POST-ORLANDO 2025
Novità dal Meeting della Società Americana di Ematologia

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Torino
Centro Congressi Lingotto
19-21 febbraio 2026

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Roche							**x**
Gilead							**x**
Takeda						**x**	
Janssen-Cilag						**x**	
Abbvie							**x**
Be-One							**x**

First line therapy

- *Chunmei Y. et al. a*bs #1859 **Azacytidine** combined with **CHOP** regimen for the treatment of newly diagnosed angioimmunoblastic T-cell lymphoma. poster session

- *Chong W. e*t al. abs #6322 **Golidocitinib** combined with **CHOP** in newly-diagnosed peripheral T-cell lymphoma: Preliminary Results from A phase 1/2 clinical trial.
poster session

- *Eldeman E.S.* et al. abs #5434 A Phase II, single-center, single-arm study evaluating the safety and efficacy of **Golidocitinib** in the management of newly diagnosed PTCL (GOLDEN Study).
poster session

- *Liling Z.* et al. . abs #1879 Efficacy and safety of **duvelisib** combined with **chidamide** as first-line treatment for angioimmunoblastic T-cell lymphoma (AITL).
poster session

Relapsed/Refractory Peripheral T-cell lymphomas

Building on CD30 directed therapy:

- *Weber T.* et al. abs #5425 Brentuximab vedotin plus DHAP as effective salvage therapy in CD30+ peripheral T-cell lymphoma: a retrospective multicenter study. poster session

Anti-IL2

- *Miller R. et al. a*bs #778 Final results of a phase 1 trial with **soquelitinib (SQL),** a selective interleukin-2-inducible T cell kinase (ITK) inhibitor for treatment of relapsed/refractory (R/R) T cell lymphomas (TCL). oral session

Relapsed/Refractory Peripheral T-cell lymphomas

PI3K inhibitors

- Ranjit N. et al. abs #5432 Single center updated analysis of patients with Relapsed/Refractory peripheral T-cell lymphoma treated with **linperlisib.**

poster session

- Zinzani P.L. et al. abs #3634 **Duvelisib** in patients with relapsed/refractory peripheral T-cell lymphoma: Final results from the phase 2 PRIMO trial - impact of prior therapy and expanded safety analysis

poster session

Relapsed/Refractory Peripheral T-cell lymphomas

JAK-1 Inhibitor

- *Eldeman E.S*. et al. #5422 Durable responses in the updated 2-year follow-up of patients from a single-center with relapsed/refractory peripheral T-cell lymphoma treated with golidocitinib. poster session

Selinexor

- *Carniti C. e*t al. abs #1868 Adding **selinexor to ifosfamide, etoposide and desametasone** does not improve the outcome in relapsed and refractory peripheral T-cell lymphomas: First report of phase II S-ide study. poster session

Relapsed/Refractory Peripheral T-cell lymphomas

Immunomodulatory drugs

- Xu T. et al. Ranjit N. et al. abs #780 A prospective clinical study on the combination of **anti-PD1 monoclonal antibody with lenalidomide and azacitidine** for the treatment of relapsed/refractory peripheral T-cell lymphoma. oral session

