS:** 8%

By BsAb:

❖ Teclistamab → CRS 11%, ICANS 0%

❖ Elranatamab → CRS 8%, ICANS 13%

❖ Talquetamab → CRS 20%, ICANS 19%

❖ Monocentric **real-world study** (University of Miami)

❖ october 2022 – june 2024

❖ **72 RRMM patients**

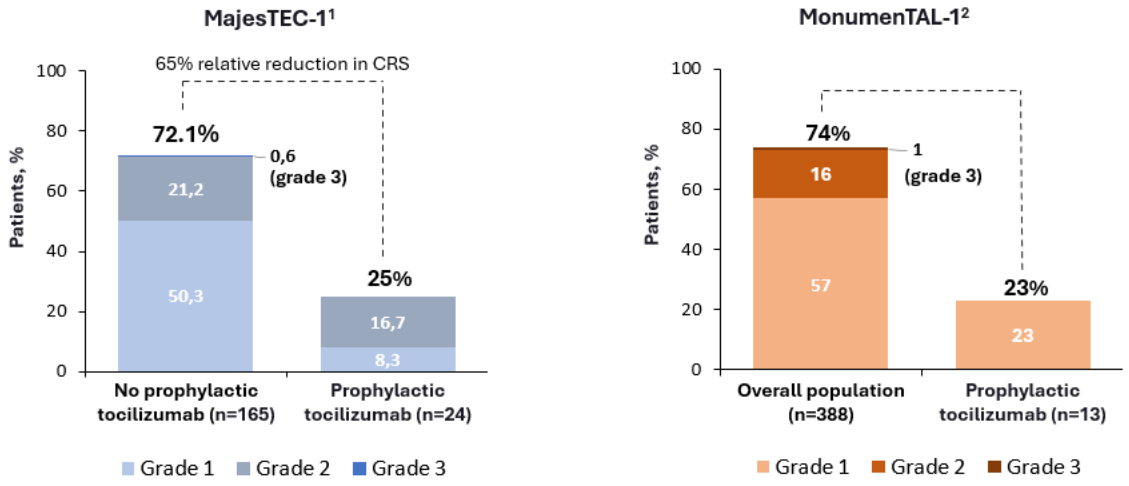
8033 **Poster Session**

Evaluation of prophylactic tocilizumab (toci) for the reduction of cytokine release syndrome (CRS) to inform the management of patients (pts) treated with teclistamab in MajesTEC-1.

Niels W.C.J. van de Donk, Alfred L. Garfall, Lotfi Benboubker, Katarina Uttervall, Kaz Groen Laura Rosiñol, Caroline Hodin, Tara Stephenson, Danielle Trancucci, Alfredo Perales-Puchalt Rachel Kobos, Arnob Banerjee, Maria-Victoria Mateos; Amsterdam University Medical Center, Vrije Universiteit Amsterdam, Amsterdam, Netherlands; Abramson Cancer Center, Perelman School o Medicine, University of Pennsylvania, Philadelphia, PA; Hopital Bretonneau, Centre Hospitalie Régional Universitaire, Tours, France; Karolinska University Hospital, Stockholm, Sweden; Amsterdan UMC, Amsterdam, Netherlands; Hospital Clínic de Barcelona, IDIBAPS, Barcelona, Spain; Janssen Research & Development BE, Antwerp, Belgium; Janssen Research & Development, Spring House, PA Janssen Research & Development, Raritan, NJ; Janssen Research & Development, Springhouse, PA; University Hospital of Salamanca, Salamanca, Spain

van de Donk et al. *J Clin Oncol* 2023

CRS incidence in patients receiving prophylactic tocilizumab



Dexamethasone may also be used to manage grade 1 (and possibly grade 2) CRS, including in the outpatient setting when combined with prophylactic tocilizumab, or where tocilizumab is not available[3]

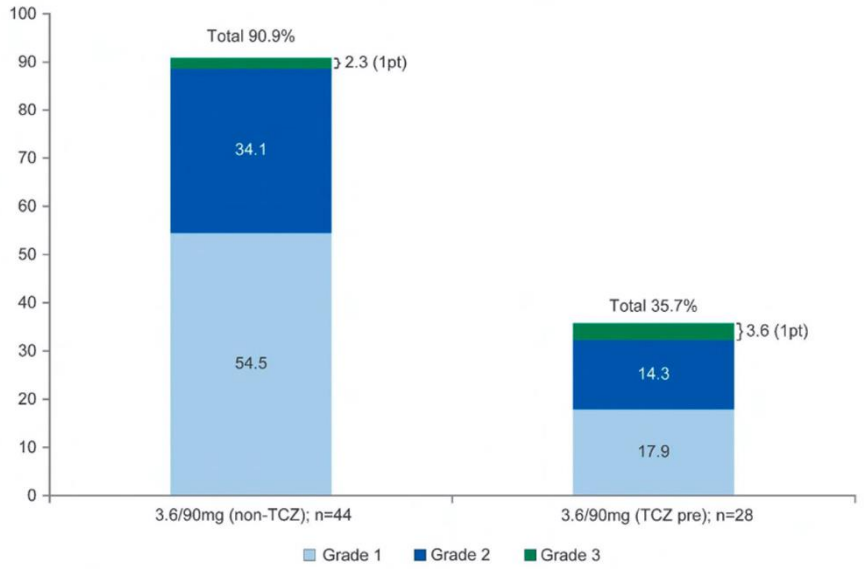
1. van de Donk N, et al. ASCO 2024 (Abstract No. 7517 – oral presentation); 2. Dytfeld D, et al. EHA 2025 (Abstract No. PS1760 – abstract); 3. Davis JA, et al. Blood Cancer J 2025;15:32.

blood®

653.MYELOMA AND PLASMA CELL DYSCRASIAS: PROSPECTIVE THERAPEUTIC TRIALS | NOVEMBER 15, 2022

Pretreatment with Tocilizumab Prior to the CD3 Bispecific Cevostamab in Patients with Relapsed/Refractory Multiple Myeloma (RRMM) Showed a Marked Reduction in Cytokine Release Syndrome Incidence and Severity

Suzanne Trudel, Nizar J. Bahlis, Andrew Spencer, Rayan Kaedbey, Paula Rodriguez Otero, Simon J Harrison, Chihunt Wong, Grant R. Goodman, Rin Nakamura, Voleak Choeurng, James Cooper, Maria-Victoria Mateos



Suzanne Trudel et al. *Blood* 2022

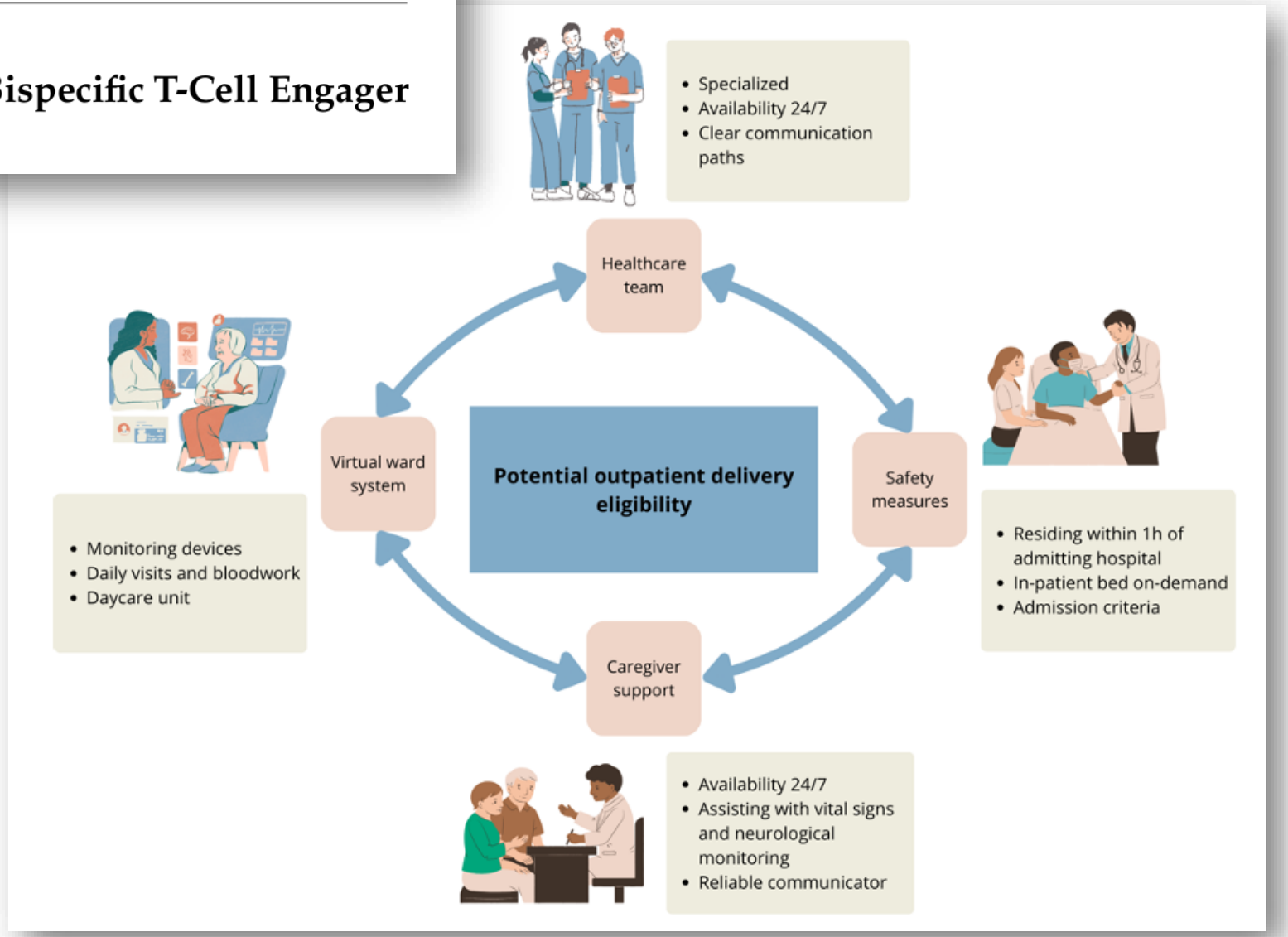
Current Oncology

MDPI

Review

Perspectives on Outpatient Delivery of Bispecific T-Cell Engager Therapies for Multiple Myeloma

