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Tabelecleucel, an allogeneic cell therapy for EBV+PTLD, Clinical Program Update

TAVI Forum 14

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Regulatory Status and Use of Slides by Medical Affairs

- Tabelecleucel is not approved by the FDA and the safety or effectiveness of the product, or its use has not been established
- The use of these slides is in compliance with FDA Guidance titled “Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices”

FDA, US Food and Drug Administration.

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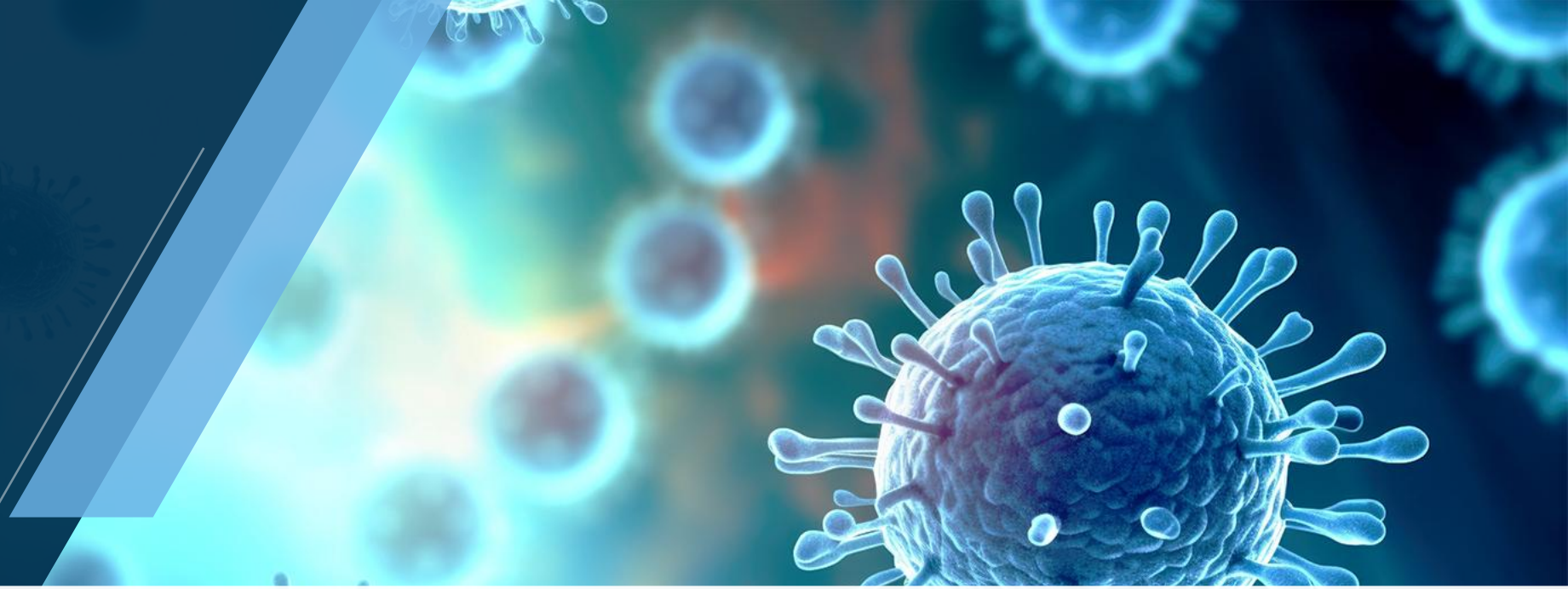


Epstein-Barr Virus-Positive (EBV+) Post-Transplant Lymphoproliferative Disease (PTLD)

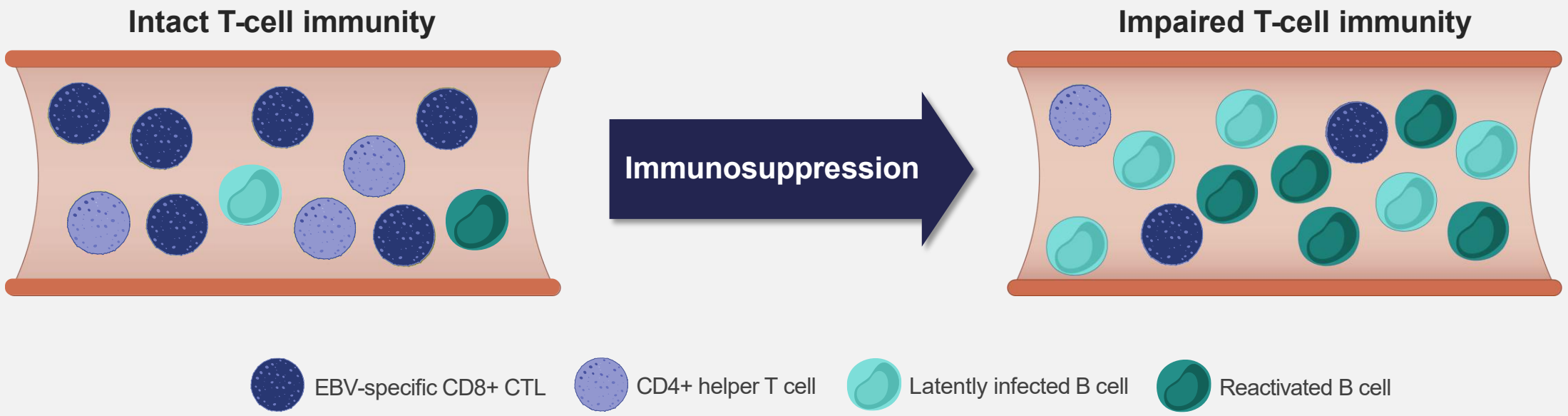
Impaired T-cell Immunity Post-transplant Plays a Significant Role in The Development of EBV+ PTLD[1,2]

Immunocompetent individual

T cells keep the EBV infection under control by killing infected B cells[1,2]

Transplant patients

With impaired T-cell immunity, reactivated EBV can cause B cells to transform and rapidly proliferate, causing a range of malignancies, such as PTLD[1-3]



CD, cluster of differentiation; CTL, cytotoxic T-lymphocyte; EBV, Epstein-Barr virus; PTLD, post-transplant lymphoproliferative disease.

1. Nijland ML et al. *Transplant Direct*. 2015;2(1):e48. **2.** Cohen JI. *N Engl J Med*. 2000;343:481-492. **3.** Crombie JL, LaCasce AS. *Front Oncol*. 2019;9:109.

