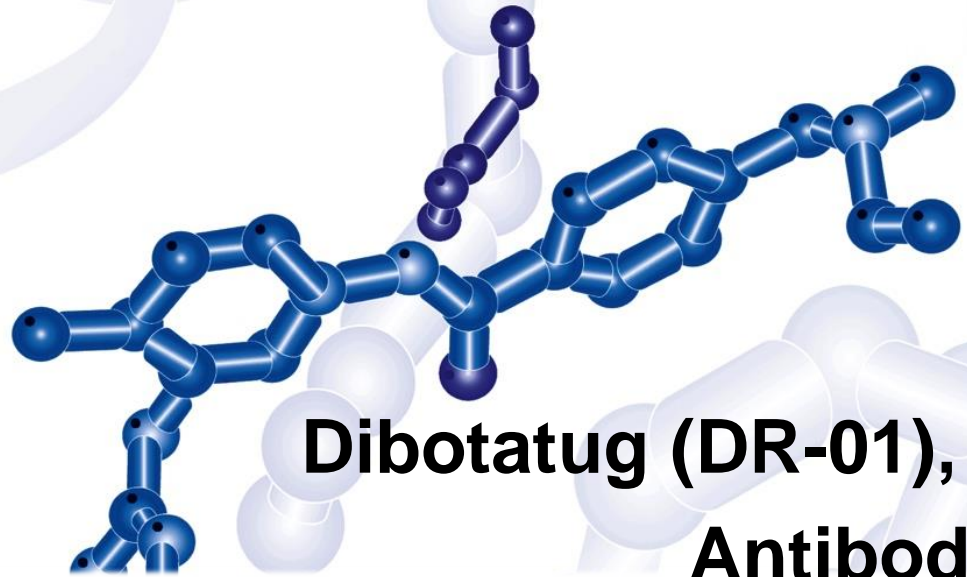




ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA
DIPARTIMENTO DI
SCIENZE MEDICHE E CHIRURGICHE

POLICLINICO DI
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EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Bologna



Dibatatug (DR-01), a Anti-CD94 Antibody

Dr. Swami Iyer,
UT MD Anderson Cancer Center

New Drugs in Hematology

President: Pier Luigi Zinzani

**Bologna,
Royal Hotel Carlton
May 18-19-20, 2026**

BOLOGNA BOLOGNA, ROYAL HOTEL CARLTON



Dibotatug (DR-01), a
Nonfucosylated
Anti-CD94 Antibody, in
Patients with
Relapsed/Refractory Cytotoxic
Lymphomas (CTL) and Large
Granular Lymphocytic
Leukemias (LGLL)

Dr. Swami Iyer
Professor of Lymphoma/Myeloma

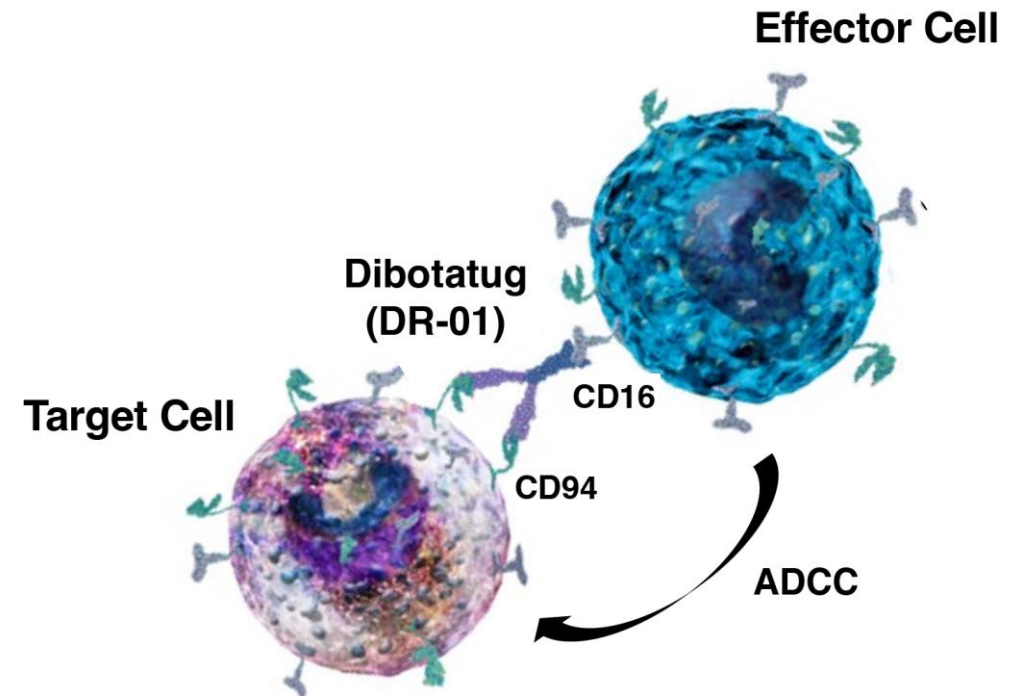
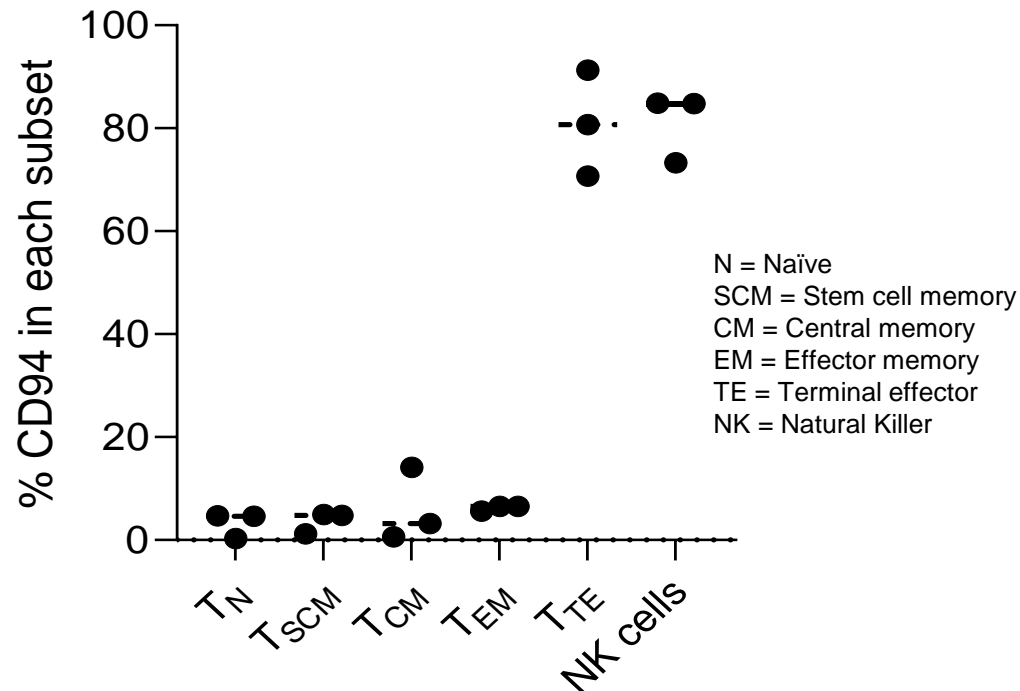


Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
CRISPR	✓					✓	
MERCK	✓						
PFIZER	✓					✓	
YINGLI	✓					✓	
ACROTECH	✓					✓	
INNATE	✓						
TRILLIUM	✓						
ASTRA ZENECA	✓						
ONO	✓						
LEGEND	✓						
SALARIUS			✓				
SECURA BIO						✓	
IMPART.AI				✓			Co-Founder