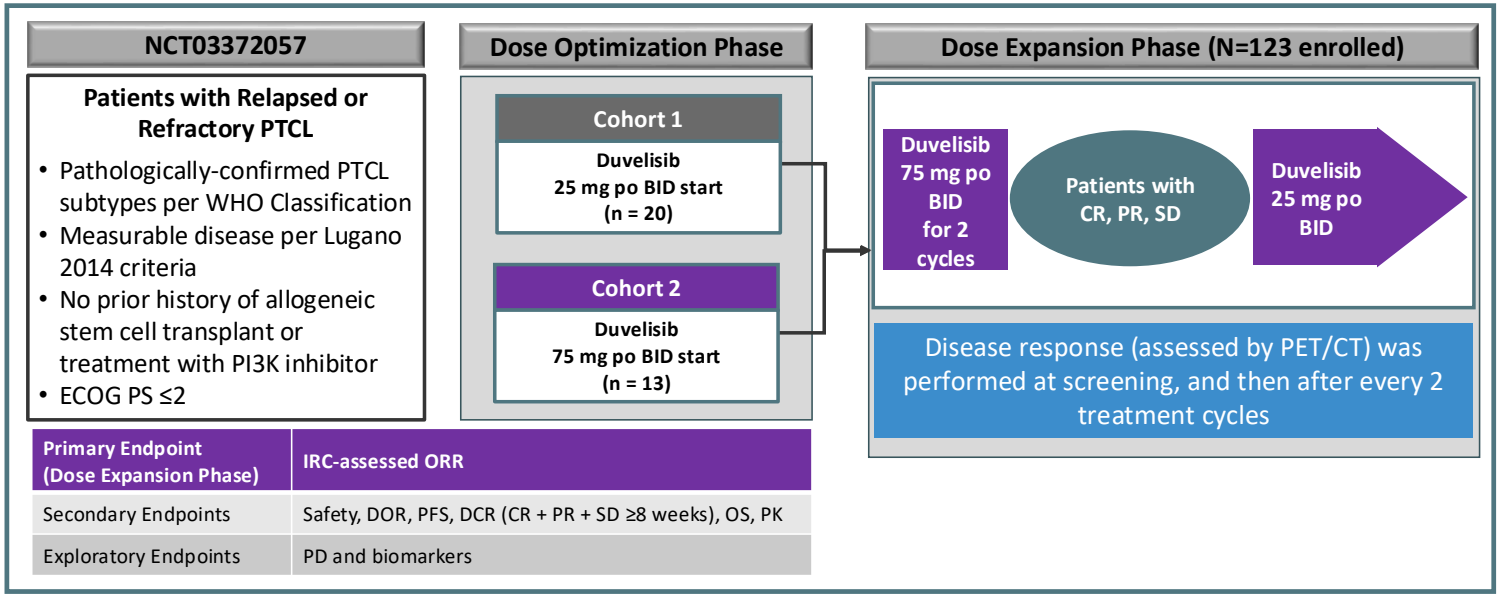
- Horwitz S. et al. abs #3646 Updated clinical data and biomarker analyses from the phase 1 study of **DR-01, a non-fucosylated anti-CD94 antibody** in patients with relapsed/refractory cytotoxic lymphomas. poster session

T –cell large granular lymphocytic Leukemia

- Jane S. et al. Ranjit N. et al. abs #779 Clinical activity, tolerability, and pharmacodynamics of **ulviprubart** in patients with T-cell large granular lymphocytic leukemia: Interim Results of A phase 1 trial oral session

- Marchi E. et al. abs #779 Initial clinical data from the phase 1 study of **DR-01**, a non-fucosylated anti-CD94 antibody in patients with large granular lymphocytic leukemia oral session

Duvelisib in patients with r/r peripheral T-cell lymphoma: Final results from the phase 2 PRIMO trial - impact of prior therapy and expanded safety analysis



Zinzani P.L. et al. Abs #3634 ASH Meeting 2026

Baseline Characteristics

Characteristic	PRIMO-EP (N=123)
Median age (range), years	65 (21-92)
≥65 years, (n), %	66 (53.7)
Male, n (%)	67 (54.5)
Median time from initial diagnosis (range), months	18.2 (0.2, 195.5)
Median time from most recent R/R diagnosis (range), months	1.15 (0, 142.9)
Baseline histology, n (%)	
Peripheral T-cell lymphoma-NOS	53 (43.1)
Angioimmunoblastic T-cell lymphoma	37 (30.1)
Anaplastic large-cell lymphoma (ALCL)^	20 (16.3)
Other*	13 (10.6)
Median number of prior anticancer therapies (range)	2 (1, 9)
Disease stage at baseline‡	
I	5 (4.1)
II	5 (4.1)
III	41 (33.3)
IV	71 (57.7)
Type of prior anticancer therapy	
CHOP-based chemotherapy‡‡	83 (67.5)
BV/BV-containing chemotherapy	47 (38.2)
Salvage chemo after CHOP-based chemotherapy	43 (35.0)
Autologous stem cell transplant	25 (20.3)
Romidepsin**	19 (15.4)
Pralatrexate	11
Primary refractory	
<CR to 1st line therapy	61 (49.6)
Best response to last therapy: SD/PD or relapse <6 mos from last dose	94 (76.4)

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Efficacy Outcomes in the PRIMO-EP (N:123)

Efficacy outcomes in the full PRIMO-EP population:

- Overall response rate (ORR): **48%**
- Complete response rate (CRR): **33%**
- Median duration of response (mDOR): 7.9 months
- Median progression free survival (mPFS): 3.4 months
- Median overall survival (mOS): 12.4 months
- **AITL subgroup**: **ORR 62%, CRR 51%, mDOR 11.7 months, mPFS 8.3 months, mOS 18.1 months**
- Nineteen patients (**15%**) received stem cell transplantation (SCT) after PRIMO (11/12 with planned SCT at time of duvelisib treatment discontinuation plus 8 additional patients).