- Key requirements for outpatient delivery of TCEs
- Toxicity management



Andrée-Anne Pelland et al. Current Oncol 2025

European Journal of Haematology

WILEY

European Journal of Haematology

ORIGINAL ARTICLE OPEN ACCESS

European Expert Panel Consensus on Outpatient Administration of Teclistamab and Talquetamab in Patients With Multiple Myeloma: Feasibility, Key Considerations, and Future Directions

All experts completed a 17- question survey, participated in an individual follow- up call, and attended an online consensus meeting in September 2024

Outpatient preparation and patient selection

Infrastructure preparation

- Experience administering BsAbs in an inpatient setting
- Access to a hematology department/hematologist familiar with CRS, ICANS, and infections
- Access to emergency department and ICU
- Robust protocols put in place to guide HCPs with outpatient administration
- All relevant HCPs trained on the new process
- On-duty onco-hematologist ready to be contacted by outpatients receiving BsAbs if needed

Patient eligibility criteria†

- ECOG performance status score 0–2
- No high tumor burden or rapidly progressive disease
- If comorbidities, these must be well controlled; no active infection
- Presence of a caregiver residing at the same home as the patient to monitor for AEs
- Patient lives within 30–60 minutes of the hospital
- Patient/caregiver can be considered "reliable"

No difference in eligibility criteria expected for those receiving teclistamab vs talquetamab

Treatment initiation

Actions **prior** to SUD

- Administer mandatory premedications (paracetamol, antiallergic, dexamethasone‡)
- Provide patients/caregivers with simple education on the signs and symptoms of CRS and ICANS
- Provide patient notices and cards to patients/caregivers
- Provide patients/caregivers with anticipated prescriptions (paracetamol, dexamethasone§)
- Provide patients/caregivers with a prescription for a thermometer, blood pressure monitor, and pulse oximeter

No changes to the preferred SUD schedule are likely to be needed in an outpatient setting

Thomas Lund et al. European Journal of Haematology. May 2025

European Journal of Haematology

WILEY

European Journal of Haematology

ORIGINAL ARTICLE OPEN ACCESS

European Expert Panel Consensus on Outpatient Administration of Teclistamab and Talquetamab in Patients With Multiple Myeloma: Feasibility, Key Considerations, and Future Directions

The expert panel expects up to 50% of patients receiving BisAb could be treated in an outpatient setting within 3 years

Post SUD management

AE monitoring

- Patients/caregivers to monitor patient temperature, blood pressure, and oxygen saturation 2–3 times a day
- Patients/caregivers to contact on-duty onco-hematologist if experiencing AEs

AE management

- HCPs must follow a predefined infection management strategy (IMWG and EMN guidelines)[¶,‖]
- Patients to follow the directions of on-duty onco-hematologist when needed
- Patients who develop a fever should take paracetamol
- If patient develops signs and symptoms of grade 2 CRS, the anticipated prescription of dexamethasone can be taken following telephone instructions from the on-duty onco-hematologist
- Patients should be prepared to travel to the hospital within 1 hour if experiencing signs of persistent grade 2 CRS

Thomas Lund et al. European Journal of Haematology. May 2025

Received: 20 April 2024 | Accepted: 4 July 2024
DOI: 10.1002/hem3.132

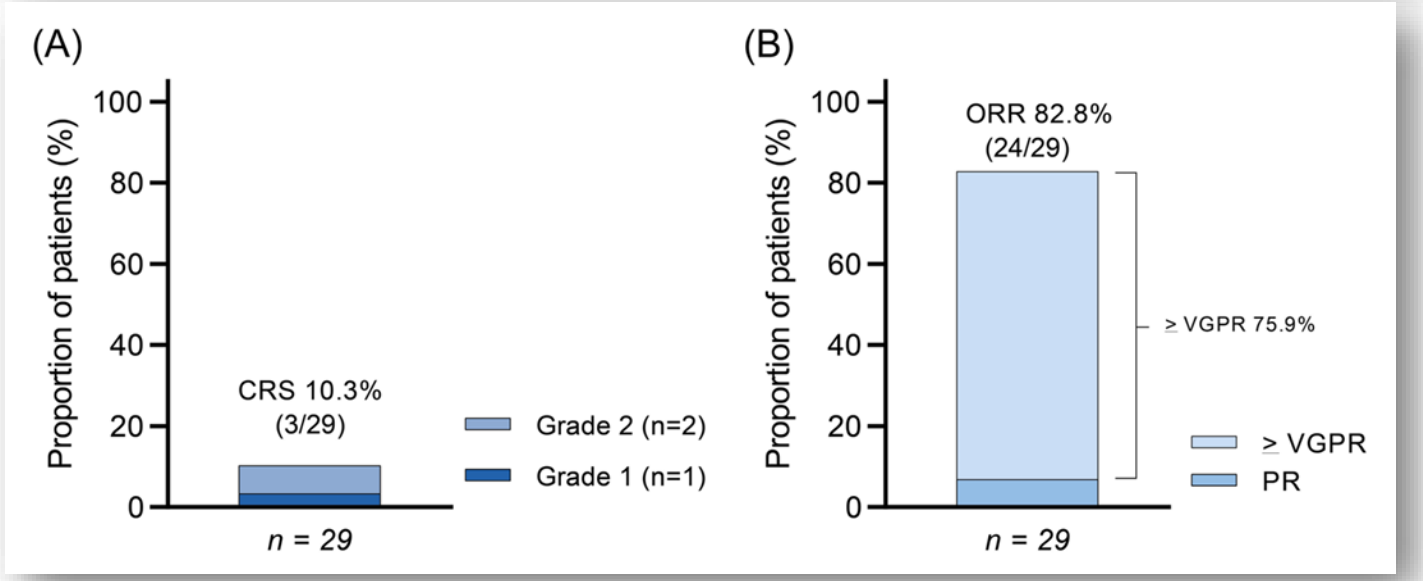
HemaSphere EHA EUROPEAN HEMATOLOGY ASSOCIATION

LETTER

Prophylactic tocilizumab reduces the incidence of cytokine release syndrome in relapsed/refractory myeloma patients treated with teclistamab: Implications for outpatient step-up dosing

Charlotte L. B. M. Korst[1,2] | Kaz Groen[1,2] | Patricia W. C. Bosman[1,2] | Fleur van der Valk[3] | Christie P. M. Verkleij[1,2] | Sandy Kruyswijk[1,2] | Maaike E. M. de Ruijter[1,2] | Dianne M. Heijink[1,2] | Maria T. Kuipers[1,2] | Sonja Zweegman[1,2] | Niels W. C. J. van de Donk[1,2]

Correspondence: Niels W. C. J. van de Donk (n.vandedonk@amsterdamumc.nl)



29 pts (25 inpatient; 4 outpatient)
Prophylaxis with tocilizumab **prior to step up dose 1 (1 hour before)** results in a marked reduction in the occurrence of teclistamab-induced CRS without a negative impact on response

(In MajesTEC1 arm of Prophylaxis with Toci, was admistered 4 hours before)

Grade 2 CRS despite prophylactic tocilizumab had high tumor burden (80% MM cells in bone marrow [BM] biopsy) and rapidly progressive disease

Circulating tumor cells in one cases

Korst et al. *HemaSphere* 2026

REGULAR ARTICLE

blood advances

Check for updates

Tocilizumab prophylaxis for patients with multiple myeloma treated with bispecific antibodies

Andrew Kowalski, Jill Lykon, Benjamin Diamond, David Coffey, Marcella Kaddoura, Francesco Maura, James Hoffman, Abhishek Pandey, Dickran Kazandjian,* and Ola Landgren*

Myeloma Division, Sylvester Comprehensive Cancer Center, University of Miami, Miami, FL