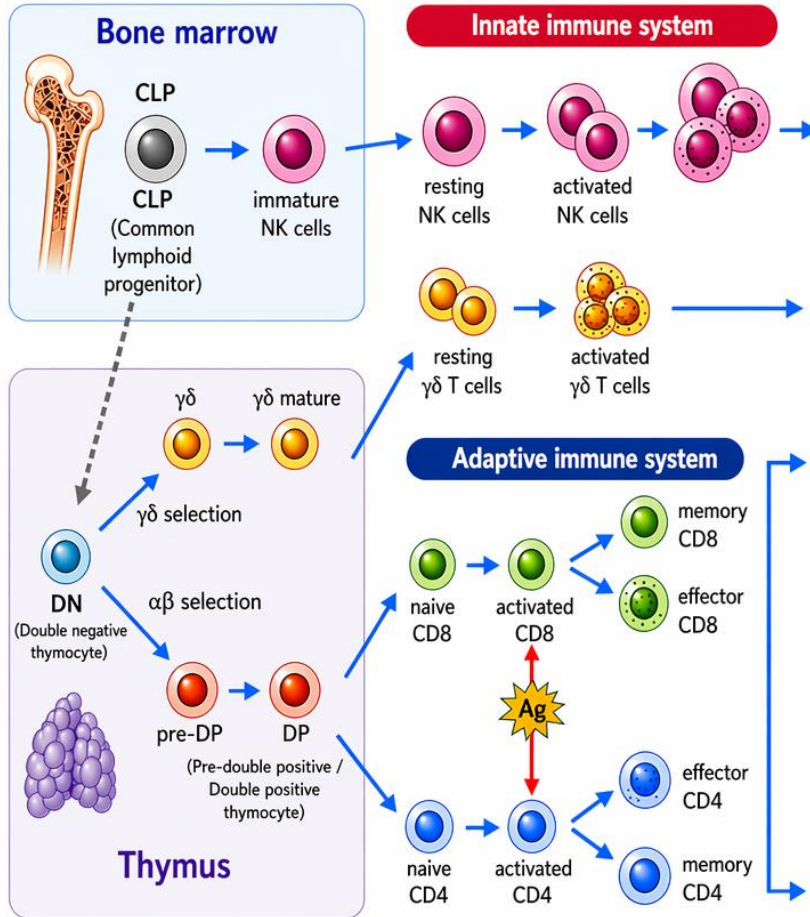
Dibotatug (DR-01) is a non-fucosylated IgG antibody targeting CD94

- Non-fucosylated IgG antibody targeting CD94 expressed on terminal effector CD8⁺ T subsets, and NK cells
- Dibotatug engages Fc-gamma receptors, such as CD16a and triggers antibody-dependent cellular cytotoxicity (ADCC) by effector cells, resulting in rapid target cell depletion

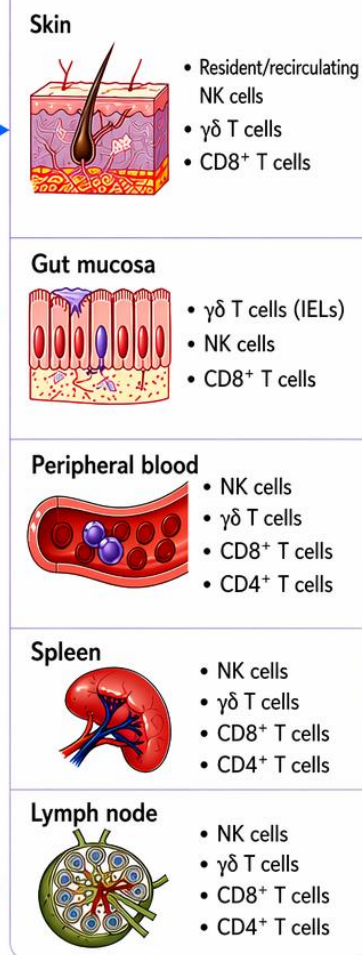
CD94 expression on CD8 T cell subsets and NK cells in healthy donor PBMCs



CELL DEVELOPMENT & MATURATION



TISSUE DISTRIBUTION



CYTOTOXIC T CELL LYMPHOMA SUBTYPES

Lymphoma subtype	Immunophenotype (Typical)	Primary site / Tissue tropism
Extranodal NK/T cell lymphoma, nasal type	CD56 ⁺ cytoplasmic CD3 ϵ ⁺ EBER ⁺ (in situ hybridization ⁺)	Upper aerodigestive tract (nasal cavity, nasopharynx, oropharynx, etc.)
Primary cutaneous $\gamma\delta$ T cell lymphoma (PCGD-TCL)	$\gamma\delta$ TCR ⁺ CD3 ⁺ , CD56 ⁻	Skin
Enteropathy-associated T cell lymphoma (EATL)/MEITL	$\gamma\delta$ TCR ⁺ CD3 ⁺ , CD8 $\alpha\alpha$ ⁺ , CD56 ⁻	Small intestine (mucosal epithelium, lamina propria)
Hepatosplenic T cell lymphoma (HSTCL)	$\alpha\beta$ TCR ⁺ CD3 ⁺ , CD8 $\alpha\beta$ ⁺ , CD56 ⁻	Liver, spleen, bone marrow, peripheral blood
Cytotoxic peripheral T cell lymphoma, NOS	$\alpha\beta$ TCR ⁺ CD3 ⁺ , CD8 ⁺ , TIA-1 ⁺ , Granzyme B ⁺ , Perforin ⁺	Lymph nodes, peripheral blood, multiple extranodal sites

CD94 uniting target for cytotoxic T cell

Note: Each color represents a unique COO or subtype.

Cytotoxic NK/T-cell lymphomas are rare and have a high unmet need

- Group of rare lymphoma subtypes (<15% of non-Hodgkin lymphoma)¹
- Characterized by cytotoxic cells expressing CD94
- Patients with relapsed/refractory (R/R) CTLs have no established treatment options and very poor outcomes
- Median overall survival (mOS) <1 year in newly diagnosed HSTCL, EATL, and ENKTL patients²
- mOS <6 months in relapsed/refractory (R/R) ENKTL³

Cytotoxic Lymphoma Histologies

ENKTL, nasal type

ET-CTCL

EATL

ANKL

MEITL

HVLPD

HSTCL

PTCL-NOS*

SPTCL

Cutaneous PTCL-NOS*

PC $\gamma\delta$ TCL

*Requiring additional markers such as CD8 or CD56, and/or cytotoxicity (granzyme B, TIA1, perforin); ANKL: aggressive NK leukemia; EATL: enteropathy-associated TCL; ENKTL: extranodal NK/TCL; ET-CTCL: epidermotropic cytotoxic TCL; HSTCL: hepatosplenic TCL; HVLPD: Hydroa vacciniforme-like lymphoproliferative disorder; MEITL: monomorphic epitheliotropic intestinal TCL; PC $\gamma\delta$ TCL: primary cutaneous $\gamma\delta$ TCL; PTCL-NOS: peripheral TCL, not otherwise specified; SPTCL: subcutaneous panniculitis-like TCL; TCL: T-cell lymphoma

1. Lymphoma Research Foundation. T-cell lymphoma fact sheet 2025. https://lymphoma.org/wp-content/uploads/2025/08/T-Cell-Lymphoma-Guide_2025.pdf
2. Vose et al. J Clin Oncol 2008;26:4124-4130.
3. Bellei M et al. Haematologica 2018;103:1191-1197

First-in-Human Phase 1/2 Study Design

Study Design

- Phase 1/2, open-label dose-escalation/extension and optimization (NCT05475925)