Efficacy Outcomes by number of prior regimens

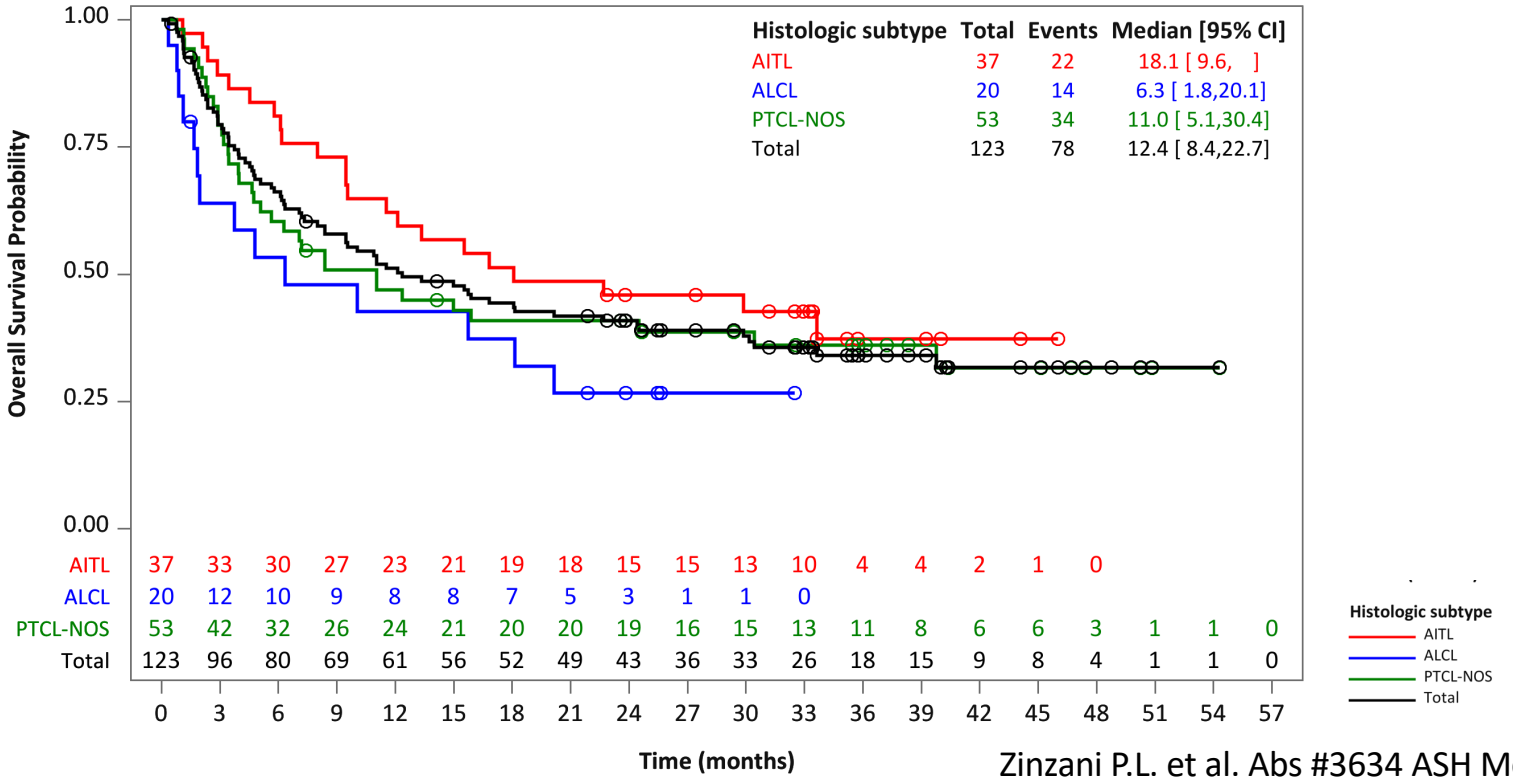
Efficacy outcome	1 prior line, n (%) (n=34)	2 prior lines, n (%) (n=29)	≥3 prior lines, n (%) (n=59)
ORR, n (%)	10 (29.4%)	19 (65.5)	29 (49.2)
CRR , n (%)	6 (17.6)	15 (51.7)	19 (32.2)
Median DOR (95% CI), months	6.5 (1.9, –)	11.7 (4.4, 21.0)	4.1 (1.9, 8.8)
Median PFS (95% CI), months	1.9 (1.7, 8.3)	9.0 (3.6, 22.7)	3.0 (1.7, 3.7)
Median OS (95% CI), months	30.2 (9.6, –)	22.7 (6.3, –)	7.3 (4.5, 10.9)

Efficacy Outcomes by prior anticancer therapy

Prior therapies, n/N (%)	CR	PR	SD
CHOP-based therapy (CHOP/R-CHOP or CHOEP/EPOCH) (n=83)	27/83 (32.5)	12/83 (14.5)	4/83 (4.8)
BV or BV/chemo (n=47)	16/47 (34.0)	4/47 (8.5)	3/47 (6.4)
Salvage chemo after CHOP-based therapy (n=43)	19/43 (44.2)	3/43 (7.0)	0
Autologous SCT (n=25)	6/25 (24.0)	7/25 (28.0)	1/25 (4.0)
Romidepsin* (n=19)	6/19 (31.6)	2/19 (10.5)	0