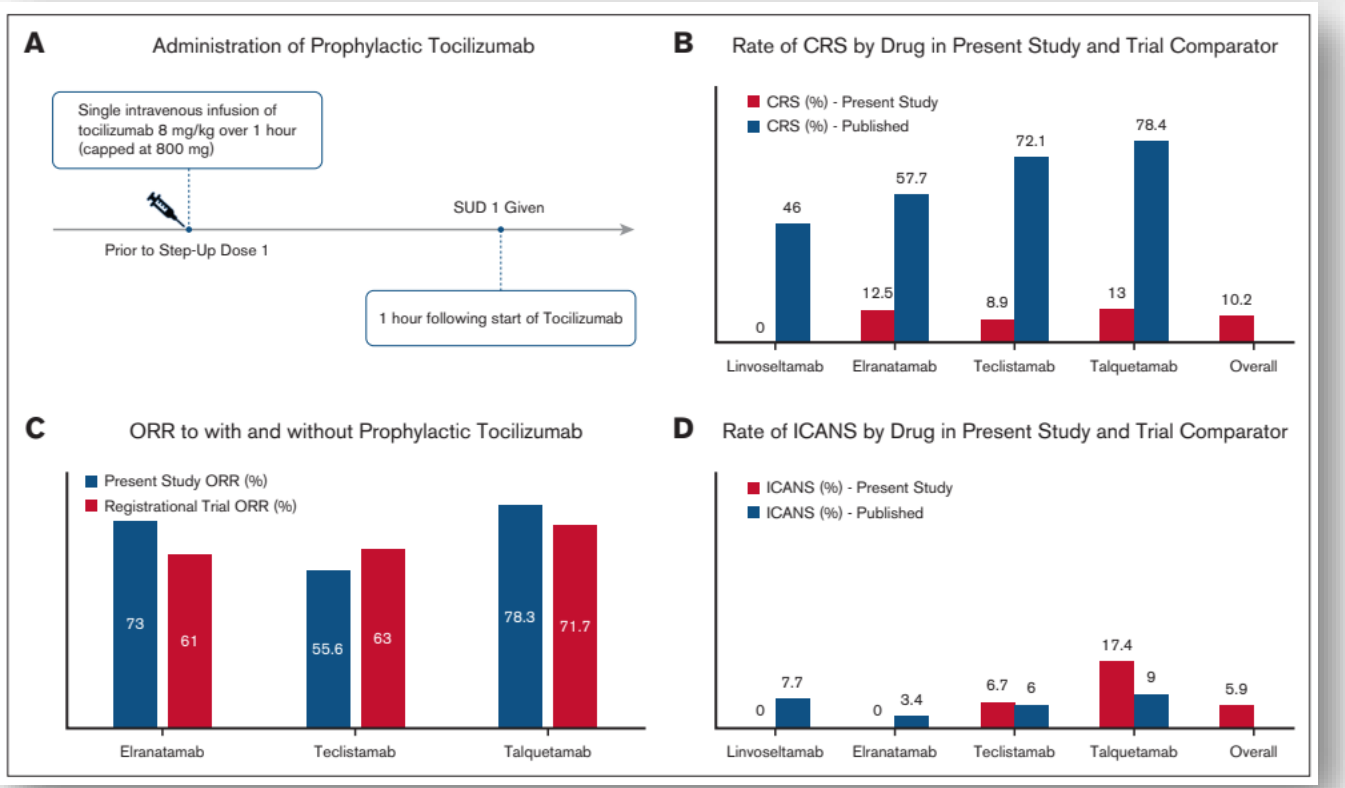


Table 1. Patient demographics

Variable	All patients (N = 119)
Treatment, n (%)	
Elra	40 (33.6)
Tec	45 (37.8)
Linvo	10 (8.4)
Tal	23 (19.3)
Tec/Tal	1 (0.8)
Age, y	
Median (range)	67 (35-87)
≥75, n (%)	29 (24.4)
Sex, n (%)	
Female	62 (52.1)
Male	57 (47.9)
Race	
Black	22 (18.5)
White	97 (81.5)
Hispanic ethnicity, n (%)	49 (41.2)

Rate of CRS
Teclistamab 8.9%
Elranatamab 12.5%
Linvoseltamab 0%
Talquetamab 13%
The overall rate of ICANS (5.9%) was low but similar to rates without prophylactic tocilizumab.
CRS was limited to grade 1 for 10 of 12 events
No grade 3 CRS events
No additional doses of tocilizumab or corticosteroids were given for CRS

Andrew Kowalski et al. *Blood advance.* Oct 2025

Recruiting

Outpatient Administration of Teclistamab or Talquetamab for Multiple Myeloma

ClinicalTrials.gov ID NCT05972135

Study Overview

Brief Summary

This is a phase II study to evaluate the outpatient administration of Teclistamab or Talquetamab in Multiple Myeloma patients

Detailed Description

- This is a three-arm, non-randomized, multicenter, prospective study in adult patients with RRMM, who are administered Teclistamab (TECVAYLI™) or Talquetamab (TALVEY™), in the post-marketing setting.
- Teclistamab (TECVAYLI™) is a humanized IgG-4 PAA bispecific antibody designed to target the CD3 receptor complex on T cells and BCMA on B-lineage cells.
- Talquetamab (TALVEY™) is a humanized IgG-4 bispecific antibody designed to target the CD3 receptor complex on T cells and GPRC5D-expressing multiple myeloma (MM) cells This study will investigate the use of prophylactic tocilizumab or prophylactic dexamethasone to reduce the incidence and severity of CRS associated with teclistamab or talquetamab administration, to enable administration of the step-up dosing regimen of teclistamab or talquetamab in an outpatient setting.

Study Start (Actual)

2023-10-23

Primary Completion (Estimated)

2027-08

Study Completion (Estimated)

2027-10

Enrollment (Estimated)

100

Study Type

Interventional

Phase

Phase 2

Study Record Dates

More Information

Recruiting

Self-administration of Subcutaneous Elranatamab in the Patients' Homes. (ERICA)

ClinicalTrials.gov ID NCT06015542

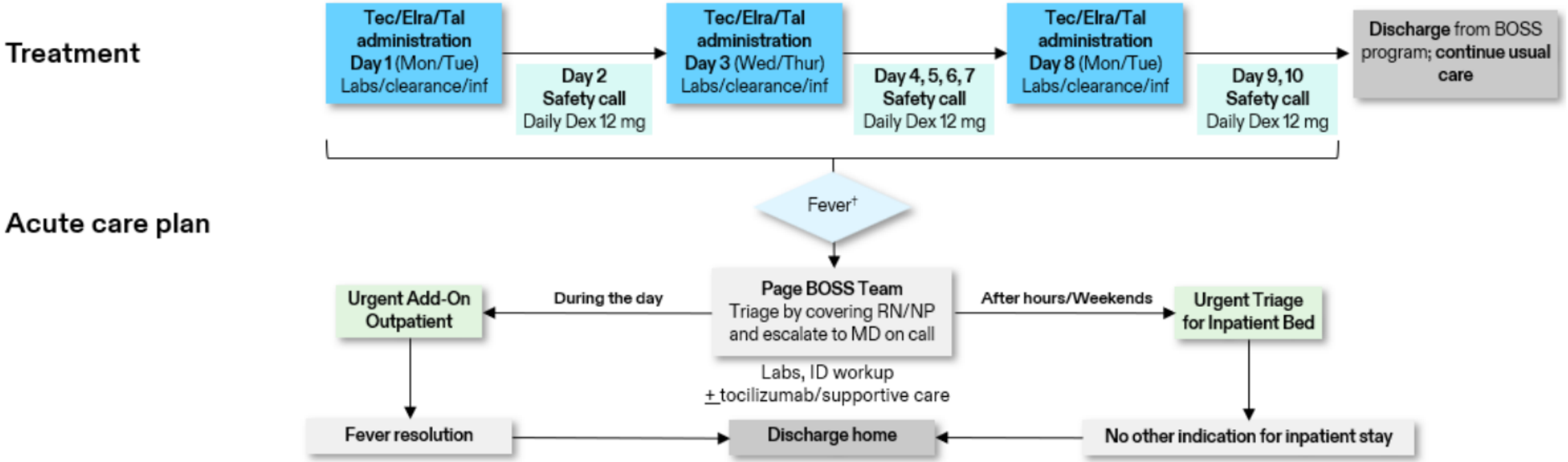
Sponsor Thomas Lund

Information provided by Thomas Lund, Odense University Hospital (Responsible Party)

Last Update Posted 2026-02-10

Bispecific Outpatient Safe Step-up (BOSS) program

Figure 1. BOSS Program Scheme[4]



Adapted from: Cirstea D et al, Poster presented at IMS 2025 (Abstract PA-0017)
BOSS=Bispecific Outpatient Safe Step-up; dex=dexamethasone; elra=elranatamab; NP=nurse practitioner; RN=registered nurse; tal=talquetamab; tec=teclistamab.

prophylactic 12 mg dexamethasone given on Days 2, 4-7, and 9-10

patients did not receive tocilizumab prophylactically

Cirstea D, et al. Poster presented at 22nd Annual Meeting & Exposition International Myeloma Society. 2025

Bispecific Outpatient Safe Step-up (BOSS) program

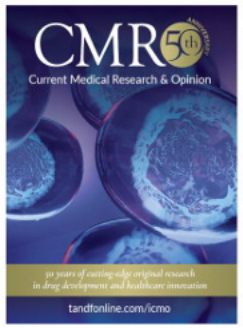
Table 2. Adverse Events Incidence[5]

Adverse Events of Interest	BOSS program Elranatamab, n=11	iSUD program Elranatamab, n=30
CRS, n (%)	2 (18.2%)	16 (53.3%)
ICANS, n (%)	1 (9.1%)	7 (23.3%)
Infections, n (%)	1 (9.1%)	6 (20%)

In the whole BOSS cohort, CRS occurred exclusively post-SUD#1, while in iSUD CRS were 34% post-SUD#1, 42% post-SUD#2, 11% post-SUD#3, and 13% post-full dose. In BOSS the median onset for ICANS occurred earlier (6 hours) than in iSUD (77 hours). Overall, 87% of patients in the BOSS cohort had no hospital stay (13/15), while in the iSUD cohort, the median hospital stay was 8-days.[5]

87% of patients avoid hospitalization

Cirstea D, et al. Poster presented at 22nd Annual Meeting & Exposition International Myeloma Society. 2025



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Current Medical Research and Opinion

ISSN: 0300-7995 (Print) 1473-4877 (Online) Journal homepage: www.tandfonline.com/journals/icmo20

Experiences with real-world teclistamab administration in community and outpatient settings: a mixed-methods study of hematology providers

Benjamin Derman, Jane Jijun Liu, Nicholas Bouchard, Lindsay Figg, Justin LaPorte, Salil Goorha, Kaley Pagan, Anand Tandra, Asya Varshavsky, Gilbert Ko, Dee Lin, Agne Paner-Straseviciute, Meaghan Roach, Richard Murphy, Amal Jamaleddine, Nicole Bariahtaris, Jessica Fowler, Niodita Gupta-Werner & Muhamed Baljevic

- ❑ survey, interviews, and roundtable discussion with US providers
- ❑ Patient-level requirements for outpatient SUD (n=20) included care giver support (90%), proximity to administering site (70%), good performance status (65%), and low disease burden (30%).
- ❑ structured protocols, and adequate organizational support (multi-disciplinary approach)
- ❑ Scheduling: shifting their SUD on days 1-3-8 (as opposed to days 1-3-5 or days 1-4-7)
- ❑ At the time of the study, tocilizumab was not approved for the prevention of CRS, making reimbursement difficult.