The Signs and Symptoms of EBV+ PTLD Are Heterogeneous, and Disease Progression is Rapid and Aggressive[1-4]

Presentation:

From incidental, asymptomatic findings to fulminant presentation, including organ failure and spontaneous tumor lysis[1]

Target organs[2]

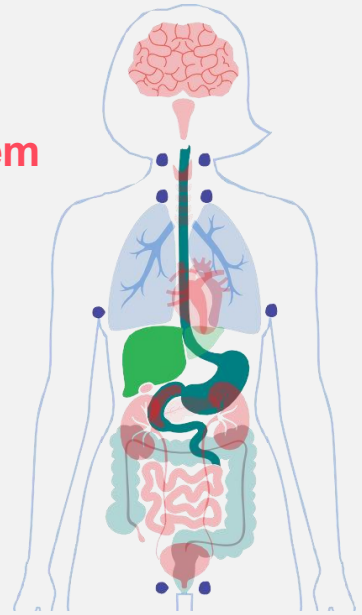
Central nervous system

Lungs

GI Tract

Lymph Nodes

Liver



Symptoms[2,3]

B symptoms*:* fever, night sweats, weight loss, lymphadenopathy

Rare*:* encephalitis/myelitis, pneumonitis, hepatitis, and hemophagocytic lymphohistiocytosis

EBV+ PTLD diagnosis[2]:
Achieved through biopsy alongside detection/monitoring of EBV titer and imaging tests

Disease progression[3,4]:
Rapid and aggressive

EBV+ PTLD requires early diagnosis and a robust treatment plan[1-4]

EBV, Epstein-Barr virus; GI, gastrointestinal; PTLD, post-transplant lymphoproliferative disease.

1. Dierickx D et al. *N Engl J Med*. 2018;378:549-562. **2.** Styczynski J and Giebel S EBMT Handbook 2019; Chapter 45. **3.** Fujimoto A et al. *Cancers (Basel)*. 2020;12:328. **4.** Abbas F et al. *World J Transplant*. 2020;10(2):29-46.

Given the Poor Prognosis for Patients With Relapsed/Refractory EBV+ PTLD, There Is an Urgent Unmet Need for Novel Therapies

Critical unmet need remains for[1,2]:

- Consistent monitoring of EBV levels for better detection of disease
- Tailored treatment strategy
- Less toxic therapies with longer survival

- EBV+ PTLD disease **progression can be rapid and aggressive**[3,4]
- Approximately **half of EBV+ PTLD cases are refractory** to initial treatment or **relapse**[5]

- Patients with disease failing to respond to initial therapy have **poor prognosis**[1]
- Additionally, toxicity associated with standard lymphoma-directed chemotherapy in transplant recipients can result in treatment-related mortality[1]

- Overall **survival is low** in patients who have failed initial treatment[1]:
  - Reported median overall survival of **0.7 months** after hematopoietic cell transplant (HCT) after failure of rituximab ± chemotherapy and **4.1 months** after solid organ transplant (SOT) after failure of rituximab with chemotherapy

With no approved treatment options for relapsed/refractory EBV+ PTLD, there is a significant unmet need for new therapies[2]

EBV, Epstein-Barr virus; HCT, hematopoietic cell transplant; PTLD, post-transplant lymphoproliferative disorder; SOT, solid organ transplant.

1. Mahadeo KM et al. *Lancet Oncol*. 2024;25(3):376-387. **2.** Dierickx D, Habermann TM. *N Engl J Med*. 2018;378(6):549-562. **3.** Fujimoto A, Suzuki R. *Cancers (Basel)*. 2020;12(2):328. **4.** Abbas F et al. *World J Transplant*. 2020;10(2):29-46. **5.** Institute for Clinical and Economic Review. Report at a glance: Epstein-Barr virus positive post-transplant lymphoproliferative disease. Published December 2024. Accessed July 15, 2025. https://icer.org/wp-content/uploads/2024/12/EBV_PTLD_RAAG_December-2024.pdf

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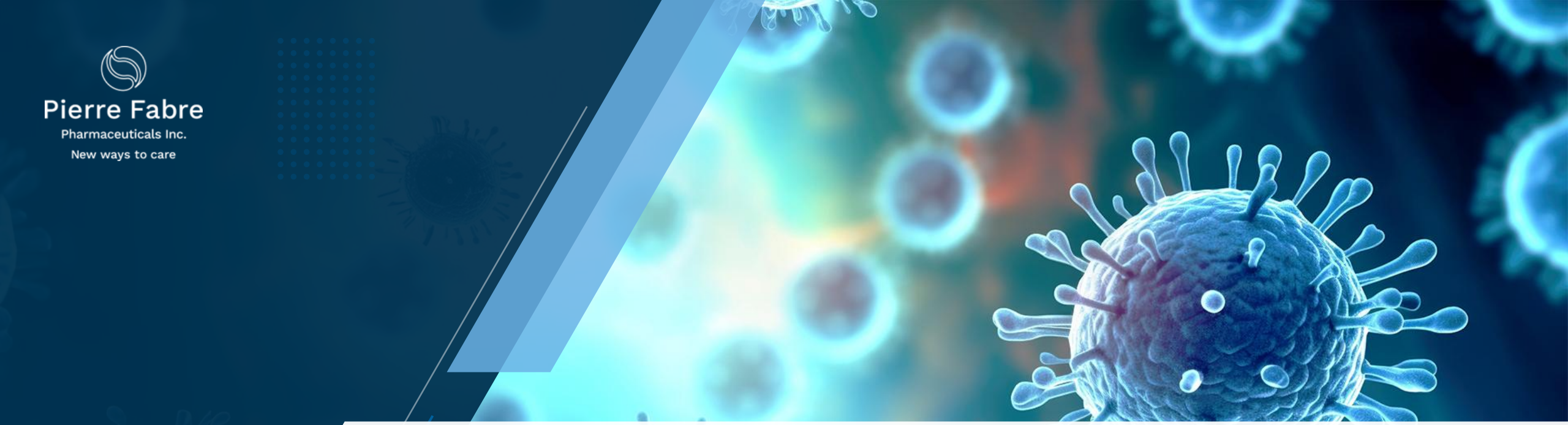