**One additional HDACi (belinostat) was used in one additional patient.

Progression free survival by histology



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Adverse events of special interest

Adverse Event of Special Interest	Any grade	Median (range) time to onset (any event), days	AESI resulting in discontinuation	Median (range) duration (any event), days	AESI resulting in death
Any AESI, n (%)	108 (87.8)	N/A	27 (22.0)	-	4 (3.3)
Colitis	3 (2.4)	223.0 (202-522)	1 (0.8)	10 (5, 17)	0
Cutaneous reactions	44 (35.8)	57.5 (1, 507)	1 (0.8)	12 (1, 273)	0
Diarrhea	41 (33.3)	64.5 (1, 616)	7 (5.7)	9 (1, 113)	0
Infections	51 (41.5)	56.0 (1, 930)	8 (6.5)	15 (1, 122)	2 (1.6)
Neutropenia	41 (33.3)	36.0 (1, 420)	1 (0.8)	8 (2, 155)	0
Pneumonia	8 (6.5)	43.0 (11, 644)	1 (0.8)	13 (2, 57)	0
Pneumonitis	2 (1.6)	33.0 (20, 71)	1 (0.8)	14 (1, 15)	1 (0.8)
Elevated aminotransferase	55 (44.7)	49.0 (1, 288)	10 (8.1)	9 (1, 274)	1 (0.8)

- TEAEs leading to dose hold/dose reduction: 37.6%/3.0% of patients;
- TEAEs (excluding PD) resulting in death: 10; of these, 4 were considered to be treatment-related (cryptococcosis, Epstein-Barr virus-associated lymphoproliferative disorder, pneumonitis, and sepsis);

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Conclusion

- In a heavily treated, R/R population, **duvelisib efficacy outcomes did not show a consistent pattern based on prior lines of therapy;**

- For R/R PTCL, a 75 mg BID dose was administered for the first 2 cycles (CLL/SLL indicated dose is 25 mg BID). Although there is a different dosing regimen for PTCL, generally there was no consistent pattern of higher rates of persisting or emerging AEs with longer treatment duration

- These data support the **tolerability** of this regimen (75 mg BID for 2 cycles followed by 25 mg BID) in R/R PTCL

- Based on efficacy in the AITL subgroup, the sponsor has initiated a randomized phase 3 study to investigate duvelisib **in a homogeneous population of R/R nodal T-follicular helper cell lymphoma (NCT06522737; TERZO)**

Zinzani P.L. et al. Abs #3634 ASH Meeting 2026

Updated Clinical Data and Biomarker Analyses from the Phase 1 Study of DR-01, a Nonfucosylated anti-CD94 Antibody in Patients with Relapsed/Refractory Cytotoxic Lymphomas

Study Design

- Phase 1/2, first-in-human, 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

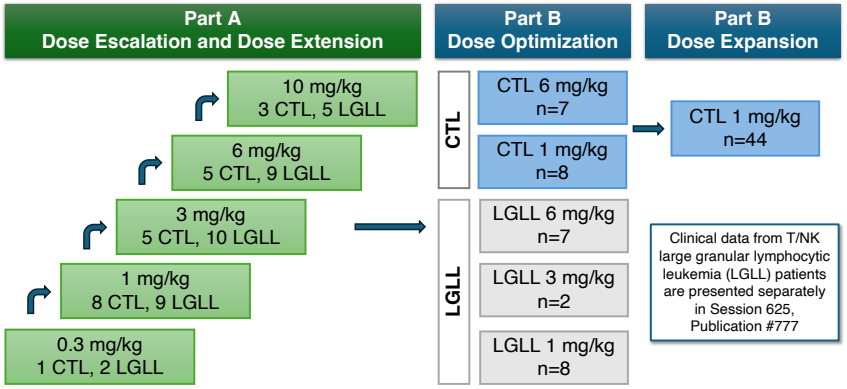
Patient Population

- 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

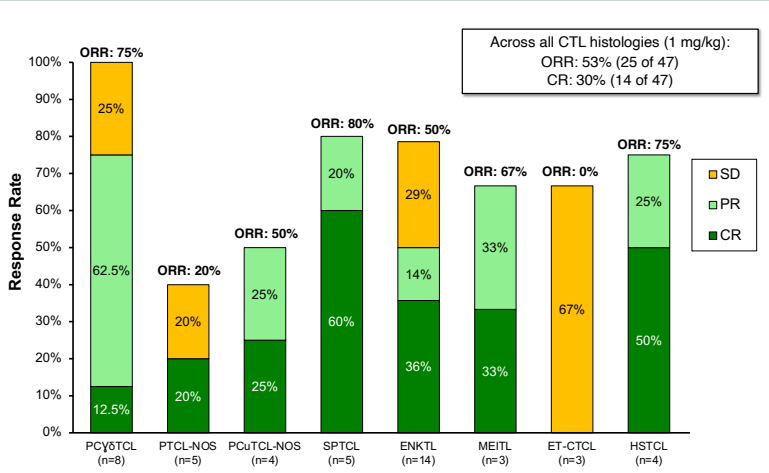
Figure 2. Study Schema: First-in-Human Phase 1/2 Study for Dibotatug