Objectives

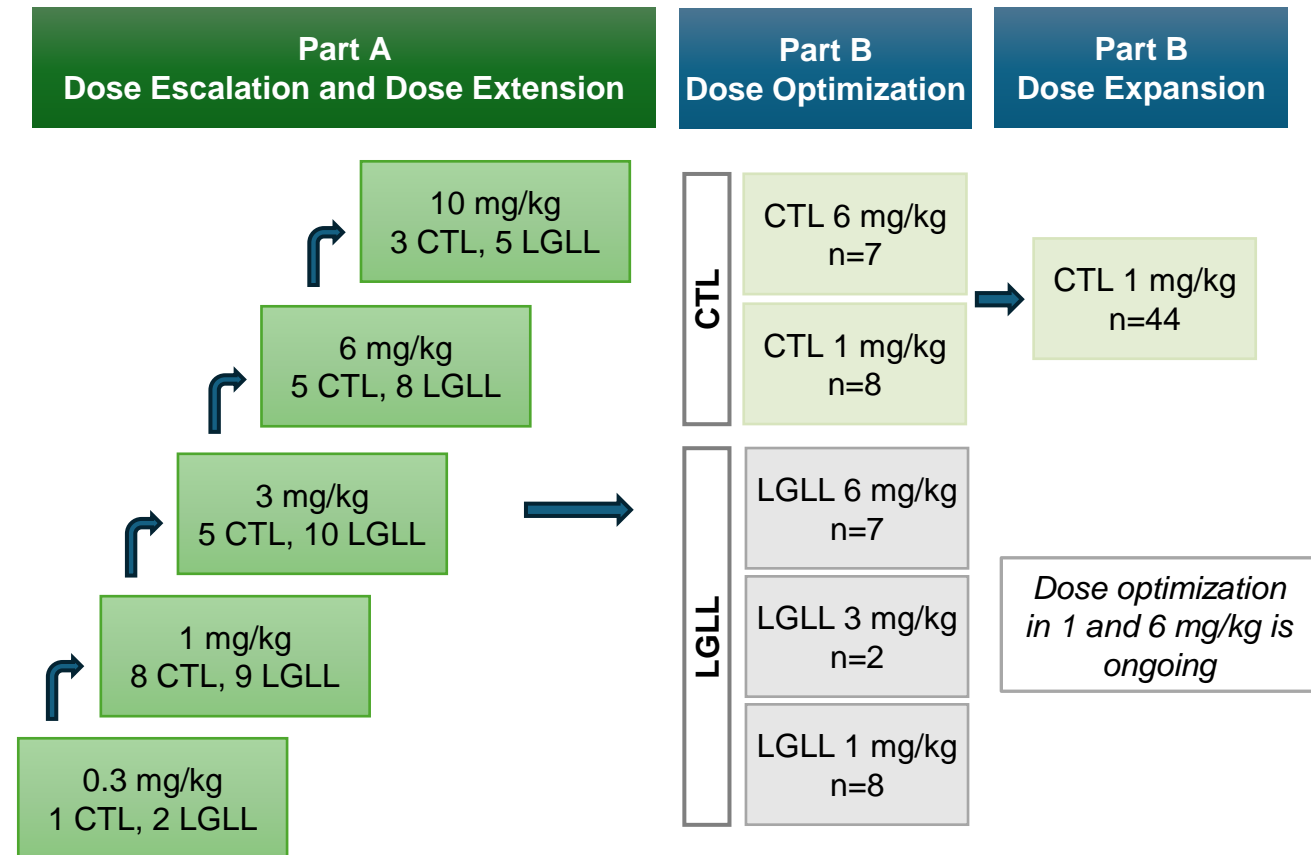
- Safety, pharmacokinetics (PK), pharmacodynamics, and initial efficacy in R/R CTL patients according to Lugano (2014), Olsen (2022), or mTPLL (2019) criteria, depending on histology and cutaneous/leukemic involvement

Patient Population

- R/R CTL
- Adequate organ function, ECOG PS 0-1
- Part A: ≥ 2 prior lines of therapy; Part B: ≥ 1 prior line of therapy

Dosing

- Dose escalation (0.3–10 mg/kg) administered IV
- Induction regimens of C1D1/D15 (primary), C1D1/D8/D15 (secondary), or C1D1-D5/D15 (tertiary) – *data for primary/secondary regimens are presented*
- Maintenance dose once every 28 days, following induction