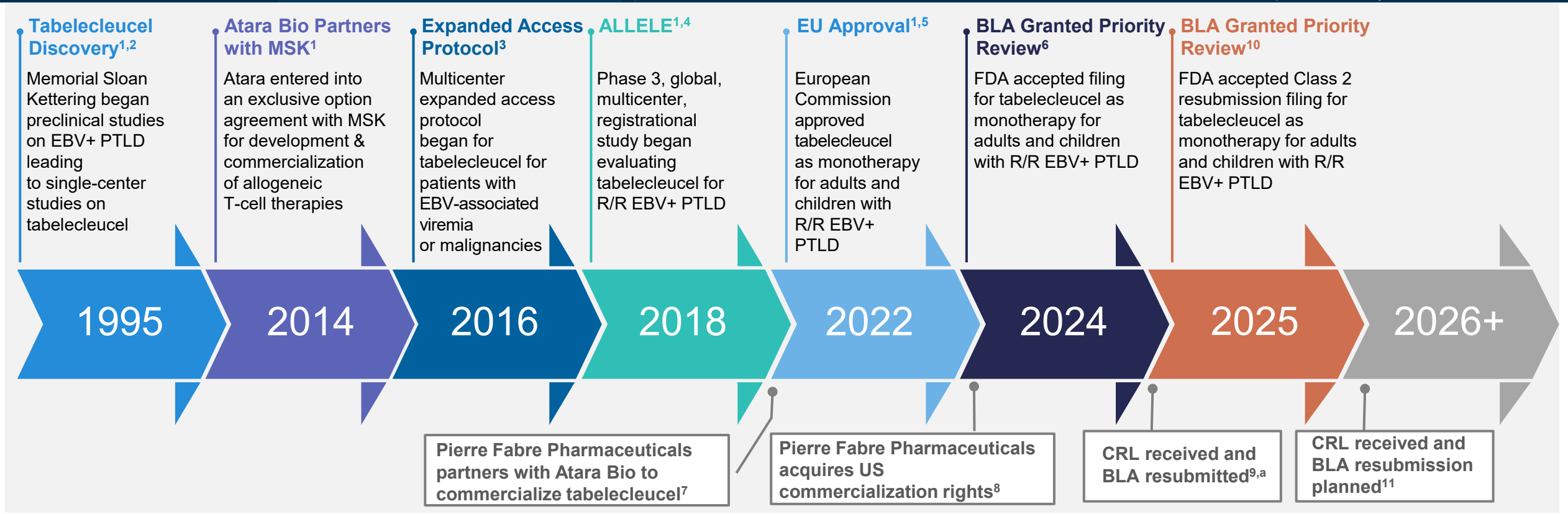
Tabelecleucel Overview

Tabelecleucel is an investigational therapy that has not been cleared by the FDA for any indication at this time. This investigational agent is not approved by the FDA, and the safety or effectiveness of the product or its use has not been established. A marketing application for the investigational product has been submitted to the FDA and is under review.

This information is provided exclusively for scientific exchange (and formulary committee evaluation) purposes only.

FDA, Food and Drug Administration.

History of Tabelecleucel



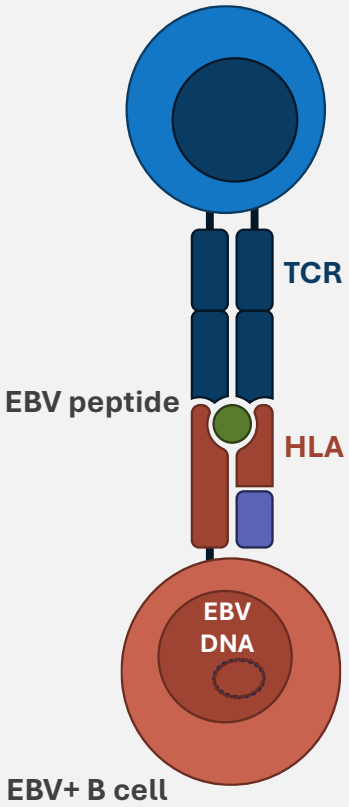
BLA, biologics license application; CRL, complete response letter; EBV, Epstein-Barr virus; FDA, Food and Drug Administration; MSK, Memorial Sloan Kettering; PTLD, post-transplant lymphoproliferative disorder; R/R, relapsed/refractory.

[a]In January 2025, the tabelecleucel program was placed on clinical hold due to GMP compliance issues identified during the pre-license inspection of the third-party manufacturing facility.

1. Keam SJ. *Mol Diagn Ther*. 2023;27(3):425-431. **2.** Biological therapy in treating patients at high-risk or with lymphoma, lymphoproliferative disease, or malignancies. Clinicaltrials.gov identifier: NCT00002663. Updated February 12, 2023. Accessed April 25, 2024. https://clinicaltrials.gov/study/NCT00002663 **3.** Expanded access protocol for tabelecleucel for patients with Epstein-barr virus-associated viremia or malignancies. Clinicaltrials.gov identifier: NCT02822495. Updated June 15, 2023. Accessed April 25, 2024. https://clinicaltrials.gov/study/NCT02822495 **4.** Tabelecleucel for solid organ or allogeneic hematopoietic cell transplant participants with Epstein-barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) after failure of rituximab or rituximab and chemotherapy (ALLELE). Clinicaltrials.gov identifier: NCT03394365. Updated April 18, 2025. Accessed April 25, 2024. https://clinicaltrials.gov/study/NCT03394365 **5.** Atara Biotherapeutics' Ebvallo™ (tabelecleucel) receives European Commission approval as first ever therapy for adults and children with EBV+ PTLD. Businesswire. Accessed April 23, 2025. https://www.businesswire.com/news/home/20221218005055/en **6.** Pierre Fabre Laboratories announces the submission by Atara Biotherapeutics of Tabelecleucel (Tab-cel®) Biologics License Application for treatment of Epstein-Barr Virus Positive Post Transplant Lymphoproliferative Disease with U.S FDA. Pierre Fabre Pharmaceuticals. Accessed April 22, 2025. https://www.pierrefabrepharmaceuticals.com/press/20240520_PR_BLA_Filing_EBVALLO.pdf **7.** Atara Biotherapeutics and Pierre Fabre Enter Strategic Collaboration to Commercialize Tabelecleucel (tab-cel®). Pierre Fabre. Published October 4, 2021. Accessed April 2025. https://www.pierre-fabre.com/en/press_release/atara-biotherapeutics-and-pierre-fabre-enter-strategic-collaboration-to-commercialize. **8.** Pierre Fabre Laboratories to accelerate their development in onco-hematology by acquiring the license for a breakthrough T-cell immunotherapy in North America. PR Newswire. Published Nov 3, 2023. Accessed April 23, 2025. https://www.prnewswire.com/news-releases/pierre-fabre-laboratories-to-accelerate-their-development-in-onco-hematology-by-acquiring-the-license-for-a-breakthrough-t-cell-immunotherapy-in-north-america-301976479.html **9.** Atara Biotherapeutics Provides Regulatory Updates on EBVALLO™ (tabelecleucel). Accessed May 14, 2025. https://investors.atarabio.com/news-events/press-releases/detail/371/atara-biotherapeutics-provides-regulatory-updates-on **10.** Atara Biotherapeutics Announces U.S. FDA Acceptance and Priority Review of the Biologics License Application for Tabelecleucel (Tab-cel®) for the Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease. Accessed August 26, 2025. https://investors.atarabio.com/news-events/press-releases/detail/376/atara-biotherapeutics-announces-u-s-fda-acceptance-and **11**. Pierre Fabre Pharmaceuticals Statement Regarding Receipt Of Complete Response Letter For Tabelecleucel Biologics License Application From The U.S. Food And Drug Administration. PR Newswire. Published January 12, 2026. https://www.prnewswire.com/news-releases/pierre-fabre-pharmaceuticals-statement-regarding-receipt-of-complete-response-letter-for-tabelecleucel-biologics-license-application-from-the-us-food-and-drug-administration-302658114.html