Benjamin Derman et al. *Current Medical Research and Opinion.* 18 Feb 2026

OPTec: A phase 2 study to evaluate outpatient (OP) step-up administration of teclistamab (Tec), a BCMA-targeting bispecific antibody, in patients (pts) with relapsed/refractory multiple myeloma (RRMM).

Robert M. Rifkin, Henning Helmut Schade, Gary Simmons, Christopher A. Yasenchak, Jessica Fowler, Thomas S. Lin, Brian Thomson, Weiming Xu; Sarah Cannon Research Institute, Rocky Mountain Cancer Centers, Denver, CO; Colorado Blood Cancer Institute, Denver, CO; Virginia Commonwealth University Massey Cancer Center, Richmond, VA; Willamette Valley Cancer Institute and Research Center, Eugene, OR; , MA; Sarah Cannon Research Institute, Development Innovations, Nashville, TN

Background: Tec is the only approved BCMA×CD3 bispecific antibody with personalized, weight-based dosing for triple-class exposed RRMM. In the MajesTEC-1 study, Tec showed deep, durable responses and a manageable safety profile. Cytokine release syndrome (CRS) occurred in 72% of pts during Cycles 1-2, and 33% of pts had recurrent CRS grade (gr) ≤3 (gr 3, 0.6%). Tocilizumab (Toci) is used to manage CRS. In a separate MajesTEC-1 cohort, pts who received prophylactic Toci (proToci) experienced less CRS, compared with pts who did not (26% vs 72%). Administering the Tec step-up dosing (SUD) regimen in the OP setting may make Tec more accessible, especially at community centers. Therefore, we are investigating whether proToci can reduce the incidence and severity of CRS associated with Tec and facilitate safe OP administration. **Methods:** This single-arm, non-randomized, multicenter, prospective study (NCT05972135) will evaluate proToci in pts treated with Tec using an OP SUD regimen. The primary endpoint is the overall incidence of CRS. Secondary endpoints include recurrent CRS gr ≥3, and any gr infections, neurotoxicity (NT) including ICANS, neutropenia, and efficacy. Eligible pts are ≥18 years with RRMM and ≥4 prior lines of therapy. Pts with rapidly progressing MM, CNS involvement, active infection, or contraindication to Toci are excluded. Toci 8 mg/kg IV is administered 2 to 4 hours prior to SUD 1 of Tec in an OP setting. The Tec SUD regimen consists of 0.06 mg/kg subcutaneously (SC), 0.3 mg/kg SC 2 to 4 days later, and 1.5 mg/kg SC

no pts experienced CRS or ICANS or required hospitalization

Rifkin et al. Poster presented at American Society of Clinical Oncology (ASCO) Annual Meeting June 2024

OPTec: A Phase 2 Study to Evaluate Outpatient Step-Up Administration of Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma (RRMM): Updated Results

Robert Rifkin[1,2], Henning Schade[3], Gary Simmons[4], Christopher Yasenchak[5], Jessica Fowler[6], Thomas S Lin[6], Lijuan Kang[7], Weiming Xu[2], Ryan J Caddell[8] (non-author presenter)

[1]Rocky Mountain Cancer Centers, Denver, CO, USA; [2]Sarah Cannon Research Institute, Nashville, TN, USA;

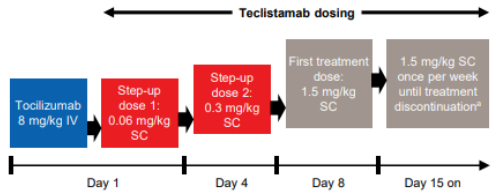
Introduction

- Teclistamab (Tec) is the first approved bispecific antibody targeting CD3 and B-cell maturation antigen for the treatment of adults with relapsed/refractory (RR) multiple myeloma (MM) who have received ≥4 lines of prior therapy[1]
- In the phase 1/2 MajesTEC-1 study (NCT03145181/ NCT04557098), rapid, deep, and durable responses were observed over a median 30.4 months follow-up in patients (pts) with RRMM, with a manageable safety profile[2]
- As all bispecific antibodies for MM can cause cytokine release syndrome (CRS) and neurologic toxicity, US Prescribing Information recommends pts be hospitalized during Tec step-up dosing[1]
- However, CRS occurred less frequently (26% vs 73%)[3] with tocilizumab (Toci) administration before the first Tec step-up dose, with no effect on efficacy or infections[3,4]
- This study assesses the potential benefits of administering Toci before the first step-up dose of Tec to reduce CRS incidence and support safe outpatient administration of Tec

Methods

- This is a phase 2, nonrandomized, single-arm study (NCT05972135) of Tec outpatient administration in pts with RRMM
- Eligible pts are adults who have MM, have received 4 or more prior therapies for MM, are triple-class exposed, and have an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1
- Tec is administered in the outpatient setting using a step-up dosing schedule, in which pts receive 2 step-up doses of Tec (0.06 mg/kg and 0.3 mg/kg subcutaneously [SC]) before the first full treatment dose (1.5 mg/kg SC), with subsequent doses administered at 1.5 mg/kg SC once weekly and an option to switch to once every 2 weeks based on response (**Figure 1**)
- 2 to 4 hours before the first step-up dose of Tec, all pts receive a single dose of Toci (8 mg/kg intravenously)
- Intravenous (IV) immunoglobulin (IVIG) was strongly recommended for immunoglobulin G (IgG) levels <400 mg/dL
- The primary endpoint is the incidence of any-grade CRS in the first 2 cycles; secondary endpoints include overall response rate and incidence of any-grade recurrent CRS, any-grade infections, any-grade neurotoxicity, and hospitalizations

Figure 1: Study treatment administration



Step-up dose 2 and the first treatment dose may be given between 3 to 5 days after step-up dose 1/2 and up to 7 days after step-up dose 1/2 to allow for resolution of AEs.
[a]Dosing may be reduced to 1.5 mg/kg SC once every 2 weeks in patients who achieve partial response or better after 6 months of study treatment. AE, adverse event.

Results

Demographics

Table 1: Patient demographics (treated population)

Characteristic	Total (N=16)
Age in years, median (range)	74 (53–86)
Sex, n (%)	
Female	9 (56.3)
Male	7 (43.8)
Race, n (%)	
Black or African American	1 (6.3)
White	11 (68.8)
Unknown/unreported	4 (25.0)
Baseline ECOG PS, n (%)	
0	2 (12.5)
1	14 (87.5)
Number of lines of prior therapy, median (range)	4 (4–11)

Patient disposition

Table 2: Patient disposition (treated population)

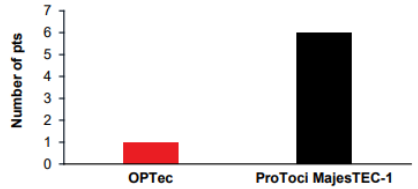
	Total (N=16)
Patient status, n (%)	
On treatment	13 (81.3)
On study	14 (87.5)
Completed study	1 (6.3)
Discontinued study	1 (6.3)
Progressive disease, n (%)	2 (12.5)

- Pts were discontinued from treatment due to progressive disease (2 pts, 12.5%) and completing treatment per protocol (1 pt, 6.3%)
- 1 pt with diffuse bony lesions had a serious AE (SAE) of bilateral leg weakness and pain unrelated to Tec or Toci, was withdrawn from the study, and died 2 weeks later of progressive disease
- The median treatment duration was 9.6 months (range, 0.03–11.08)

Safety

- CRS
  - 1 pt (6.3%) experienced CRS (grade 1, occurring in cycle 1), which was considered related to Tec and which was managed with dexamethasone (**Figure 2**)

Figure 2: CRS in OPTec vs ProToci cohort in MajesTEC-1



CRS occurred in 1 of 16 pts (6.3%) in OPTec and 6 of 24 pts (25.0%) in the ProToci cohort in MajesTEC-1.[3]
ProToci, prophylactic tocilizumab.

- Infections and IgG
  - A total of 7 pts (43.8%) experienced 12 infections, of which 10 infections were grade 2 and 2 infections were considered related to study treatment
  - There were 2 grade ≥3 infections: a grade 3 urinary tract infection and grade 4 sepsis, which was considered an SAE
  - 8 pts (50.0%) experienced quantitative IgG <400 mg/dL, of whom 6 received IVIG
- Neurotoxicity
  - No pts developed immune effector cell–associated neurotoxicity syndrome (ICANS) due to study treatment
- Hospitalizations
  - 1 pt was hospitalized due to treatment-related delirium with febrile neutropenia
- No pts met stopping criteria (grade >3 CRS or neurotoxicity/ICANS)
- A preliminary pharmacokinetics (PK) analysis in pts from this trial showed that observed Toci PK are consistent with the literature[2]
- The most common treatment-related AEs (TRAEs; ≥15% of all pts) were injection site reaction (5 pts, 31.3%; 3 pts, grade 1; 2 pts, grade 2), headache and neutropenia (4 pts each, 25.0%), and fatigue and hypogammaglobulinemia (3 pts each, 18.8%)
- The most common grade ≥3 TRAEs (≥5% of all pts) were neutropenia (4 pts, 25.0%) and febrile neutropenia, increased alanine aminotransferase, anemia, back pain, hypertension, and decreased platelet count (1 pt each, 6.3%)

Table 3: Safety summary (treated population)

	Total (N=16) n (%)
Any TEAE	15 (93.8)
Grade ≥3 TEAE	13 (81.3)
Any-Grade TRAE	12 (75.0)
Grade ≥3 TRAE	8 (50.0)
Any SAE	6 (37.5)
Any treatment-related SAE	1 (6.3)
Any TEAE leading to death	0
Any TEAE leading to treatment discontinuation	0

TEAE, treatment-emergent adverse event.