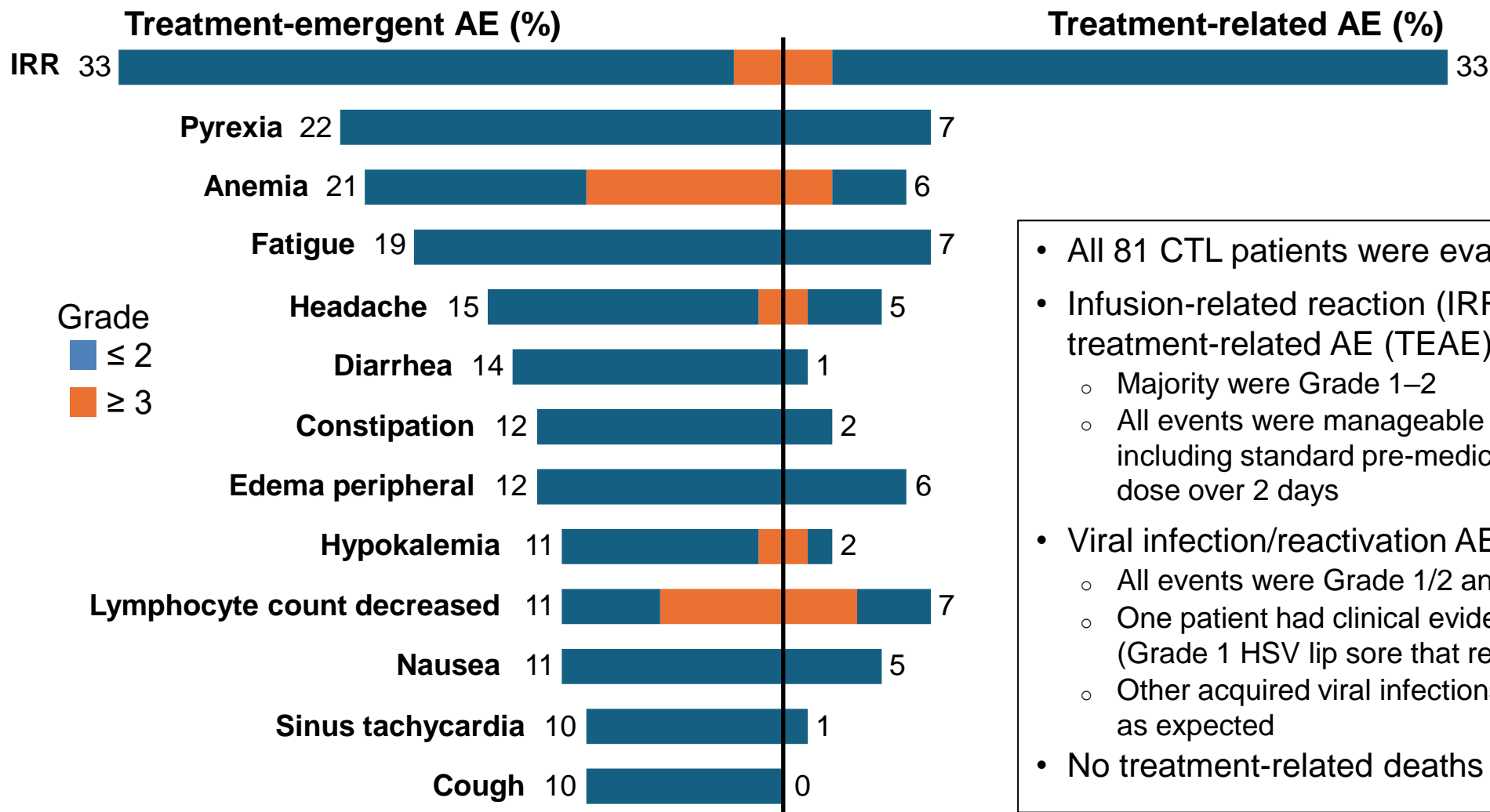


CTL: Baseline Demographics and Characteristics

	0.3 mg/kg (n=1)	1 mg/kg (n=60)	3 mg/kg (n=5)	6 mg/kg (n=12)	10 mg/kg (n=3)	Total (N=81)
Age, median (range)	53	53 (18–82)	61 (46–71)	48 (26–81)	59 (23–74)	53 (18–82)
Male, n (%)	1 (100)	36 (60)	3 (60)	4 (33)	1 (33)	45 (56)
Race, n (%)						
White	1 (100)	31 (52)	4 (80)	5 (42)	2 (67)	43 (53)
Black or African Am.	0	4 (7)	0	1 (8)	1 (33)	6 (7)
Asian	0	16 (27)	0	3 (25)	0	19 (24)
American Indian	0	1 (2)	0	0	0	1 (1)
Native Hawaiian	0	0	1 (20)	0	0	1 (1)
Other / Unknown	0	8 (13)	0	3 (25)	0	11 (14)
ECOG PS, n (%)						
0 / 1	0 / 1 (100)	31 (52) / 29 (48)	2 (40) / 3 (60)	4 (33) / 8 (67)	1 (33) / 2 (67)	38 (47) / 43 (53)
CTL histology, n (%)						
PCγδTCL	0	11 (18)	0	3 (25)	2 (67)	16 (20)
PTCL-NOS (nodal)	0	8 (13)	2 (40)	2 (17)	0	11 (14)
PTCL-NOS (cutaneous)	0	4 (7)	0	0	0	4 (5)
SPTCL	0	5 (8)	0	2 (17)	0	7 (9)
ENKTL	0	17 (28)	1 (20)	1 (8)	0	19 (24)
MEITL	0	5 (8)	1 (20)	2 (17)	0	8 (10)
ET-CTCL	1 (100)	4 (7)	1 (20)	1 (8)	0	7 (9)
HSTCL	0	5 (8)	0	0	1 (33)	6 (7)
EATL	0	1 (2)	0	0	0	1 (1)
Other: NKTCL	0	0	0	1 (8)	0	1 (1)
No. prior LoT, median (range)	8 (8–8)	2 (1–14)	5 (2–7)	3 (1–6)	4 (2–9)	3 (1–14)
Reason for discontinuation from last therapy, n (%)						
Lack of response	1 (100)	23 (38)	2 (40)	5 (42)	2 (67)	33 (41)
Intolerance	0	2 (3)	1 (20)	3 (25)	0	6 (7)
Prior autologous or allogeneic HSCT, n (%)	0	8 (13)	3 (60)	2 (17)	0	13 (16)

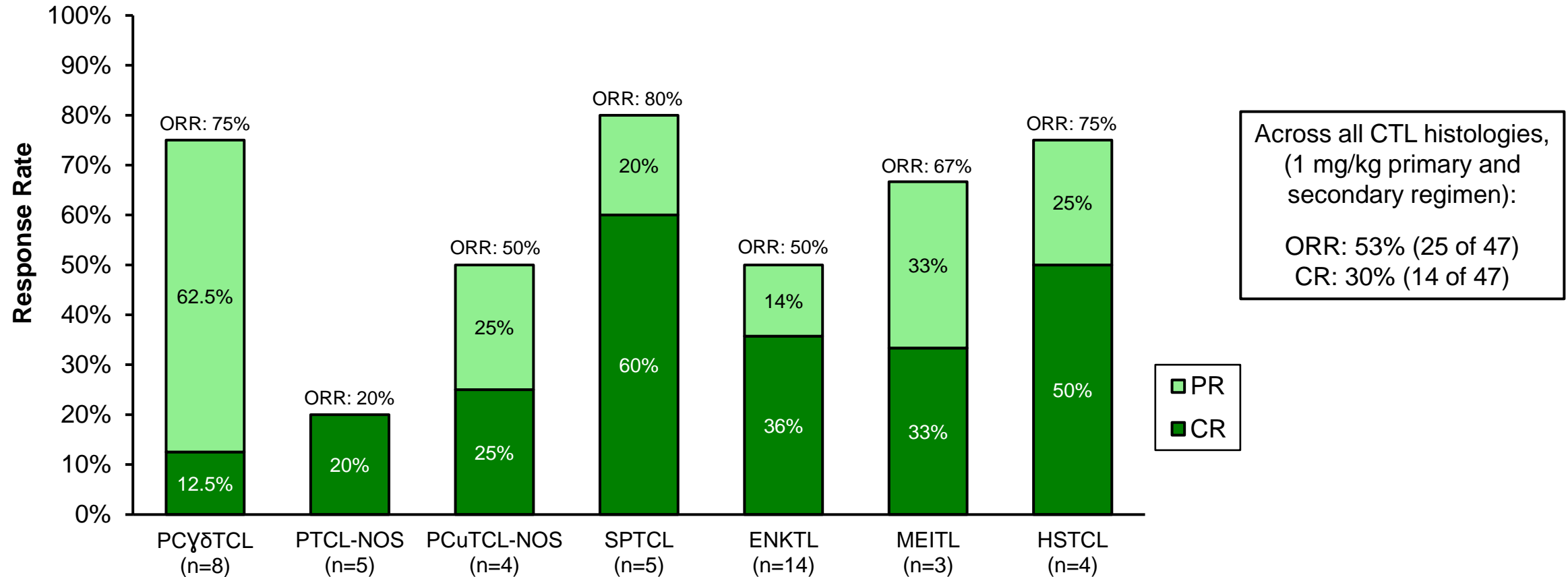
Data cutoff: 17 Oct 2025. LoT, lines of therapy; HSCT, hematopoietic stem cell transplant

CTL: Most Common ($\geq 10\%$) Adverse Events (AEs)



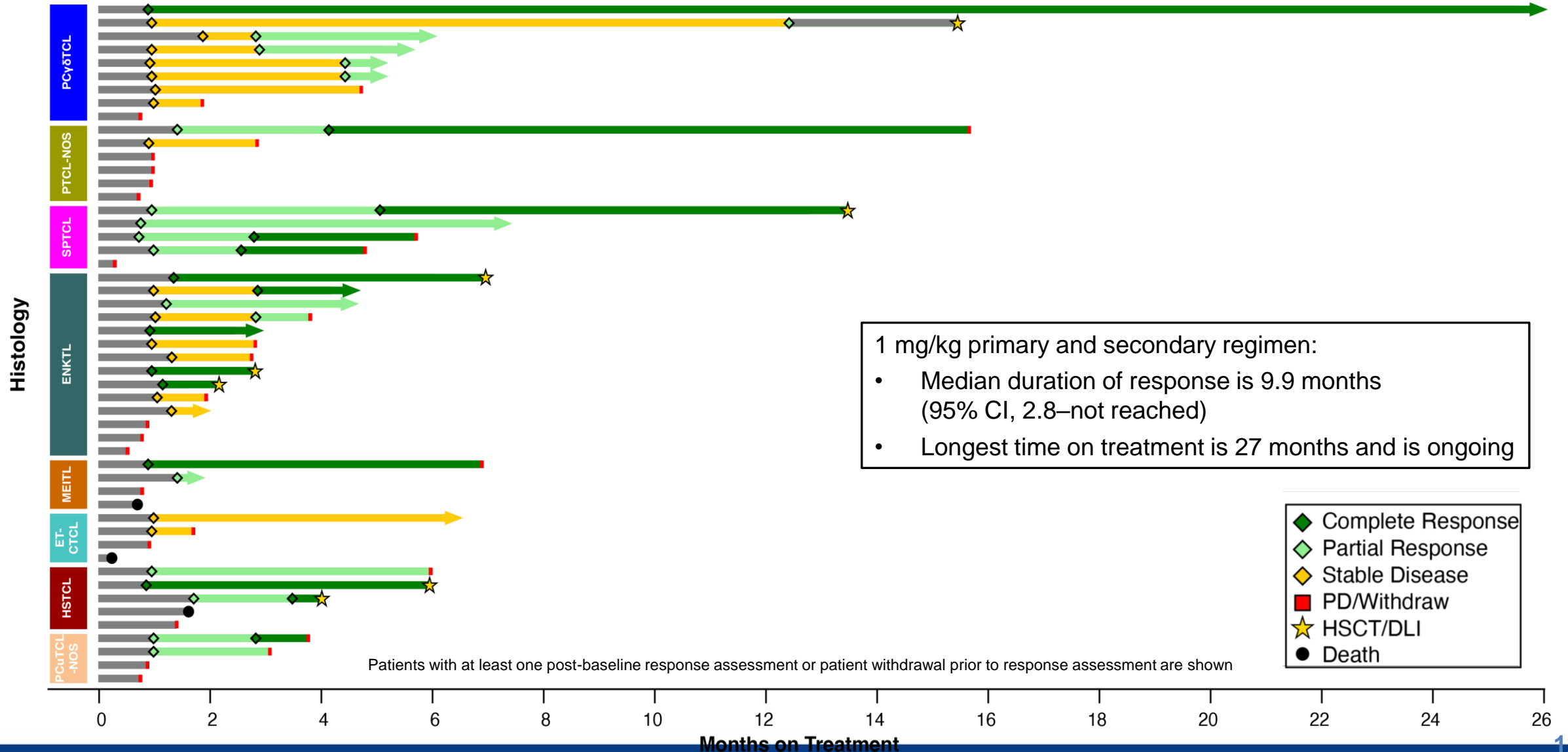
- All 81 CTL patients were evaluable for safety
- Infusion-related reaction (IRR) is the most common treatment-related AE (TEAE)
 - Majority were Grade 1–2
 - All events were manageable with mitigation strategies including standard pre-medications and splitting the initial dose over 2 days
- Viral infection/reactivation AEs
 - All events were Grade 1/2 and non-serious (n=5)
 - One patient had clinical evidence of viral reactivation (Grade 1 HSV lip sore that resolved)
 - Other acquired viral infections (e.g. COVID-19) resolved as expected
- No treatment-related deaths were observed