Horwitz S. et al. Abstract # 3646 ASH Meeting 2025

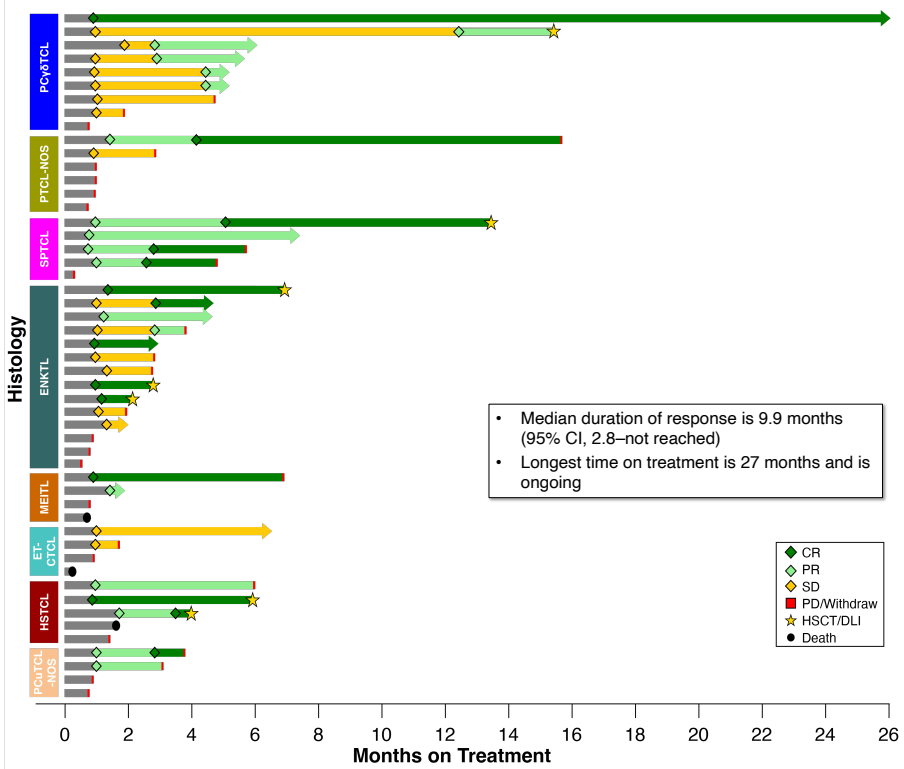
Results

Figure 4. Promising Responses with CRs across Multiple Histologies at 1 mg/kg



CR, complete response; ORR, overall response rate (CR+PR); PR, partial response; SD, stable disease. Disease evaluable is defined as patients with at least one baseline and one post-baseline response assessment; only histologies with at least 1 response of SD or better and only patients receiving primary and secondary regimens are shown.

Figure 5. Duration of Dibotatug Treatment and Responses of CTL Patients Treated with 1 mg/kg, Grouped by Histology



DLI, donor lymphocyte infusion; HSCT, hematopoietic stem cell transplant; PD, progressive disease. Patients receiving the primary and secondary regimens and those with at least one post-baseline response assessment or patient withdrawal prior to response assessment are shown. Histologies shown have enrolled at least two patients in each category (1 EATL patient is not shown).

Horwitz S. et al. # 3646 ASH Meeting 2025

Conclusion

- Dibotatug (DR-01) continues to demonstrate promising safety and efficacy, supporting its development as a potential CTL treatment option

- IRR is the most common treatment-related AE, typically occurring during first dose and manageable with standard mitigation strategies

- **53% ORR** with high proportion of CRs across multiple CTL histologies

- Durable responses are observed with a median duration of response of 9.9 months

- **Biomarker analyses show that CD94 has near universal expression (95%) across CTL samples**. Data suggest that **patients with CTL may benefit from** dibotatug **regardless of baseline CD94 expression** by IHC.