Efficacy

- Of 11 pts evaluable for response, 100% responded to therapy, with 45% having either stringent complete response (sCR) or complete response (CR) as their best overall response (**Figures 3** and **4**)

Figure 3: Best overall response (evaluable population)

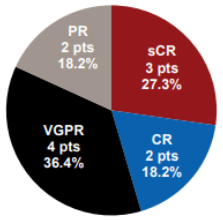
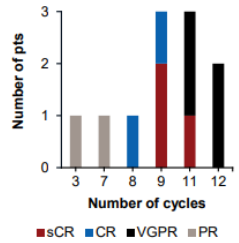


Figure 4: Number of cycles treatment was received



A total of 11 of 16 patients (68.8%) were evaluable for response as of the time of presentation. PR, partial response; VGPR, very good partial response.

Conclusions

- Only 1 of 16 pts experienced a CRS event when tocilizumab was administered before the first step-up dose of teclistamab
- Administering tocilizumab before the first step-up dose of teclistamab reduced the risk of CRS and supports administration of teclistamab in the outpatient setting
- Prophylactic tocilizumab did not appear to increase the risk of serious infections or to reduce the efficacy of teclistamab
- No new safety signals have been observed
- The protocol has been amended to allow pts to receive either teclistamab or talquetamab after 2+ lines of treatment
- The talquetamab arm is now open and enrolling

Acknowledgments
We would like to thank the patients and their families for their participation; the study staff for their contributions; our pharmaceutical funding partner, Johnson & Johnson; and Jennifer Blalock, Danielle Kelley, BSN, and Manoj Pant, MS, for their support in preparing the original poster. Medical writing support for this adapted encore was provided by Renee E Granger, PhD, of Eloquent Scientific Solutions, and funded by Johnson & Johnson.

Disclosures
RJC is an employee of Johnson & Johnson.

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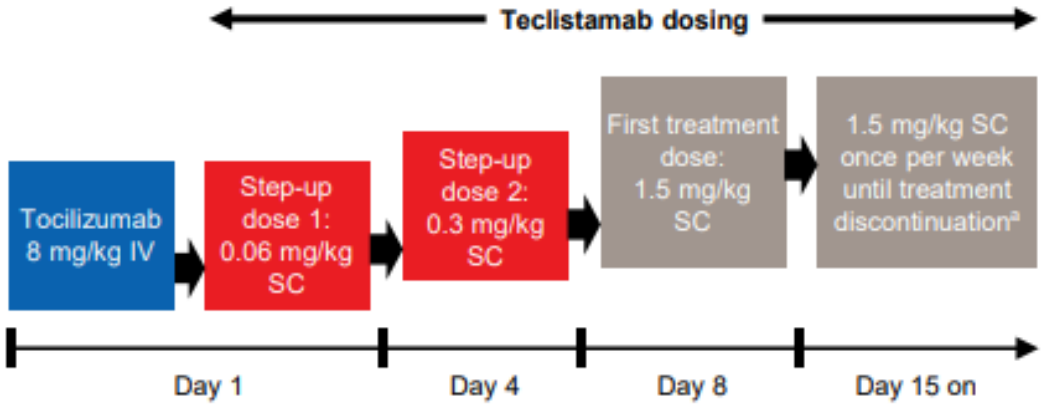
Multiple Myeloma

OPTec: A Phase 2 Study to Evaluate Outpatient Step-Up Administration of Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma (RRMM): Updated Results



Step-up dose 2 and the first treatment dose may be given between 3 to 5 days after step-up dose 1/2 and up to 7 days after step-up dose 1/2 to allow for resolution of AEs.
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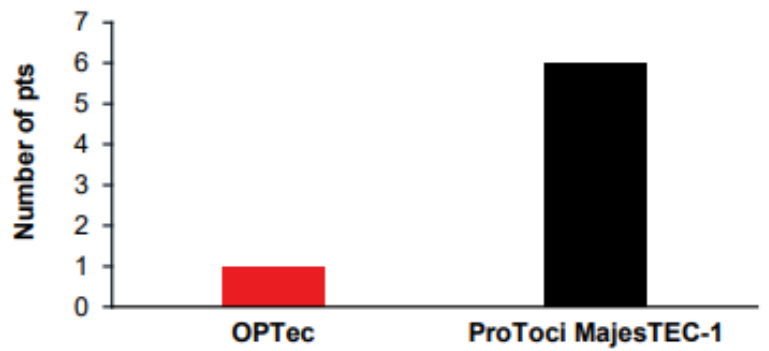
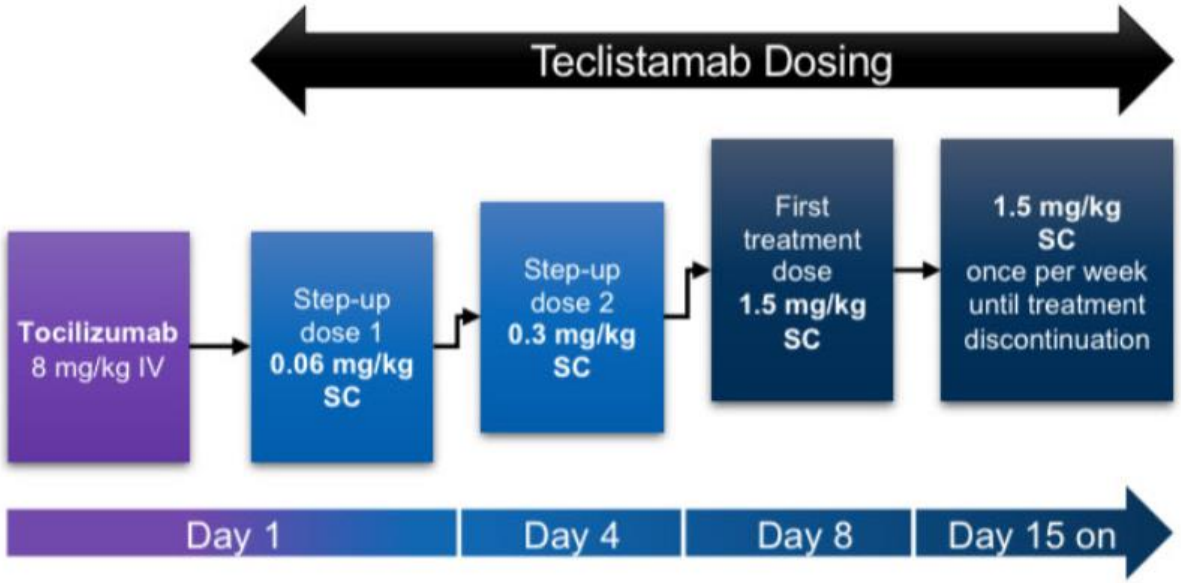
Figure 2: CRS in OPTec vs ProToci cohort in MajesTEC-1



CRS occurred in 1 of 16 pts (6.3%) in OPTec and 6 of 24 pts (25.0%) in the ProToci cohort in MajesTEC-1.[3]
ProToci, prophylactic tocilizumab.

Robert Rifkin et al. 66° ASH meeting 2024, Poster n. 654

OPTec: Prophylactic Tocilizumab Prior to Step-Up Dosing of Teclistamab Mitigates Risk of CRS in the Outpatient Setting[1]



- Only 2/24 patients experienced a CRS event (both G1); no patients developed ICANS on treatment
- Prophylactic toci reduced risk of CRS without impacting efficacy of tec or risk of infections, supporting administration of tec in the outpatient/community setting

NCCN Guidelines now include prophylactic tocilizumab as a consideration prior to the first step-up dose of bispecific therapy[2]

Forsberg PA et al. SOHO September 3-6, 2025

PA-008

Economic Value of Tocilizumab Prophylaxis to Prevent Cytokine Release Syndrome During Outpatient Teclistamab or Talquetamab Initiation for Relapsed/ Refractory Multiple Myeloma

Amir Ali[1], Arveen Kaur[2], Felice Yang[2], Yi-Hsuan Liu[2], Joseph Goble[2], Xinke Zhang[2], Niodita Gupta-Werner[2], Tonya Le Blanc[2], Arielle G Bensimon[3], Ariel F Grajales-Cruz[4]

Key Takeaways

- Outpatient (OP) administration of bispecific SUDs along with prophylactic use of toci is becoming more common in clinical practice; however, economic data remain limited
- These findings support the economic feasibility of OP administration of SUDs of Tec and Tal when toci is used prophylactically

Conclusion

- For patients initiating Tec or Tal for RRMM, an OP SUD approach with prophylactic toci, previously associated with fewer CRS events, demonstrated lower cost of care compared with the conventional IP SUD approach

Results

- Total per-patient costs for the IP versus OP approaches were estimated as follows (**Table 1**): $28,158 versus $19,316 for Tec, resulting in a cost difference of −$8841; $27,469 versus $18,924 for Tal QW, resulting in a cost difference of −$8545; and $54,718 versus $42,097 for Tal Q2W, resulting in a cost difference of −$12,621
  - The cost differences were predominantly attributable to the reduction in IP days with the OP approach