CTL: Promising Responses with CRs across Multiple Histologies



ORR: Overall response rate (CR+PR)
Only histologies with at least 1 response of PR or better are represented

CTL: Swimlane plot of patients receiving target dose of 1 mg/kg

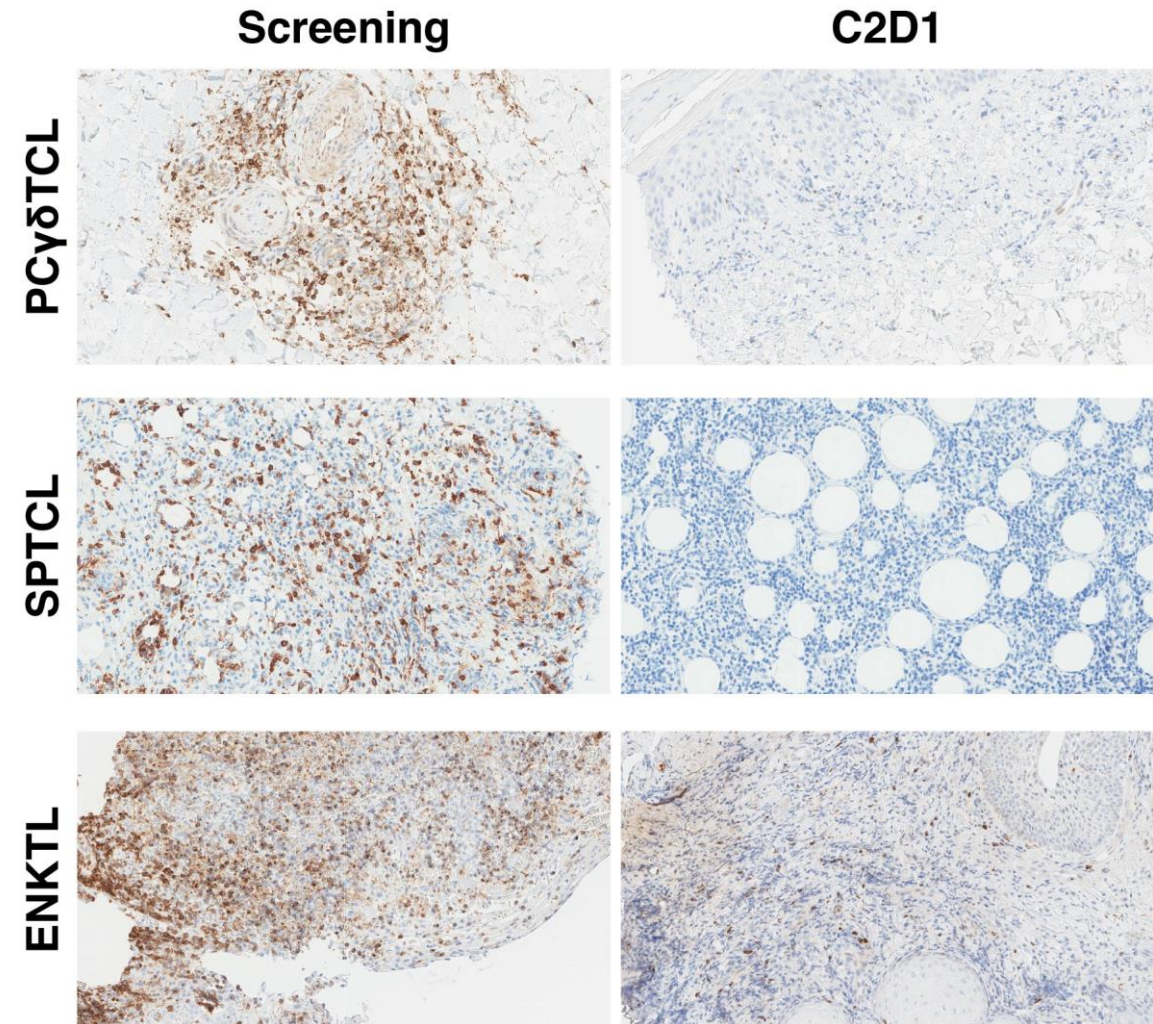
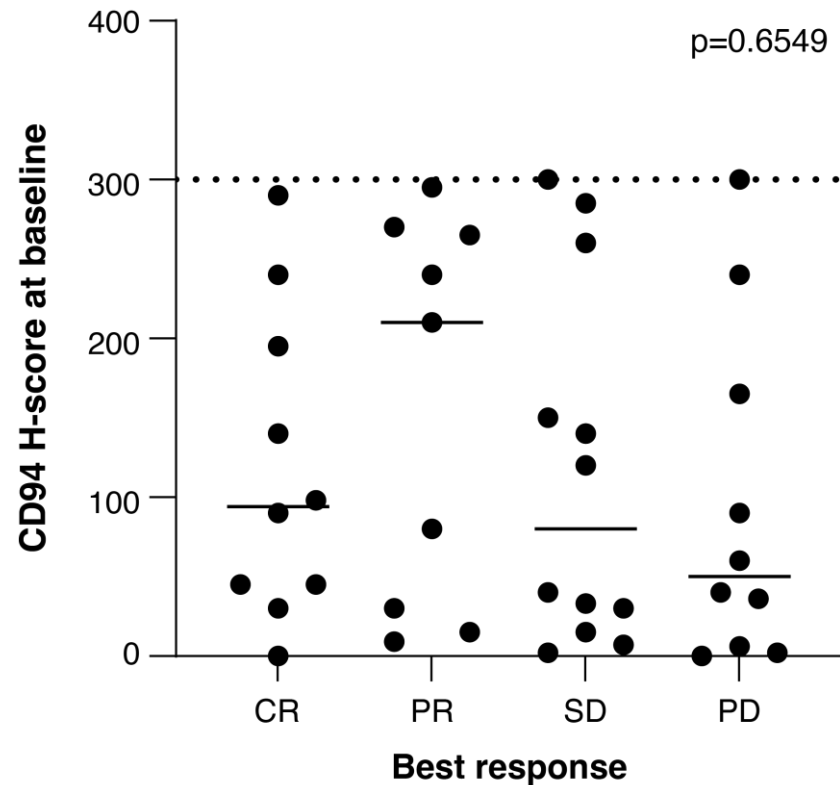


CTL: Near universal CD94 expression across CTL histologies

Histology	CD94+ by IHC		Total % positive	Median H-score (IQR)
	DR-01-ONC-001 samples	Sourced Samples*		
PC $\gamma\delta$ TCL	10/10	5/5	15/15 (100%)	45 (250)
PTCL-NOS (nodal, CD8+, $\gamma\delta$ +)	7/7	-	7/7 (100%)	15 (39)
PTCL-NOS (cutaneous)	2/3	6/6	8/9 (89%)	60 (222)
ENKTL	8/8	16/18	24/26 (92%)	180 (139)
MEITL	2/2	-	2/2 (100%)	218 (NA)
ET-CTCL	7/7	2/2	9/9 (100%)	33 (94)
SPTCL	5/5	11/11	16/16 (100%)	68 (54)
HSTCL	1/2	-	1/2 (50%)	148 (NA)
Total	42/44 (95%)	40/42 (95%)	82/86 (95%)	