- Phase 2 (Part B) is ongoing and continues to enroll CTL patients globally

Horwitz S. et al. # 3646 ASH Meeting 2025

Durable responses in the updated 2-year follow-up of patients from a single-center with r/r PTCL treated with golidocitinib

Methods

- We included pts enrolled from a single-center in the JACKPOT8 part B trial, a single-arm, multinational, phase 2 study (NCT04105010).
- Eligible pts (18 years, r/r PTCL, performance status ECOG 0-2) were given golidocitinib 150 mg orally once daily in 21-day cycles until PD or other discontinuation criteria were met.
- We evaluated baseline characteristics, ORR and the co-primary endpoints; 2-year PFS and 2-year OS, assessed using the Kaplan-Meier method.
- Correlatives were analyzed between responders (CR and PR) and non-responders (PD) using Fisher's exact test with a $p < 0.05$ for statistical significance.

Results

Tabel 1. Variable	Value
Age Median (Range), years	55 (19.8-75.2)
Gender (Female) n(%)	7 (53.8)
PTCL subtype, n	
TFH (AITL)	3
PTCL,NOS	4
ALK+ ALCL	2
ALK- ALCL	3
T-PLL	1
Stage, III-IV, n(%)	11 (84.6)
IPI score, 3-5	3 (23.1)
Frontline regimens, n(%)	
BV-CHP	10 (76.9)
CHOP	3 (23.1)
Best frontline response, n(%)	
CR	7 (53.8)
PR	3 (23.1)
SD	3 (23.1)
ASCT prior to enrolment, n	2
Golidocitinib line of therapy, n(%)	
2L	7 (53.8)
3L	4 (30.8)
4L	2 (15.4)

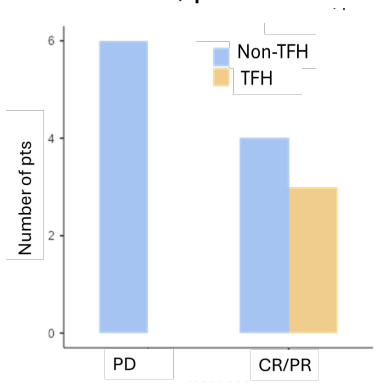
Eldeman E.S. et al. # 5434 ASH Meeting 2025

Results

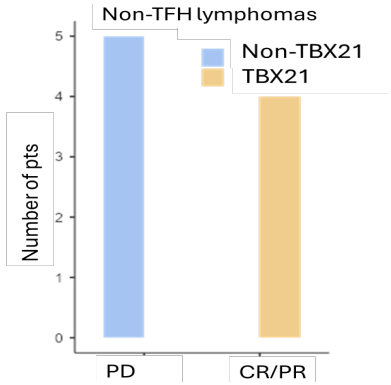
ORR: 53.8%

CR:46.1% PR:7.7.%

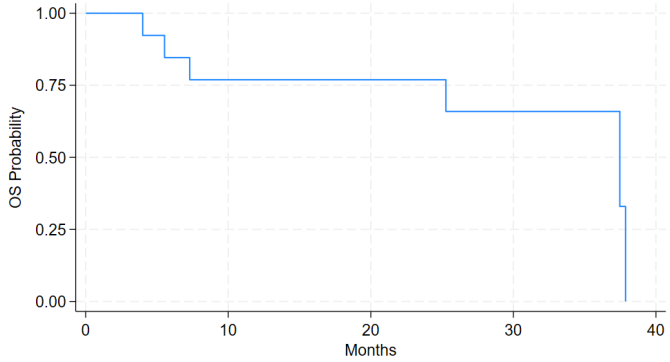
ORR: TFH 100% vs. Non-TFH 40%, p=0.192



ORR: TBX21 100% vs. Non-TBX21 0%, P=0.008



Median PFS 37.9 months
2-year PFS 58.3% (95%CI 27%-80.1%)



Median OS not reached
2-year OS was 76.9% (95%CI 44.2%-91.9%)

Eldeman E.S. al. # 3646 ASH Meeting 2025

Conclusion

- Efficacy and tolerability were comparable with the **overall cohort in the JACKPOT8** part B trial

- With the longest follow-up for golidocitinib, **responses were durable** (longest responder 3.1 years) with 2 pts remaining in CR despite therapy break, suggesting a long-lasting effect.

- Responders had a **TFH phenotype** and expressed **TBX21**, which need to be confirmed in a larger cohort.

- Given the promising results and unmet need, the ongoing GOLDEN trial aims to evaluate the safety and efficacy of golidocitinib in **the frontline management of PTCL** (NCT06630091, poster 5434).