Table 1: HCRU and costs by SUD setting

Outcomes	Tec		Tal QW		Tal Q2W	
	IP	OP with prophylactic toci	IP[a]	OP with prophylactic toci	IP	OP with prophylactic toci
HCRU during the SUD period[b]						
Number of grade ≥2 CRS events, mean	0.3	0	0.2	0	0.2	0
Number of IP days, mean	6.0	0	6.0	0	8.0	0
Number of OP administrations, mean	0	3.0	0	3.0	0	4.0
Costs per patient, mean, 2025 USD						
Total costs during the SUD period[b,c]	28,158	19,316	27,469	18,924	54,718	42,097
Drug acquisition costs for SUDs	14,545	14,545	14,152	14,152	37,259	37,259
Drug acquisition costs for toci prophylaxis	0	4515	0	4515	0	4515
Drug acquisition costs for toci treatment of grade ≥2 CRS	1149	0	852	0	841	0
IP administration costs for SUDs	12,464	0	12,464	0	16,619	0
OP administration costs for SUDs	0	199	0	199	0	265
OP administration costs for toci prophylaxis	0	58	0	58	0	58

HCRU, health care resource utilization; SUD, step-up dose; Tec, teclistamab; Tal, talquetamab; QW, weekly; Q2W, biweekly (every 2 weeks); IP, inpatient; OP, outpatient; toci, tocilizumab; CRS, cytokine release syndrome; USD, US dollars.
[a]In cohort D of TAL-1, some patients received IP SUD with prophylactic toci, and all patients received post-treatment dexamethasone administered as an 8 mg/kg dose.
[b]The SUD period was 1 week for Tec and Tal QW and 2 weeks for Tal Q2W. IP SUD assumed to require a 6-day hospitalization (1-3-5) for Tec and Tal QW and 8-day hospitalization (1-3-5-7) for Tal Q2W, based on the TEC-1 and TAL-1 trials.
[c]Acquisition and administration costs may not sum to total costs during the SUD period due to rounding.

- Sensitivity analyses using biosimilar toci pricing demonstrated even greater cost savings for the OP approach, with differences of −$9725 for Tec, −$9506 for Tal QW, and −$13,586 for Tal Q2W, as shown in **Figures 1** to **3**

Figure 1: Base-case and sensitivity analyses of Tec SUD settings for biosimilar product use

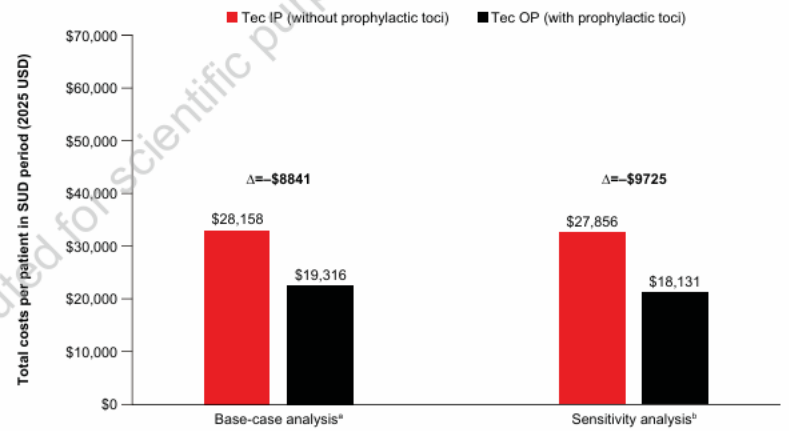
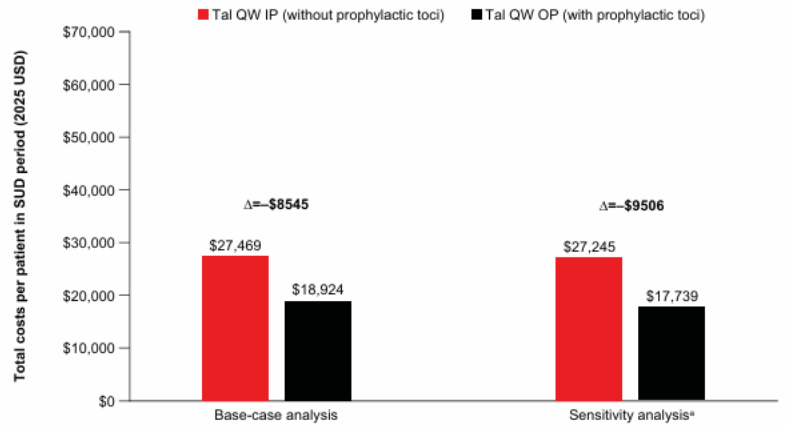
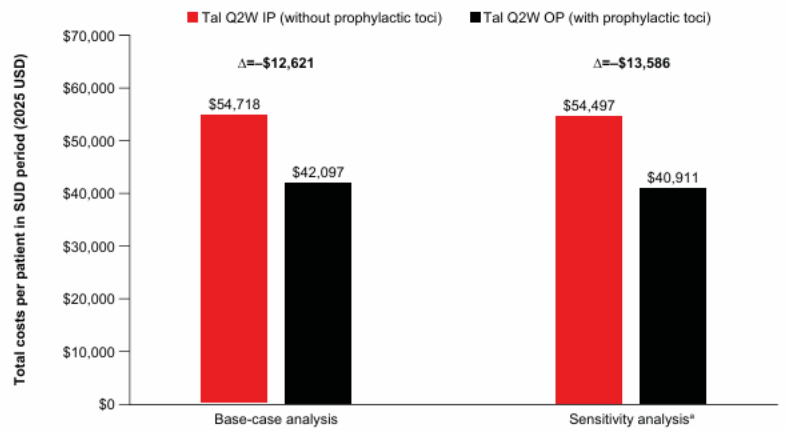


Figure 2: Base-case and sensitivity analyses of Tal QW SUD settings for biosimilar product use



Tal, talquetamab; QW, weekly; SUD, step-up dose; IP, inpatient; toci, tocilizumab; OP, outpatient; USD, US dollars.
[a]The sensitivity analysis was conducted under the assumption of biosimilar pricing, including for the administration of reactive toci.

Figure 3: Base-case and sensitivity analyses of Tal Q2W SUD settings for biosimilar product use



N Gupta-Werner et al. 22° IMS meeting 2025, Toronto. Poster n. PA-008

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RECEIVED 16 May 2025
ACCEPTED 30 June 2025
PUBLISHED 30 July 2025

CITATION
Garfall AL, Banerjee R, Frenzel L, Khandanpour C, Lin Y, Ottoni E, Rifkin R, Rockwell S, Rodriguez C, Villefort H and Zamagni E (2025) A roadmap to

A roadmap to implementing outpatient administration of bispecific antibodies in multiple myeloma

Alfred L. Garfall[1], Rahul Banerjee[2], Laurent Frenzel[3], Cyrus Khandanpour[4,5,6], Yi Lin[7], Erica Ottoni[8], Robert Rifkin[9], Sarah Rockwell[10], Cesar Rodriguez[11], Humberto Villefort[12] and Elena Zamagni[13,14]*

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Garfal AL et al. Frontiers 2025

Three clinician advisory workshops (United States, Europe, and Latin America)

key factors to operationalize BsAb use in outpatient and community settings

- careful planning
- a well-prepared multidisciplinary team (MDT)
- Clear protocols,
- roles/ responsibilities,
- capacity planning,
- patient selection criteria,
- step-up dosing procedure,
- admission processes,
- patient/caregiver education requirements,
- adverse event (AE) monitoring/management

Patients initiating outpatient BsAb therapy should have

- reliable caregiver
- access to a hospital
- controlled comorbidities
- no active infections

- Patients and caregivers education (benefits, risks, and expectations)

BsAbs are appropriate for many different patients, **irrespective of age and frailty**

Garfal AL et al. Frontiers 2025

Patient suitability for outpatient BsAb treatment: Ideal patient profile

low tumor burden
Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 2
good mental status
minimal/stable complications of MM disease progression
well controlled comorbidities (eg, no history of heart failure or tachyarrhythmia)
Close proximity to the hospital
round-the clock availability of a reliable caregiver

Garfal AL et al. Frontiers 2025

Workflow diagram for BsAb administration in outpatient settings

Internal Planning and Infrastructure Setup	MDT Setup and Training	Patient and Caregiver Education	Data and Treatment Authorization	Screening and Premedications	PAG Engagement/ Patient Support (Ongoing)	SUD1	Patient Checkout and Monitoring	ED Visit/ Readmission (If Needed)	Transition of Care to Community Setting	SUD2
❑ Identify infrastructure (existing clinic or ED) ❑ Allocate resources and bed capacity ❑ Develop clear protocols and escalation pathways ❑ Identify experienced physicians to serve as "change champions" to provide support throughout the planning, integration, and training processes	❑ Identify MDT, including physicians (lead and specialists), nurses, ED, ICU, and inpatient staff, pharmacists, and authorization team ❑ Train MDT on[a-d]: • BsAb treatment process • **AE identification,** reporting, and management protocols • REMS (if applicable) ❑ Coordinate care across MDT	Review the treatment plan and provide clear information on: ❑ What to expect (eg, process, risks) ❑ Required actions for patient and caregiver ❑ How to monitor and recognize AEs[e] ❑ What to do in case of AEs (eg, who to call)	Obtain: ❑ Patient data prior to SUD1: • Baseline laboratory data, vital signs, IgG levels, **inflammatory** markers, ICE score, LDH ❑ Authorization for BsAbs and medications for AE management: • Dexamethasone • Acetaminophen • Tocilizumab[f] • IVIg	❑ Screen patient for infections ❑ Administer premedications including dexamethasone, acetaminophen, cetirizine, and antibiotic prophylaxis *Note: Prophylactic tocilizumab is not routinely used and requires prior authorization[f,g]*	Provide: ❑ At-home monitoring equipment (eg, thermometer, blood pressure cuff, pulse oximeter)[h] ❑ Contact information for physician/medical team in case of AEs ❑ Medications to manage AEs ❑ Supportive and education resources	❑ Inform ED, ICU, and rapid response team of patient's treatment ❑ Administer SUD1 ❑ Monitor patient for AEs *Note: Consider administering SUD1 on Mondays to limit CRS events occurring overnight or on the weekend*	Provide: ❑ Reminder of how to use take-home monitoring equipment ❑ Instructions to recognize and act (via on-call network) on alarm symptoms (eg, fever, mental confusion) ❑ Proactive follow-up by nurse to check for/triage symptoms[i]	❑ Promptly identify BsAb recipients (eg, medical card, electronic chart alert) ❑ Notify inpatient team of arrival ❑ Inform MDT of patient status and treatment plan ❑ Alert attending hematologist in case of emergency ❑ Admit patient quickly to ensure timely administration of critical medications	❑ Collaboration plan between community center and hospital should include: • MDT roles and responsibilities • Network of contacts • Bed availability • Action plan for patients who develop AEs • On-call staff nights/ weekends • Access to the hematology department and ICU to allow patients to bypass the ED ❑ Refer patient to community setting for SUDs and/or weekly dosing following SUDs	❑ If SUD1 went smoothly, employ same process and premedications ❑ If patient had fever after SUD1, give tocilizumab and screen for infections ❑ Collect blood work ❑ Administer SUD2