*Sourced samples from Samsung Medical Center and Stanford Cancer Center

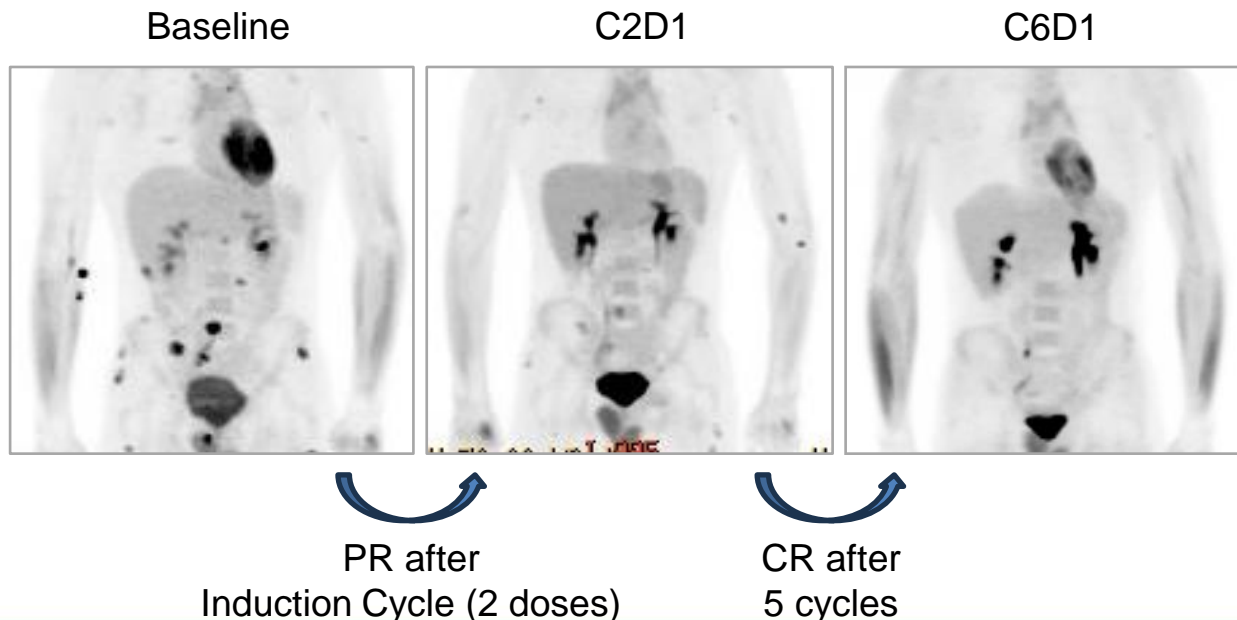
CTL: Clinical responses are observed independent of baseline CD94 expression level, and CD94⁺ cells are depleted on therapy



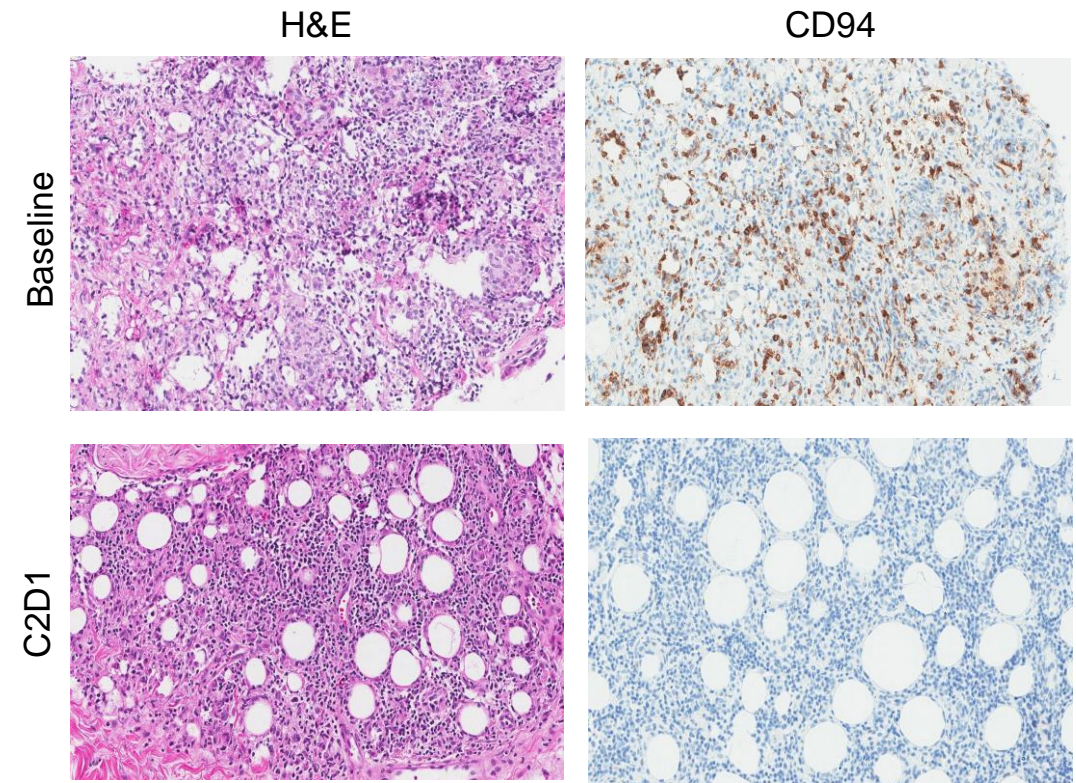
Case Study: R/R Subcutaneous Panniculitis-like TCL in CR

- 19 yo M who received 4 prior lines of therapy, including corticosteroids, cyclosporine, MTX and romidepsin
- Patient achieved a PR after the first cycle which deepened to a CR after 5 cycles
- After 14 cycles on dibotatug, the patient received an allogeneic HSCT and remains in remission an additional 23 months later

