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Developing Cancer Immunotherapies

# TD Cowen Health Care Conference

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# Advancing Allogeneic CAR T Cell Therapy for B-cell Malignances

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Address areas of high and growing unmet medical need. Post-autologous CART and other CART-naïve indications

Highly scalable one-to many therapeutic model offering broader patient access, quicker treatment initation and streamlined manufacturing

FDA Fast Track Designation allows for greater FDA engagement and priority review. FDA support for registrational pathway received Nov 2025

Potential for First-in-class allogeneic CAR T-cell therapy in a $2b+ market opportunity

# Manufactured with Proprietary ARCUS Gene Editing

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**Targeted Insertion of a CAR Gene into the TCRα Locus:**

- **I-CreI**: Nature's editing system, **evolved** for highly precise, versatile gene editing
- **ARCUS**: I-CreI **engineered** to target desired genetic sites
- Robust, "one-step" allogeneic CAR T cell manufacturing process in which the CAR transgene is inserted directly into the *TRAC* gene encoding the T Cell Receptor-α constant region.
- This knocks *out* the TCR while knocking *in* the CAR.

| KEY ADVANTAGES | |
|---|---|
| **Safety** | Non-integrating vector minimizes off-target editing; natural "off switch" |
| **Ease of delivery** | Small size permits both LNP and AAV delivery |
| **Control of edits** | Efficient knock-in or knockout |
| **Proprietary technology** | More than 50 issued U.S. and foreign patents |

**One-step process relies on AAV vector that contributes to azer-cel's good safety profile and minimizes the risk of cancer transformation associated with lentiviral vectors**

# Azer-cel Global Ph 1/1b Study

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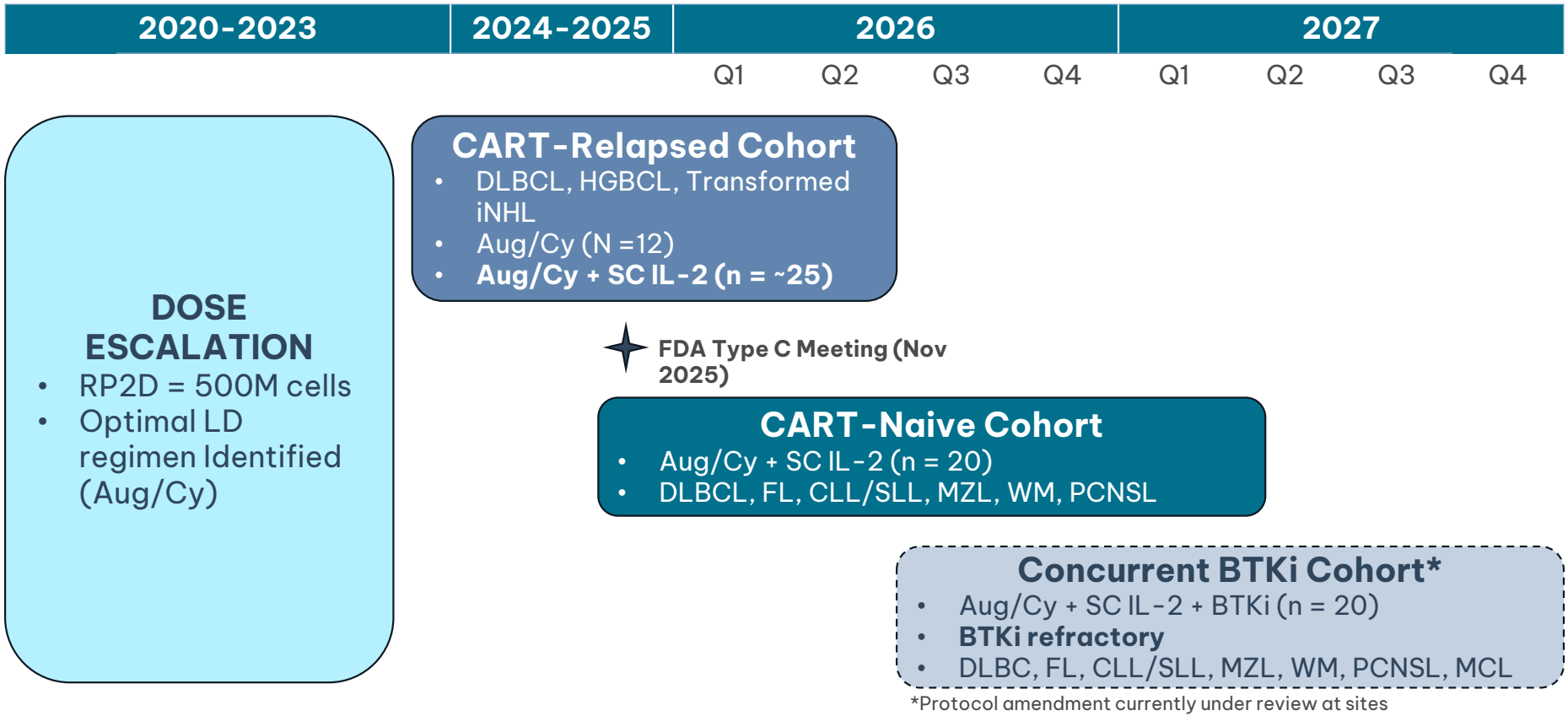
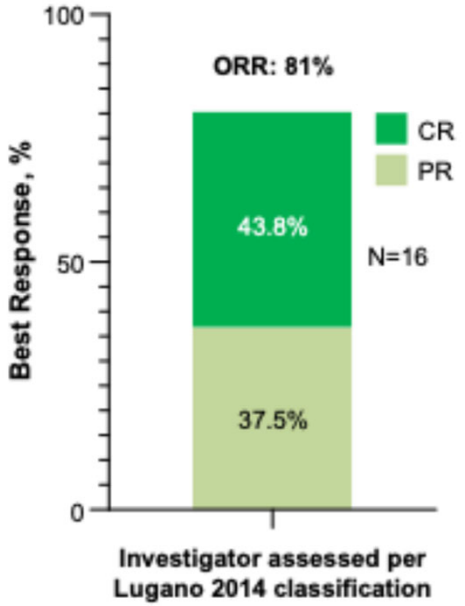
**Enrolling at 10 sites in the US and 5 sites in Australia**