Original Study

Check for updates

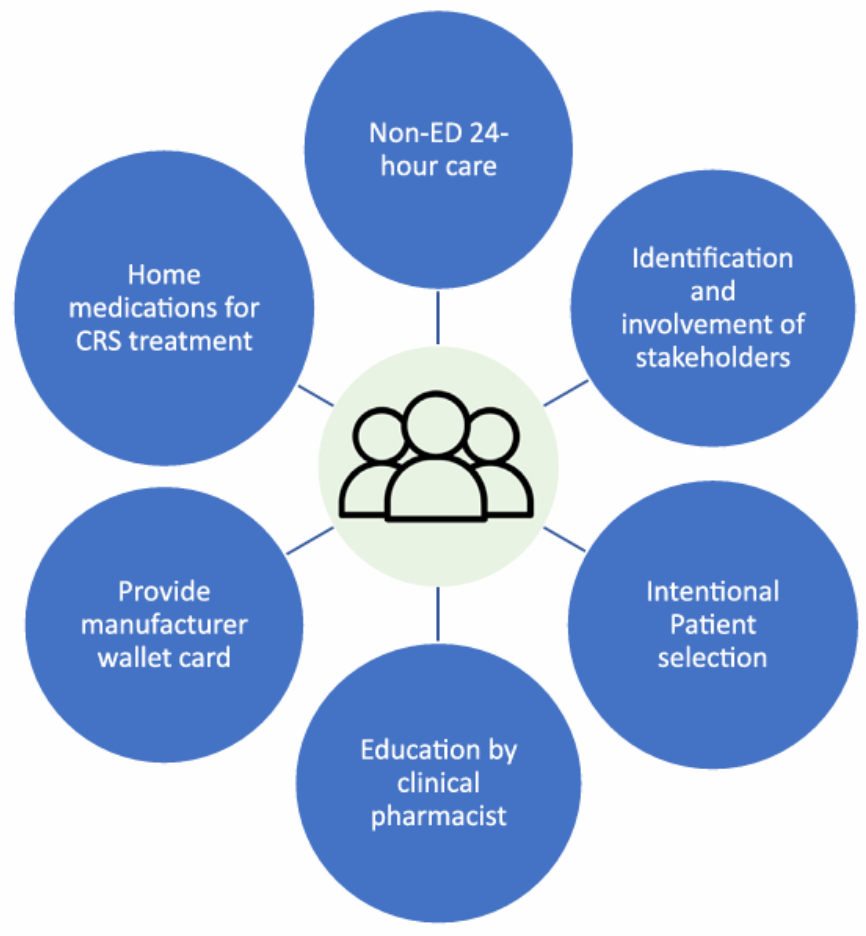
Feasibility and Safety of Outpatient Model for Administration of Bispecific Antibodies: Proceedings from an International Myeloma Society 21st Annual Meeting Oral Abstract

Sara A Scott, Danielle L. Roberts, Vikas A. Gupta, Nisha S. Joseph, Craig C. Hofmeister, Madhav V. Dhodapkar, Sagar Lonial, Ajay K. Nooka, Jonathan L. Kaufman

One of the first models to successfully demonstrate the feasibility and safety of transition BsAb SUD administration to the OP setting.

Scott S. et al. *Clinical Lymphoma, Myeloma and Leukemia* September2025

Figure 1 The development and implementation of an institutional protocol for outpatient administration of bispecific antibody step -up doses must take into account many factors and stakeholders while maintaining the patient as the central focus.



Eligibility:
Patients must live within 30 minutes of the center,
have a 24-hour caregiver for 48 hours post-target dose and be clinically stable.
Exclusions include rapid disease progression, >5% circulating plasma cells, ECOG ≥3, or prior grade ≥2 CRS/ICANS.

Preparation:
Pharmacist-led education, REMS card provided, and multidisciplinary coordination prior to initiation.

Dosing:
SUD on days 1, 4, and 8 (start on Monday).
Premedication: acetaminophen, diphenhydramine, dexamethasone.
Tocilizumab 8 mg/kg sc given before SUD #1.

Monitoring:
From SUD #1 to 48 hours post–target dose:
- Temperature checks Q8H
- No driving (REMS restriction)
- CRS/ICANS symptom watch
- If symptoms: take predesignated medications and report to ICC

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From 9/1/2023 to 8/31/2024, 52 patients received OP BsAb SUD.
CRS occurred in 10 patients (19.2%, 9/10 events grade 1/2) and ICANS occurred in 3 patients (5.8%, grade 1).

Table 1 Select Baseline Characteristics ($N = 52$)

Age, Median (range)	65 (38-82)
Gender, n (%)	
Male	25 (48)
Female	27 (52)
Race, n (%)	
White	25 (48)
African American	25 (48)
Asian	1 (2)
Other	1 (2)
Prior lines of therapy, median (range)	5 (2-15)
Bispecific Antibody, n (%)	
Teclistamab	19 (36.5)
Talquetamab	32 (61.5)
Elranatamab	1 (2)

Table 2 Incidence of CRS and ICANS ($N = 52$)

CRS, n (%)	10 (19.2)
Grade 1	8 (15)
Grade 2	1 (2)
Grade 3	1 (2)
Grade 4	0 (0)
ICANS, n (%)	3 (5.8)
Grade 1	3 (5.8)
Grade 2	0 (0)
Grade 3	0 (0)
Grade 4	0 (0)

Four patients (7.7%) required hospitalization for toxicity management.
All patients recovered from CRS and ICANS without additional toxicity.
Conclusion: Implementation of this OP BsAb SUD protocol is feasible with acceptable risk of CRS/ICANS and hospitalization without compromising on safety.
The low incidence of CRS/ ICANS with prophylactic tocilizumab and premedication and low hospitalization rates make this appealing for selected RRMM patients.

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IRCCS "Giovanni Paolo II"
PugliaSalute

PROTOCOLLO DI STUDIO

"Studio osservazionale, monocentrico, prospettico sulla fattibilità, sicurezza e sostenibilità della somministrazione *outpatient* di anticorpi bispecifici nel mieloma multiplo e nei linfomi r/r. Implementazione della presa in carico mediante modelli integrati di telemedicina e monitoraggio da remoto.

(Studio *EmaBisOut*)

v1.0 del 26/03/2026

EmaBisOUT PROTOCOL

Patient selection

Outpatient elegibility

Inpatient setting

Education

Screening and baseline assessment:

- evaluation of the individual patient by team
- demographic, clinical, and biological data
- assessment of the biological characteristics of MM
- frailty profiles and comorbidities
- caregivers with adequate digital education
- Proximity to healtcare center

INFECTIOUS DISEASE PROPHYLAXIS

- **Cotrimoxazole** (antibacterial prophylaxis)
- **Acyclovir** 400 mg/day or Valacyclovir (viral prophylaxis)
- Vaccinations always recommended:
  - **Pneumococcal**
  - **Zoster**
  - **Influenza**
  - **COVID-19**
- In patients with previous infections, COPD, or transplant history:
  Meningococcal and **Haemophilus** influenzae type b (Hib) vaccines should also be considered
- Other recommended vaccines and tests:
  RSV (Respiratory Syncytial Virus), **HBV** (Hepatitis B) with assessment of the HBV antibody profile,
  and baseline serologic **testing for CMV** (Cytomegalovirus)

❖ **Quantiferon:** testing for latent tuberculosis infection (LTBI) is recommended for all patients before starting treatment with bispecific antibodies.