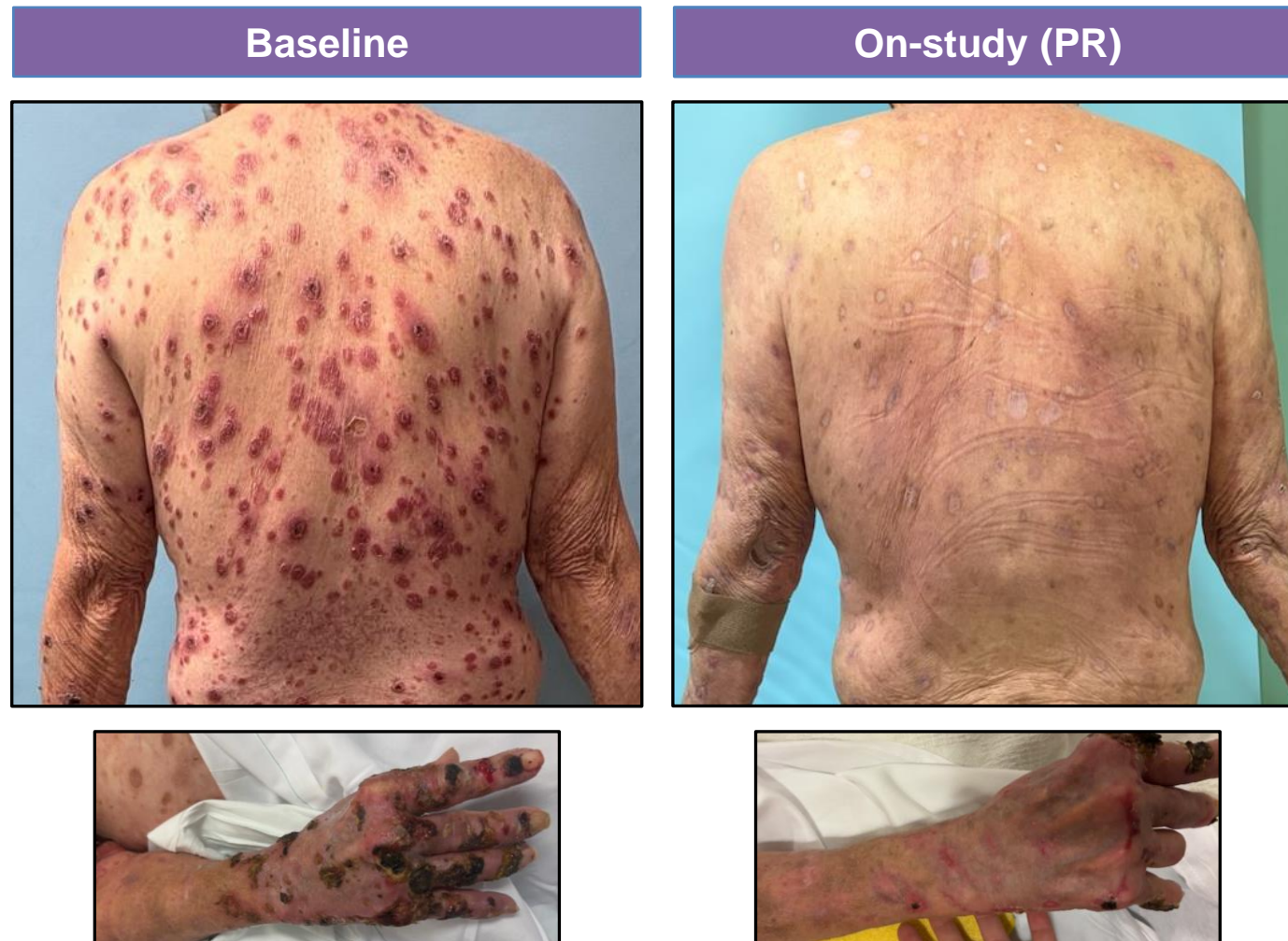
Response Assessment by PET



Depletion of CD94+ Cells by C2D1



Case Study: Achievement of a PR in PC γ δ TCL is Clinically Meaningful



- 75 yo M who was initially diagnosed in 2021 with T3BN0M0 primary cutaneous gamma-delta T-cell lymphoma (PC γ δ TCL) and was previously treated with pralatrexate
- Initiated study treatment with dibotatug in May 2025 with a baseline mSWAT of 90
- Initial response of SD at C2 and then achieved a PR at C6.
- Patient remains on study in a durable PR at C13 (last mSWAT of 4)

LGLL: Baseline patient demographics and disease characteristics

	0.3 mg/kg (n=2)	1 mg/kg (n=18)	3 mg/kg (n=12)	6 mg/kg (n=15)	10 mg/kg (n=5)	Total (N=52)
Age, median (range)	70 (64–75)	58 (31–82)	63 (52–86)	66 (24–82)	71 (45–86)	64 (24–86)
Male, n (%)	2 (100)	14 (78)	7 (58)	8 (53)	4 (80)	35 (67)
Race, n (%)						
White	1 (50)	15 (83)	10 (83)	12 (80)	4 (80)	42 (81)
Black or African-American	1 (50)	0	0	0	0	1 (2)
Asian	0	1 (6)	2 (17)	2 (13)	0	5 (10)
ECOG performance status, n (%)						
0 / 1 / 2	0 / 2 (100) / 0	6 (33) / 11 (61) / 1 (6)	5 (42) / 6 (50) / 1 (8)	5 (33) / 9 (60) / 1 (7)	1 (20) / 3 (60) / 1 (20)	17 (33) / 31 (60) / 4 (8)
LGLL subtype, n (%)						
T-LGLL / NK-LGLL	2 (100) / 0	16 (89) / 2 (11)	11 (92) / 1 (8)	14 (93) / 1 (7)	5 (100) / 0	48 (92) / 4 (8)
Primary indications for treatment, n (%)						
Neutropenia (ANC <500/ μ L)	1 (50)	9 (50)	3 (25)	4 (27)	2 (40)	19 (37)
Neutropenia with recurrent infections	0	1 (6)	0	4 (27)	0	5 (10)
Transfusion-dependent anemia	1 (50)	4 (22)	5 (42)	5 (33)	3 (60)	18 (35)
Symptomatic anemia (Hgb < 10 g/dL)	0	4 (22)	4 (33)	2 (13)	0	10 (19)
Median prior lines of therapy, n (range)	3 (1–4)	2 (1–10)	3 (1–9)	1 (1–10)	3 (2–6)	2 (1–10)
Prior therapies, n (%)						
Methotrexate	2 (100)	16 (89)	11 (92)	12 (80)	5 (100)	46 (89)
Cyclophosphamide	1 (50)	9 (50)	5 (42)	5 (33)	5 (100)	25 (48)
Cyclosporine	0	6 (33)	8 (67)	6 (40)	3 (60)	23 (44)
Alemtuzumab	0	1 (6)	2 (17)	3 (20)	0	6 (12)
Other (including investigational agents)	2 (100)	7 (39)	6 (50)	11 (73)	2 (40)	28 (54)

Data cut-off 17Oct2025. Note: Two subjects re-enrolled and are represented twice.

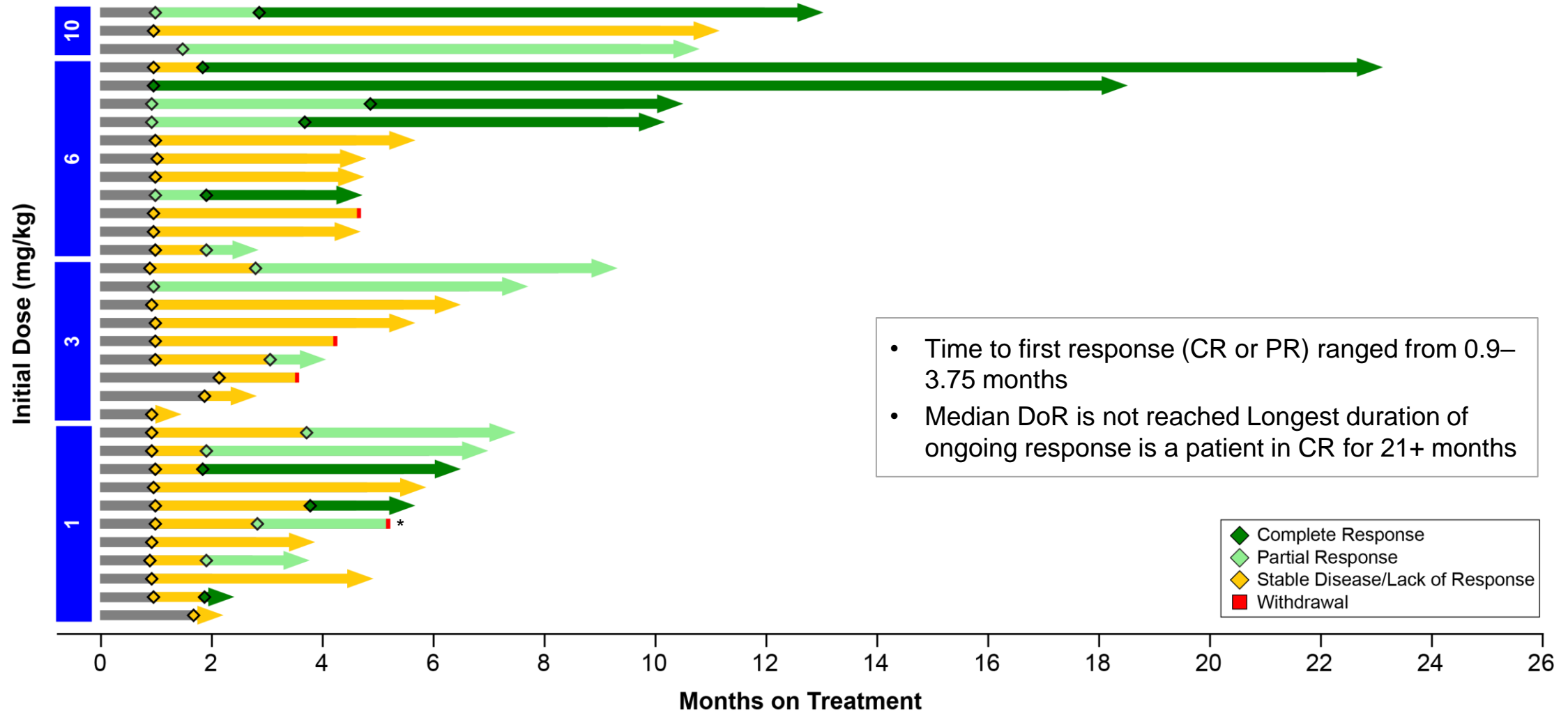
LGLL: Dibotatug shows promising response rates across dose levels (1–10 mg/kg) in R/R patients

n (%)	0.3 mg/kg (n=2)	1 mg/kg (n=13)	3 mg/kg (n=12)	6 mg/kg (n=12)	10 mg/kg (n=4)	Total (n=43)	n (%)	Secondary Induction (n=35)
ORR,	0	8 (62%)	3 (25%)	7 (58%)	2 (50%)	20 (47%)	ORR,	19 (54%)
CR	0	4 (31%)	0	6 (50%)	1 (25%)	11 (26%)	CR	10 (29%)
PR	0	4 (31%)	3 (25%)	1 (8%)	1 (25%)	9 (21%)	PR	9 (26%)
SD/LOR	2 (100%)	5 (38%)	9 (75%)	5 (42%)	2 (50%)	23 (53%)	SD/LOR	16 (46%)