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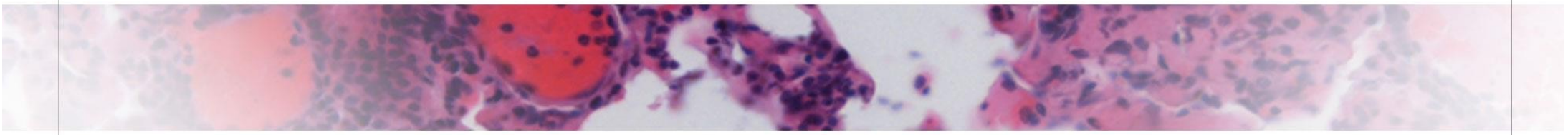

Initial Clinical Data from the Phase 1 Study of DR-01, a Non-fucosylated Anti-CD94 Antibody in Patients with Large Granular Lymphocytic Leukemia

Enrica Marchi[1], Tapan Kadia[2], Ryotaro Nakamura[3], Christina Poh[3], Costas Yannakou[4,5], Mitul Gandhi[6], Jasmine Zain[7], Steven Horwitz[7], Jenna Reed[8], Jennifer Richardson[8], Ruoshi Shi[8], Kimberley Dilley[8], Wan-Jen Hong[8], Nenad Tomasevic[8], Natali Pflug[9], Thierry Lamy[10], Marco Herling[11], Jonathan Brammer[12], Thomas P. Loughran Jr.[1]

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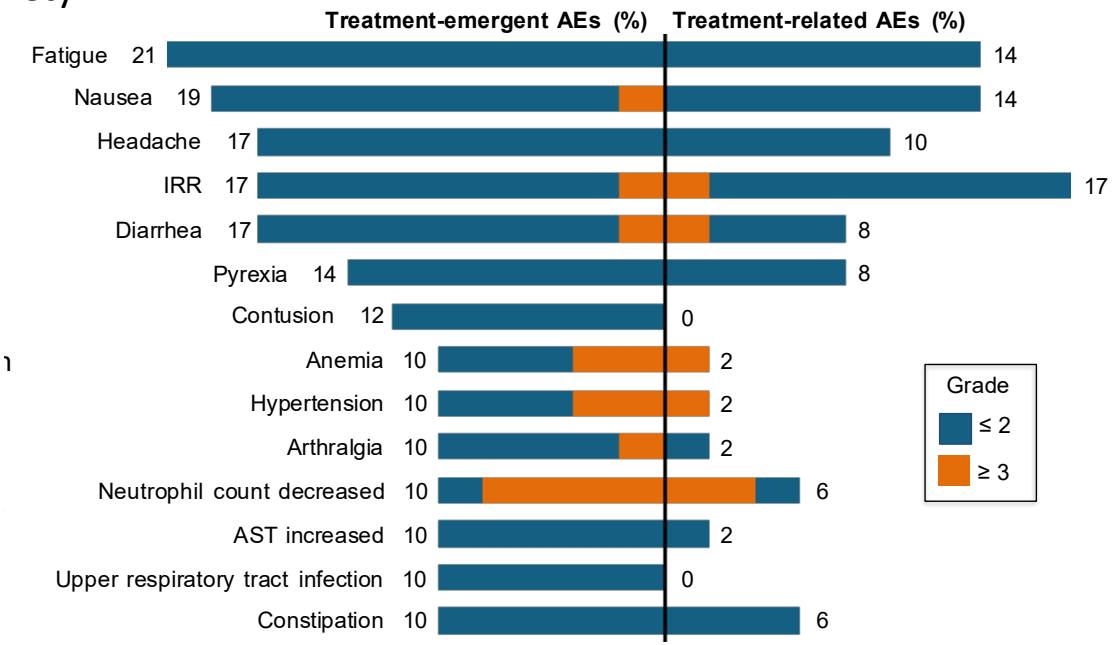
Most common adverse events in safety-evaluable patients (TEAE ≥ 10%)

At the data cut-off, **52** patients were evaluable for safety

- Majority of patients (76%) remain on study treatment
- Time on study treatment: 1–24 months
- No deaths or dose-limiting toxicities were observed
- Most frequent TRAE was infusion-related reaction **(IRR; 17%)**
  - Majority were grade 1–2 and occurred with the first dose
  - No IRR led to dose reduction or discontinuation other than in the first patient enrolled before optimization of IRR prophylaxis



Marchi E. et al. abs #779 ASH Meeting 2025

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/µL)	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.