Allogeneic T-cell Immunotherapy Differs From Chimeric Antigen Receptor (CAR) T-Cell Therapy

Allogeneic T-Cell Immunotherapy[1-3]



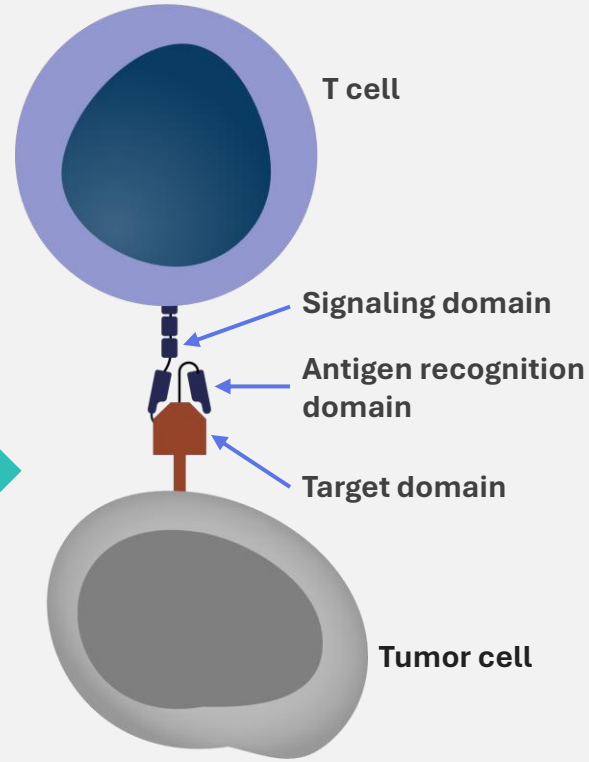
Tabelecleucel: Investigational, allogeneic, EBV-specific T cell utilizing HLA restriction

- Functions through endogenous T-cell receptor (TCR)
- No genetic modification

CAR T cell: T cell with an artificial receptor introduced, autologous, recognizes cell surface proteins or antigens

- Functions through chimeric antigen receptor (CAR)
- Genetically modified

CAR T Cell[4,5]



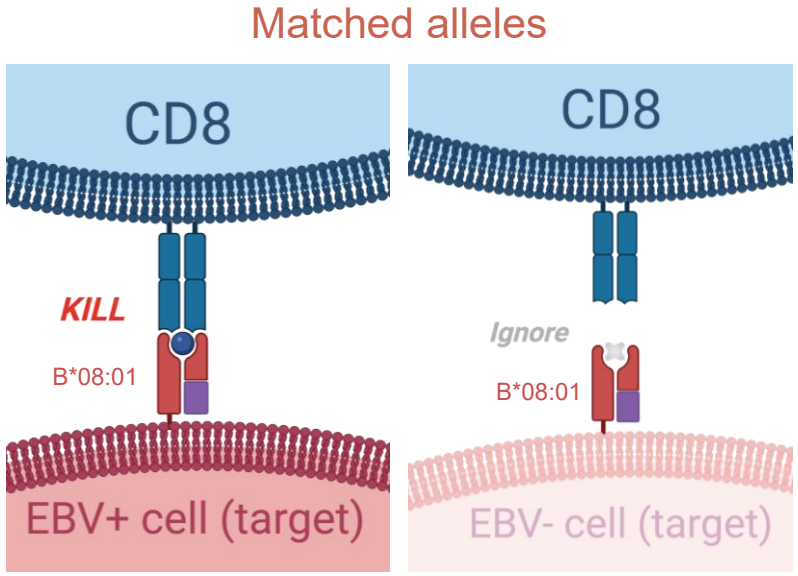
EBV, Epstein-Barr virus; FDA, Food and Drug Administration; HLA, human leukocyte antigen.

1. Shen RR et al. *Cytotherapy*. 2019;21(5 suppl):S11. **2.** Mahadeo KM et al. *Lancet Oncol*. 2024;25(3):376-387. **3.** Prockop S et al. Presented American Transplant Virtual Congress (ATC 2021). **4.** Sievers NM et al. *Int J Mol Sci.* 2020;21(10):3525. **5.** Siegler EL et al. *Front Immunol.* 2020;11:1973.

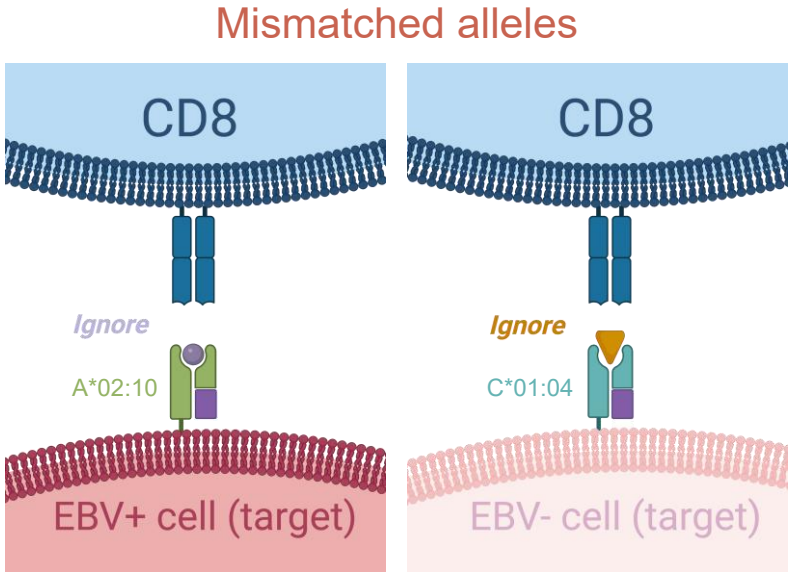
Characterization of Tabelecleucel is Based on Cytotoxicity and Alloreactivity[1-3]

Characterization: Cytotoxicity and Alloreactivity

Allogeneic EBV-specific cytotoxic T lymphocyte (CTL) can kill EBV+ targets that present the epitope in the right HLA



Allogeneic EBV-specific CTL will not recognize/kill cells of a different HLA



HLA-restricted cytotoxicity is determined by the combination of antigen peptide binding and direct contact between the HLA molecule and the T-cell receptor

CD, cluster of differentiation; CTL, cytotoxic T lymphocyte; HLA, human leukocyte antigen.