- Of 43 response-evaluable patients, **ORR was 47% (CR 26%) across dose levels and induction regimens**
 - Of the 35 patients who received the secondary induction regimen (C1D1/D2, D8 and D15) which has been selected for further evaluation, the **ORR was 54% (CR 29%)**
- CRs were observed in patients with primary indications for treatment of neutropenia and anemia; were also observed in both T-LGLL and NK-LGLL

Evaluable patients include those who received dibotatug (primary or secondary induction regimen) and had at least 1 post-baseline response assessment. ECOG E5998 (Loughran 2015) criteria was used for response assessment; For CRs, all parameters (hemoglobin ≥ 11 g/dL, ANC $> 1500/mm^3$, platelet count $\geq 100,000/mm^3$ and LGLL count $< 760/mm^3$) must have been sustained for at least 4 weeks. For PRs, response must have been maintained for 4 weeks, except for transfusion-dependent patients who must have had sustained response for ≥ 2 months.

LGLL: Responses are Durable

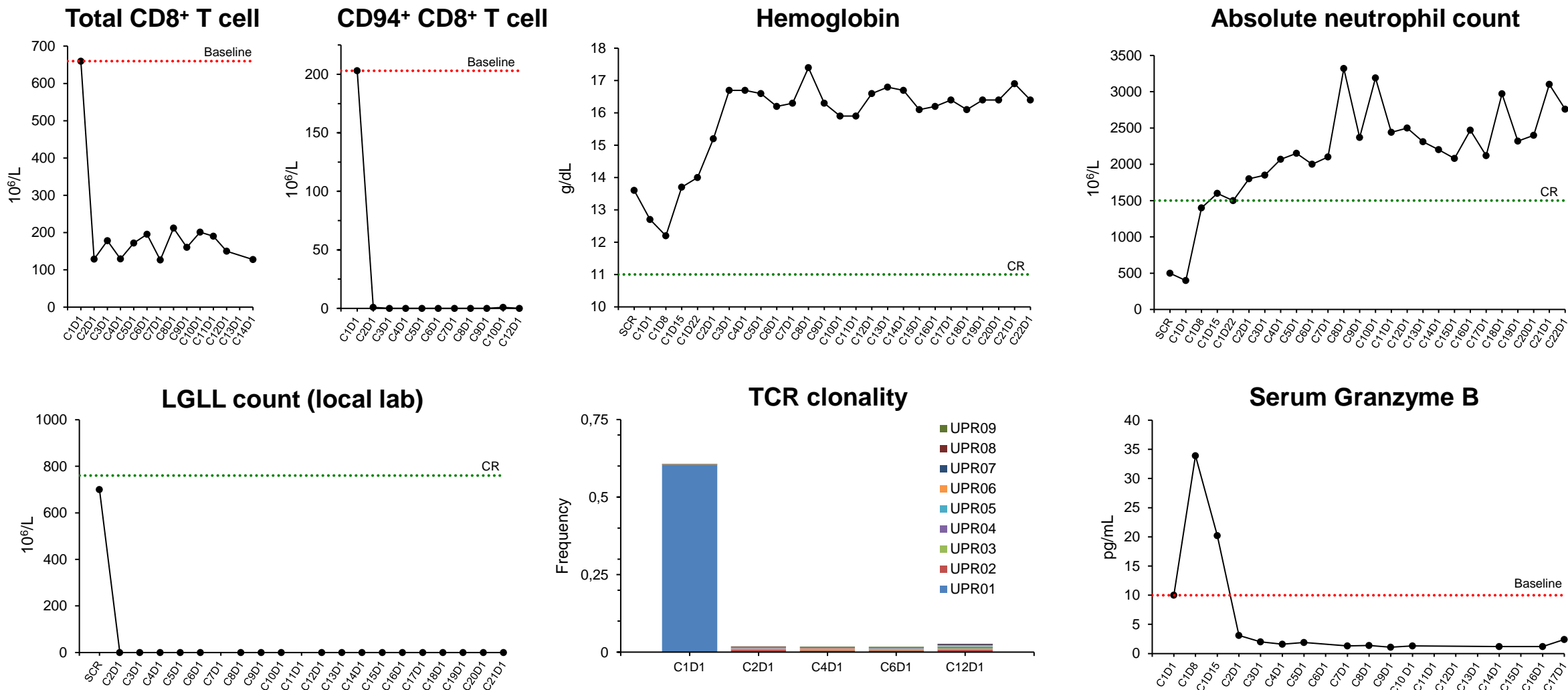


- Time to first response (CR or PR) ranged from 0.9–3.75 months
- Median DoR is not reached Longest duration of ongoing response is a patient in CR for 21+ months

◆ Complete Response
◆ Partial Response
◆ Stable Disease/Lack of Response
■ Withdrawal

Only subjects receiving secondary regimen with at least one post-baseline response assessment entered are shown (one subject on 6 mg/kg not shown due to data entry)
 *Discontinued in PR due to worsening comorbidities unrelated to study drug

Case Study: 67 yo M with T-LGLL who previously received MTX, CTX, tofacitinib and CsA in CR with rapid improvement in cytopenias and depletion of the dominant TCR clone



Conclusions

- Dibotatug (DR-01) continues to demonstrate promising safety and efficacy, supporting its development as a potential treatment option for CTL and LGLL
- IRR is the most common treatment-related AE; typically occurring during first dose and manageable with standard mitigation strategies
- For CTL, the 53% ORR with high proportion of CRs across multiple CTL histologies
- Biomarker analyses show that CD94 has near universal expression (95%) across CTL samples. Preliminary data suggest that patients with CTL may benefit from dibotatug regardless of baseline CD94 expression by IHC
- For LGLL, dibotatug shows encouraging efficacy in both previously treated T- and NK-LGLL with durable responses, including depletion of LGLL cells and dominant TCR clone
- Phase 2 is ongoing and continues to enroll patients globally, including treatment-naïve LGLL patients in the US

T Cell Lymphoma Group



Lymphoma:

- Dr.Jeff Medeiros
- Dr.Francisco Vega
- Dr.Roberto Miranda
- Dr.Carlos Torres-Cabala
- Dr.Mark Clemens
- Dr.Kelly Hunt
- Dr.Jessie Xu
- Dr.Susan Wu
- Dr. Chelsea Pinnix
- Dr.Chi Ok
- Dr.MJ You
- Dr.John Stewart
- Dr.Keyur Patel

- Dr.Christopher Flowers
- Dr.Sattva Neelapu
- Dr.Loretta Nastoupil
- Dr.Jason Westin
- Dr.Felipe Samaniego
- Dr.Nathan Fowler
- Dr.Luis Fayad
- Dr.Dai Chihara
- Dr.Madeleine Duvic
- Dr.Auris Huen
- Dr.Bouthina Dabaja
- Dr.Jillian Gunther
- Dr.Chitra Hosing
- Dr.Yago Nieto
- Dr.Samer Srour

Rare Lymphoma:

- Dr.Michael Wang
- Dr.Sairah Ahmed
- Dr.Hun Ju Lee
- Dr.Ranjit Nair
- Dr.Luis Malpica

Collaborators:

- Radiology
- LOTR
- Section Rare Lymphoma
- Dept. Lymphoma/Myeloma
- Div. Medicine

Collaborators:

- Statisticians

Preclinical

- Dr.Michael Green
- Dr.Eric Davis
- Dr.Kumar Pappa
- Dr.Pavan Bachireddy

Grazie mille!



Bloodbytes @DrSwami_Iyer