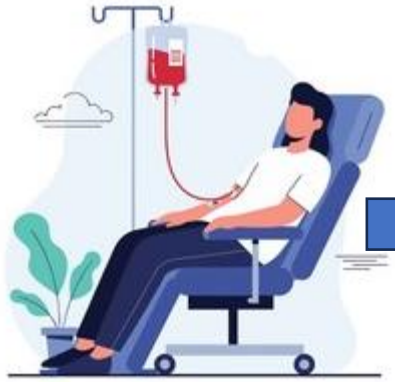
- **Immunoglobulins (Ig):**

❖ hypogammaglobulinemia <400 mg/dL
❖ recurrent infections of grade 3 or higher

Immunoglobulins to all patients as infectious prophylaxis as common opinion

Initial administration and step-up dosing phase

Scheda di avvio e fasi di SUD in Day Hospital	
Data di avvio SUD:	Data successiva SUD:
Premedicazione	Tocilizumab: si no
Parametri pre-infusione Temperatura Frequenza cardiaca Saturazione Pressione arteriosa	Parametri post-infusione Temperatura Frequenza cardiaca Saturazione Pressione arteriosa
Sintomi da neurotossicità:	(in caso di segni o sintomi legati alla infu paziente non sarà dimesso)
Eventuali azioni intraprese	
Paziente dimesso:	Paziente ricoverato:
Alla dimissione: Caregiver Saturimetro Termometro Sfigmomanometro Paracetamolo Desametasone	



- ❖ Assessment of parameters
- ❖ Premedication (Tocilizumab 8 mg/kg) 4-1 hours before
- ❖ monitoring

Scheda di avvio e fasi di SUD in Day Hospital	
Data di avvio SUD:	Data successiva SUD:
Premedicazione	Tocilizumab: si no
Parametri pre-infusione Temperatura Frequenza cardiaca Saturazione Pressione arteriosa	Parametri post-infusione Temperatura Frequenza cardiaca Saturazione Pressione arteriosa
Sintomi da neurotossicità:	(in caso di segni o sintomi legati alla infusione il paziente non sarà dimesso)
Eventuali azioni intraprese	
Paziente dimesso:	Paziente ricoverato:
Alla dimissione: Caregiver Saturimetro Termometro Sfigmomanometro Paracetamolo Desametasone	

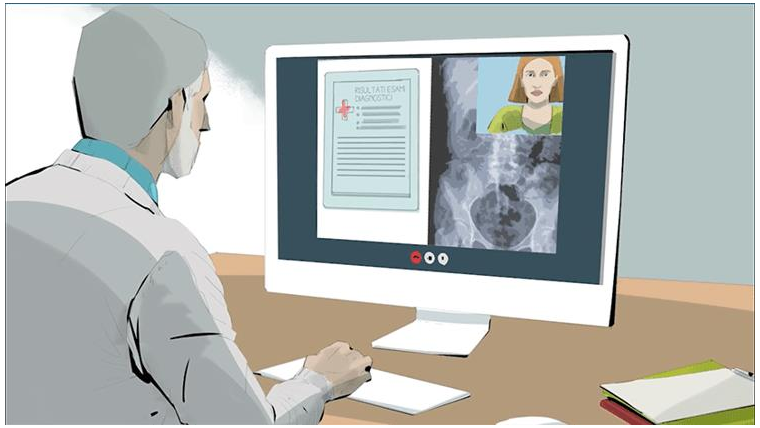
- ❖ Observation and
- ❖ eligibility for discharge

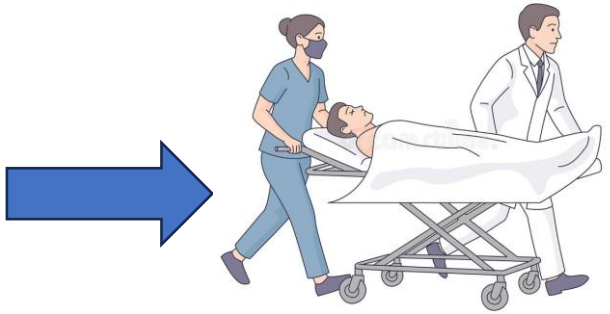
- ➢ drug administration in a controlled outpatient and/or Day Hospital setting
- ➢ close monitoring for acute CRS/ICANS toxicities;
- ➢ assessment of eligibility for protected discharge and follow-up (monitoring of vital signs and level of consciousness)

EmaBisOUT: Transition to a digitally assisted outpatient regimen

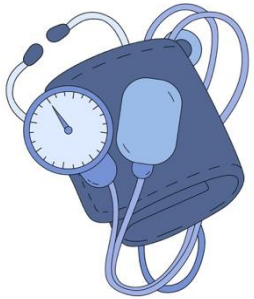
Scheda di avvio e fasi di SUD in Day Hospital	
Data di avvio SUD:	Data successiva SUD:
Premedicazione	Tocilizumab: si no
Parametri pre-infusione Temperatura Frequenza cardiaca Saturazione Pressione arteriosa	Parametri post-infusione Temperatura Frequenza cardiaca Saturazione Pressione arteriosa
Sintomi da neurotossicità:	(in caso di segni o sintomi legati alla infusione il paziente non sarà dimesso)
Eventuali azioni intraprese	
Paziente dimesso:	Paziente ricoverato:
Alla dimissione: Caregiver Saturimetro Termometro Sfigmomanometro Paracetamolo Desametasone	

❖ eligibility for discharge





❖ Potential hospital readmission

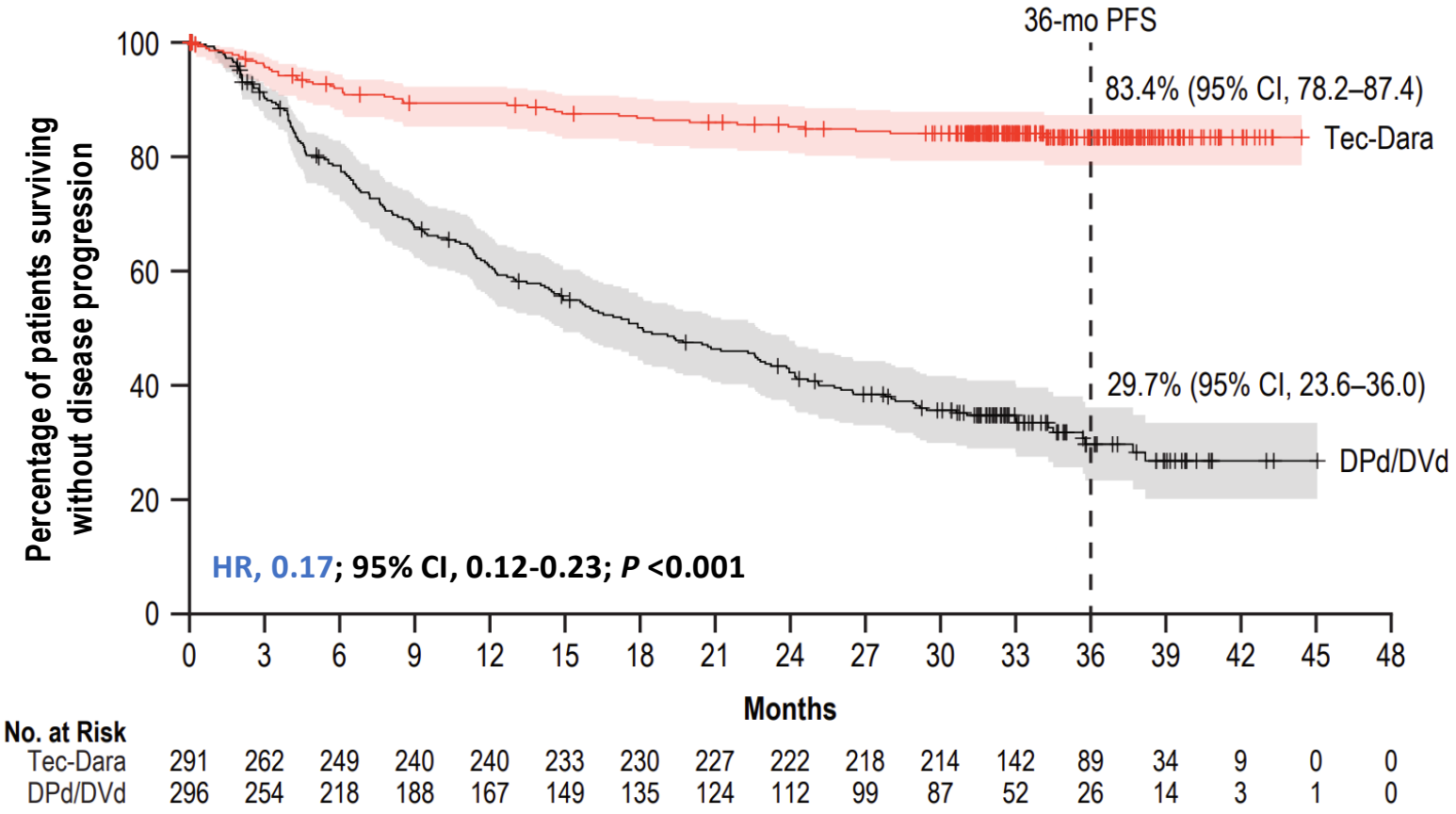


Monitoring supported by scheduled telemedicine visits and, when necessary, on-demand teleconsultations monitoring of body temperature, blood pressure, heart rate, and oxygen saturation through the provision of devices for home use.

MajesTEC-3 is a randomized, phase 3 study evaluating Tec-Dara versus investigator's choice of DPd/DVd in patients with RRMM and with 1 to 3 prior LOTs[13]

PFS

- **Median follow-up: 34.5 months**
- Median PFS was NR for Tec-Dara versus 18.1 months for DPd/DVd



From The New England Journal of Medicine, Costa LJ, et al., Teclistamab plus Daratumumab in Relapsed or Refractory Multiple Myeloma, doi: 10.1056/NEJMoa2514663.

Tec-Dara significantly improved PFS versus DPd/DVd, with 83% of patients in the Tec-Dara group alive and progression free at 3 years

CI, confidence interval; Dara, daratumumab; DPd/DVd, daratumumab and dexamethasone with either pomalidomide or bortezomib; HR, hazard ratio; NR, not reached; PFS, progression-free survival; Tec, teclistamab.
Costa LJ, et al. *N Engl J Med*. DOI: 10.1056/NEJMoa2514663.

frontiers | Frontiers in Immunology

TYPE Original Research
PUBLISHED 10 June 2024
DOI 10.3389/fimmu.2024.1405452

OPEN ACCESS

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RECEIVED 22 March 2024
ACCEPTED 24 May 2024
PUBLISHED 10 June 2024

Clinician and administrator perspectives on outpatient administration of ciltacabtagene autoleucel in relapsed or refractory multiple myeloma

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