1. Ghobadi A et al. Presented at ASTCT and CIBMTR Tandem Meeting 2025. [abstract 742]. **2.** Abbas AK, Lichtman AH, Pillai S. *Basic Immunology: Functions and Disorders of the Immune System.* 6th Ed. Philadelphia, PA: Elsevier/Saunders; 2019. **3.** Janeway CA et al. *Immunobiology: The Immune System in Health and Disease.* 5th Ed. New York, NY: Garland Science; 2001.

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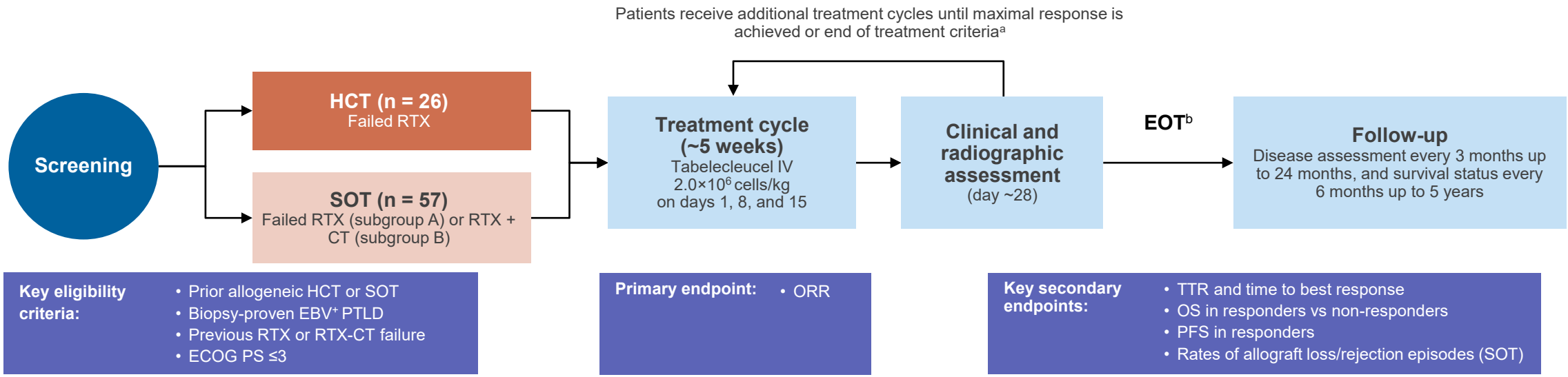
ASH 2025 Abstract

Updated Clinical Results: Subgroup analysis based on prior treatment from the Phase 3 ALLELE study of tabelecleucel for Epstein-Barr virus-driven post-transplant lymphoproliferative disease

Sarah Nikiforow, Kris Mahadeo, Sridhar Chaganti, Amer Beitinjaneh, Sylvain Choquet, Daan Dierickx, Armin Ghobadi, Roberta Valenti, Anke Friedetzky, Sandrine Roye, Ran Reshef, Susan Prockop, Robert Baiocchi

ALLELE Study Design[1]

- ALLELE is a multicenter, open label, phase 3 trial assessing the safety and efficacy of tabelecleucel in patients with relapsed or refractory EBV+ PTLD after HCT or SOT and prior treatment with RTX ± CT[1]
- Results from 75 patients enrolled in the ALLELE trial were presented previously[2]
- Here, we present updated results from a larger number of patients, with a subgroup analysis based on prior treatment
- Data cutoff date: September 10, 2024[3]



[a]In case of non-response, patients may receive tabelecleucel using a T cell line with different HLA restrictions (switch). [b]EOT (maximal response, unacceptable toxicity, start of non-protocol therapy, or failure of up to 2 [SOT patients] or 4 [HCT patients] different HLA restrictions).

CT, chemotherapy; EBV+ PTLD, Epstein-Barr virus-associated post-transplant lymphoproliferative disease; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EOT, end of treatment; HCT, hematopoietic cell transplant; HLA, human leukocyte antigen; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RTX, rituximab; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy; TTR, time to response.

1. Protocol version V5.0. 2. **2.** Ghobadi A, et al. *Blood*. 2024;144;70–71, ASH Annual Meeting. **3.** Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

ALLELE Study (Data cutoff, September 10, 2024): Patients

- 29 HCT and 57 SOT patients (21 SOT-R, 36 SOT-RC) were enrolled and treated with tabelecleucel
- Patients received a median of 2 tabelecleucel cycles
- Median follow-up time was 8.4 months

Demographics	HCT (n = 29)	SOT-R (n = 21)	SOT-RC (n = 36)	SOT total (n = 57)	Total (N = 86)
Age, median (range), y	50.0 (3.2–73.2)	46.1 (2.7–75.7)	36.1 (10.6–81.5)	41.1 (2.7–81.5)	42.6 (2.7–81.5)
Male sex, n (%)	17 (58.6)	14 (66.7)	19 (52.8)	33 (57.9)	50 (58.1)
ECOG PS score ≥2, n (%)[a]	7 (25.9)	3 (18.8)	11 (33.3)	14 (28.6)	21 (27.6)
Disease characteristics					
PTLD-adapted prognostic index in patients ≥16 years, n (%)					
High risk	14 (51.9)	3 (18.8)	16 (48.5)	19 (38.8)	33 (43.4)
Intermediate risk	13 (48.1)	11 (68.8)	13 (39.4)	24 (49.0)	37 (48.7)
Low risk	0 (0.0)	2 (12.5)	3 (9.1)	5 (10.2)	5 (6.6)
Unknown	0 (0.0)	0 (0.0)	1 (3.0)	1 (2.0)	1 (1.3)
PTLD morphology, n (%)					
Diffuse large B-cell lymphoma	18 (62.1)	14 (66.7)	26 (72.2)	40 (70.2)	58 (67.4)
Plasmablastic lymphoma	1 (3.4)	0 (0.0)	2 (5.6)	2 (3.5)	3 (3.5)
Other	10 (34.5)	7 (33.3)	8 (22.2)	15 (26.3)	25 (29.1)
Median (range) time, mo					
From transplant to EBV+ PTLD diagnosis	3.8 (0.6–66.0)	9.6 (3.6–314.4)	13.2 (2.4–278.4)	10.8 (2.4–314.4)	–
From EBV+ PTLD diagnosis to 1st tabelecleucel infusion	2.0 (0.6–28.1)	4.6 (1.2–46.5)	9.0 (1.4–190.5)	7.1 (1.2–190.5)	4.6 (0.6–190.5)

[a]In patients ≥16 years of age.