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Dibotatug shows promising response rates across dose levels (1–10 mg/kg)

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)
ORR,	0	8 (62%)	3 (25%)	7 (58%)	2 (50%)	20 (47%)
CR	0	4 (31%)	0	6 (50%)	1 (25%)	11 (26%)
PR	0	4 (31%)	3 (25%)	1 (8%)	1 (25%)	9 (21%)
SD/LOR	2 (100%)	5 (38%)	9 (75%)	5 (42%)	2 (50%)	23 (53%)

n (%)	Secondary Induction (n=35)
ORR,	19 (54%)
CR	10 (29%)
PR	9 (26%)
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

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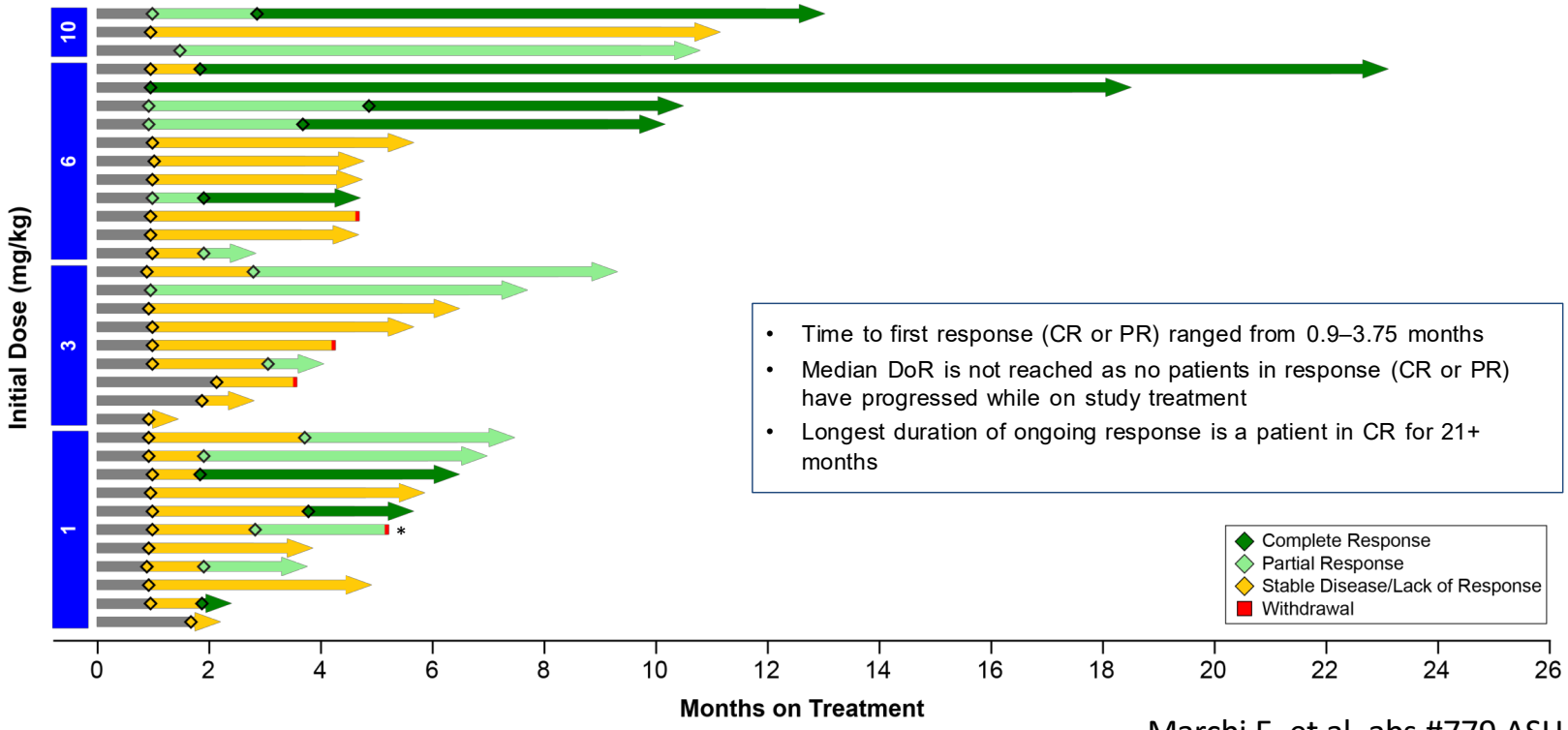
Responses are durable and all are ongoing



- Time to first response (CR or PR) ranged from 0.9–3.75 months
- Median DoR is not reached as no patients in response (CR or PR) have progressed while on study treatment
- Longest duration of ongoing response is a patient in CR for 21+ months

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Conclusions

- Dibotatug (DR-01) is safe and well-tolerated
  - IRR is the most common treatment-related AE, and is manageable with standard mitigation strategies
- Dibotatug shows encouraging efficacy in both previously treated T- and NK-LGLL
  - Of the 35 patients who received the secondary induction regimen, the ORR was 54%
  - Durable responses with rapid onset were observed, including clearance of the dominant TCR clone
- No loss of response while on study treatment
- Longest duration of response is 21+ months and ongoing
- Study is ongoing and enrolling LGLL patients globally
- Results support development of dibotatug as a potential LGLL treatment option

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