EBV+ PTLD, Epstein-Barr virus-associated post-transplant lymphoproliferative disease; ECOG PS, Eastern Cooperative Oncology Group performance status; HCT, hematopoietic cell transplant; PTLD, posttransplant lymphoproliferative disease; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy.

1. Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

ALLELE Study (Data cutoff, September 10, 2024): Prior Therapies and Transplant Type

Treatment and prior therapies	HCT (n = 29)	SOT-R (n = 21)	SOT-RC (n = 36)	SOT total (n = 57)	Total (N = 86)
Median lines of prior systemic treatment, n (range)	1 (1-4)	1 (1-2)	2 (1-5)	1 (1-5)	1 (1-5)
Prior rituximab monotherapy, n (%)	29 (100.0)	21 (100.0)	25 (69.4)	46 (80.7)	75 (87.2)
Prior chemotherapy, n (%)	4 (13.8)	0 (0.0)	36 (100.0)	36 (63.2)	40 (46.5)
Prior chemotherapy in combination with rituximab, n (%)	1 (3.4)	0 (0.0)	33 (91.7)	33 (57.9)	34 (39.5)
Prior immunotherapy, n (%)	1 (3.4)	0 (0.0)	2 (5.6)	2 (3.5)	3 (3.5)
Transplant type, n (%)					
Kidney	-	7 (33.3)	10 (27.8)	17 (29.8)	-
Heart	-	3 (14.3)	11 (30.6)	14 (24.6)	-
Lung	-	4 (19,0)	7 (19,4)	11 (19.3)	-
Liver	-	3 (14.3)	2 (5.6)	5 (8.8)	-
Multivisceral	-	4 (19.0)	6 (16.7)	10 (17.5)	-

HCT, hematopoietic cell transplant; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy.

1. Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

ALLELE Study (Data cutoff, September 10, 2024): Tabelecleucel Exposure

Tabelecleucel exposure	HCT (n = 29)	SOT-R (n = 21)	SOT-RC (n = 36)	SOT total (n = 57)	Total (N = 86)
Number of tabelecleucel cycles, median (range)	2 (1-5)	3 (1-5)	2 (1-6)	2 (1-6)	2 (1-6)
Number of tabelecleucel infusions, median (range)	6 (2-15)	9 (1-15)	6 (2-18)	6 (1-18)	6 (1-18)
Tabelecleucel treatment duration, median (range), months	2.1 (0.2-8.1)	2.7 (0.0-8.8)	1.7 (0.03-6.5)	1.9 (0.0-8.8)	1.9 (0.0-8.8)
Number of unique lots received, n (%)					
1 (primary lot)	17 (58.6)	15 (71.4)	23 (63.9)	38 (66.7)	55 (64.0)
2 (1st restriction switch)	9 (31.0)	6 (28.6)	13 (36.1)	19 (33.3)	28 (32.6)
3 (2nd restriction switch)	3 (10.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.5)

HCT, hematopoietic cell transplant; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy.

1. Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

ALLELE Study (Data cutoff, September 10, 2024): Efficacy, Treatment Response

Treatment response	HCT (n = 29)	SOT-R (n = 21)	SOT-RC (n = 36)	SOT total (n = 57)	Total (N = 86)
ORR, n responders, (%)	14 (48.3)	11 (52.4)	16 (44.4)	27 (47.4)	41 (47.7)
95% CI	29.4, 67.5	29.8, 74.3	27.9, 61.9	34.0, 61.0	36.8, 58.7
ORR before 1st restriction switch, n (%)	13 (44.8)	11 (52.4)	10 (27.8)	21 (36.8)	34 (39.5)
95% CI	26.4, 64.3	29.8, 74.3	14.2, 45.2	24.4, 50.7	29.2, 50.7
TTR, median (range), mo	1.0 (0.6–9.0)	2.1 (0.9–4.7)	2.2 (0.7–4.7)	2.1 (0.7–4.7)	1.1 (0.6–9.0)
Time to best response (range), mo	1.0 (0.6-9.0)	3.0 (0.9-7.3)	2.5 (0.7-19.8)	3.0 (0.7-19.8)	2.0 (0.6-19.8)
DOR, median (95% CI), mo[a]	19.0 (1.5, NE)	15.7 (0.6, NE)	NE (6.8, NE)	NE (6.8, NE)	23.0 (12.1, NE)

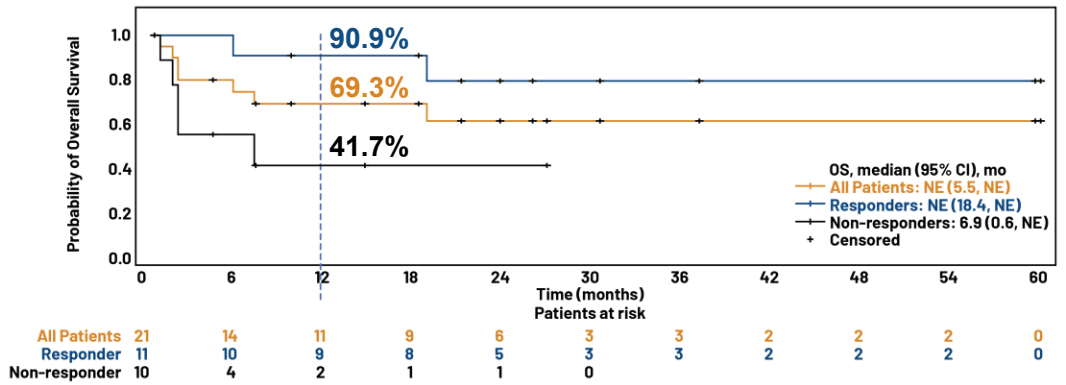
[a]Time from initial response until progression after last response or death from any cause in patients who achieve complete or partial response to tabelecleucel with ≤2 different HLA restrictions.
DOR, duration of response; HCT, hematopoietic cell transplant; HLA, human leukocyte antigen; NE, not estimable; ORR, objective response rate; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy; TTR, time to response.

1. Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

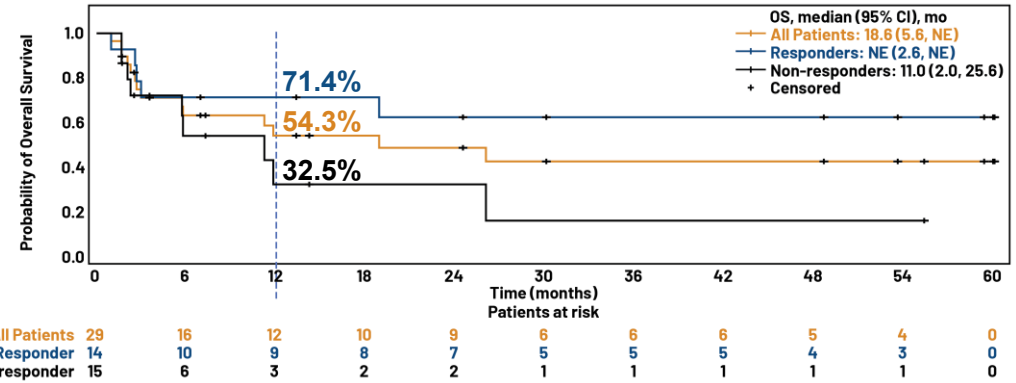
ALLELE Study (Data cutoff, September 10, 2024): Efficacy, Survival Outcomes

Survival outcomes	HCT (n = 29)	SOT-R (n = 21)	SOT-RC (n = 36)	SOT total (n = 57)	Total (N = 86)
PFS in responders, median (95% CI), mo[a]	21.0 (2.6, NE)	16.6 (5.5, NE)	NE (4.4, NE)	NE (13.0, NE)	23.9 (16.6, NE)
OS, median (95% CI), mo	18.6 (5.6, NE)	NE (5.5, NE)	21.6 (5.0, NE)	NE (9.0, NE)	25.6 (11.0, NE)
12-month OS rate, % (95% CI)					
All patients	54.3 (33.3, 71.2)	69.3 (44.0, 84.9)	58.6 (40.0, 73.2)	62.6 (48.0, 74.1)	59.7 (47.8, 69.7)
Responders	71.4 (40.6, 88.2)	90.9 (50.8, 98.7)	85.6 (53.3, 96.2)	88.1 (67.5, 96.0)	82.3 (66..4, 91.2)
Non-responders	32.5 (8.5, 59.8)	41.7 (10.9, 70.8)	35.1 (14.2, 57.0)	37.3 (19.2, 55.5)	35.3 (19.8, 51.1)

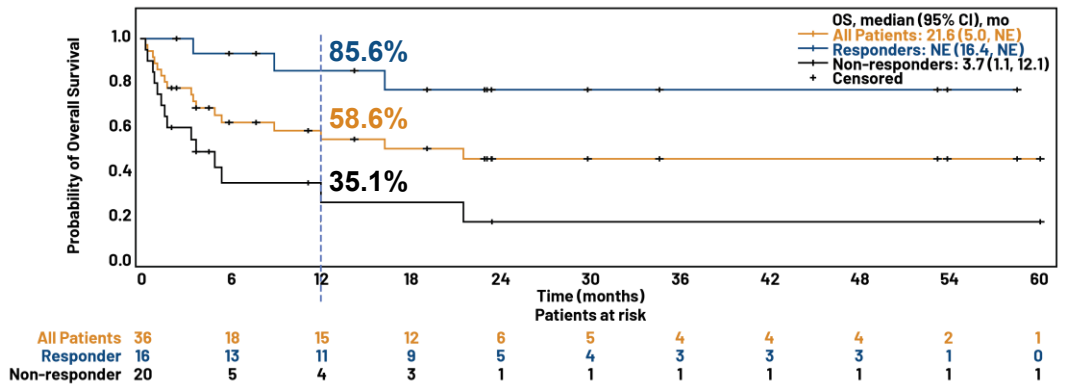
SOT-R: Overall survival



HCT: Overall survival



SOT-RC: Overall survival



[a]Time from first tabelecleucel dose until progression/relapse after last response or death (whichever occurs first) in full analysis set.
HCT, hematopoietic cell transplant; NE, not estimable; ORR, objective response rate; OS, overall survival; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy; TTR, time to response.

1. Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

ALLELE Study (Data cutoff, September 10, 2024): Safety

- Treatment-related SAEs were reported in 1 HCT and 7 SOT patients
- No fatal SAEs were related to tabelecleucel
- 1 SOT patient was reported with grade 1 fever considered as a sign of possible treatment-related CRS with no sign of severity
- No reports of:
  - Tumor flare
  - IRRs
  - ICANS
  - Immunogenicity events
  - Transmission of infection
- No reports of GvHD or organ transplant rejection were deemed treatment-related

Summary of TEAEs

	HCT (n = 29)	SOT-R (n = 21)	SOT-RC (n = 36)	SOT total (n = 57)	Total (N = 86)
All reported TEAEs, n (%)					
Any	28 (96.6)	18 (85.7)	35 (97.2)	53 (93.0)	81 (94.2)
SAE	17 (58.6)	12 (57.1)	26 (72.2)	38 (66.7)	55 (64.0)
Fatal SAE	5 (17.2)	2 (9.5)	7 (19.4)	9 (15.8)	14 (16.3)
Treatment-related TEAEs, n (%)					
Any	9 (31.0)	10 (47.6)	14 (38.9)	24 (42.1)	33 (38.4)
SAE	1 (3.4)	3 (14.3)	4 (11.1)	7 (12.3)	8 (9.3)
Fatal SAE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Treatment-emergent identified and potential risks including AESI, n (%)					
CRS	0 (0.0)	0 (0.0)	1 (2.8)	1 (1.8)	1 (1.2)
GvHD[a]	3 (10.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.5)
Transplant rejection	0 (0.0)	1 (4.8)	3 (8.3)	4 (7.0)	4 (4.7)

[a]Two cases were acute GvHD, including 1 with maculopapular rash, and 1 case was chronic GvHD. All cases were non-serious, and none led to treatment discontinuation.
AESI, adverse events of special interest; CRS, cytokine release syndrome; GvHD, graft-vs-host disease; HCT, hematopoietic cell transplant; ICANS, immune effector cell-associated neurotoxicity syndrome; IRRs, infusion-related reactions; SAE, serious adverse event; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy; TEAE, treatment-emergent adverse event.
1. Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

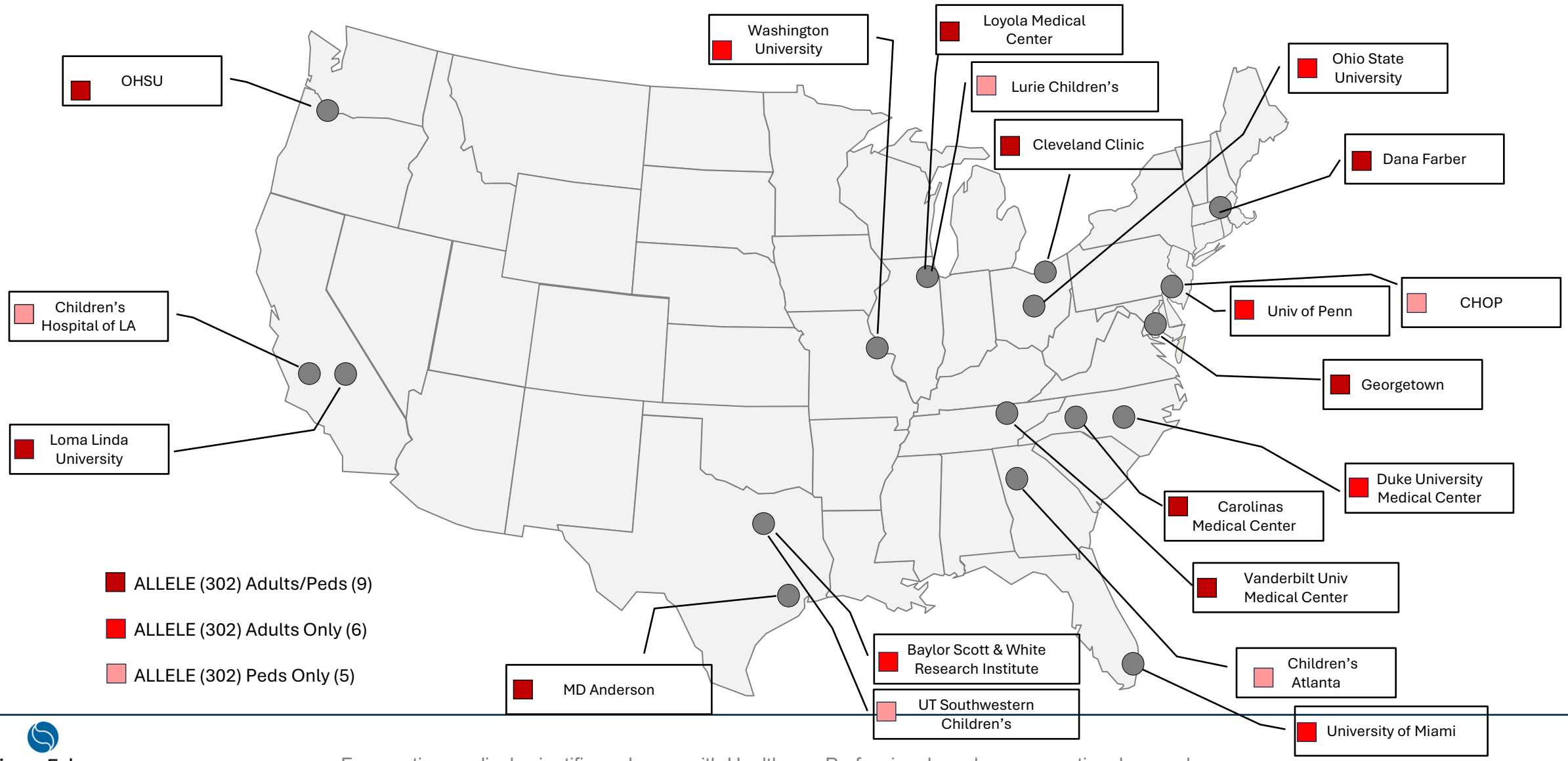
ALLELE Study (Data cutoff, September 10, 2024): Conclusions

- Results observed from ALLELE showed the efficacy of tabelecleucel with an ORR of 48.3% in the HCT cohort and 47.4% in the SOT cohort
- The reported ORR for SOT-R was 52.4%, and for SOT-RC, it was 44.4%
- The safety profile of tabelecleucel was consistent with previous reports. No new safety findings were identified
- Tabelecleucel may provide a treatment option for patients with R/R EBV+ PTLD, a population with limited therapeutic alternatives and poor prognosis

EBV+ PTLD, Epstein-Barr virus-associated post-transplant lymphoproliferative disease; HCT, hematopoietic cell transplant; ORR; objective response rate; R/R, relapsed or refractory; SOT, solid organ transplant; SOT-R, SOT and failed rituximab; SOT-RC, SOT and failed rituximab and chemotherapy.

1. Nikiforow S, et al. Presented ASH 2025; December 6-9, 2025; Orlando, FL. Abstract 1934.

ALLELE Clinical Trial Sites in the US[1]



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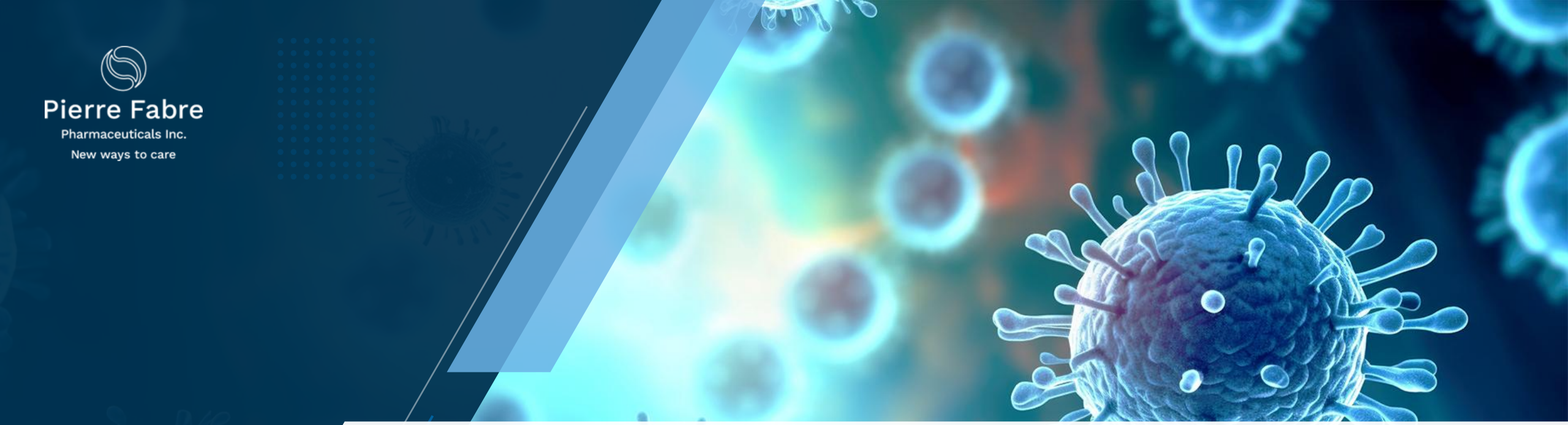

Thank you!
For additional information please contact:
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