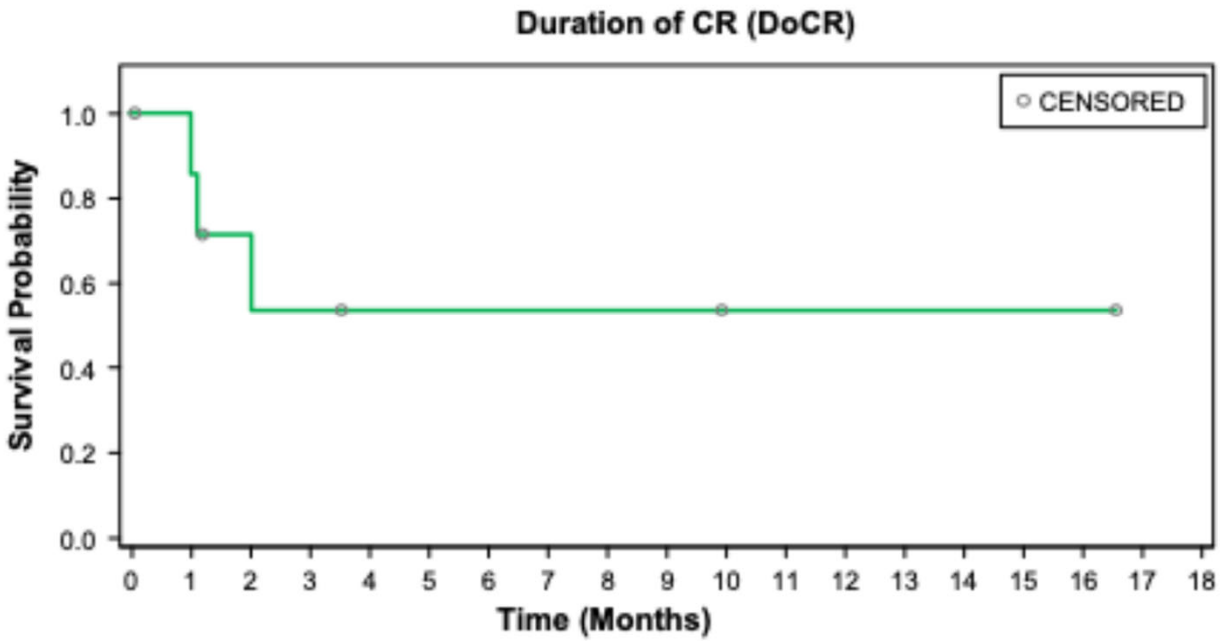



*Protocol amendment currently under review at sites

# High response rates with durability in heavily pre-treated CART-relapsed patients






Median duration of CR is not reached

**Heavily Pre-treated Population**

- Median of 4 lines of prior therapy (56% Primary refractory to 1L therapy)
- Duration of response to prior auto-CART ≤6 mo in 61% of patients
- 44% (n = 8) received prior CD20 x CD3 T-cell engager after auto-CART

# Patient Case Study: Cancer Free for 22+ months

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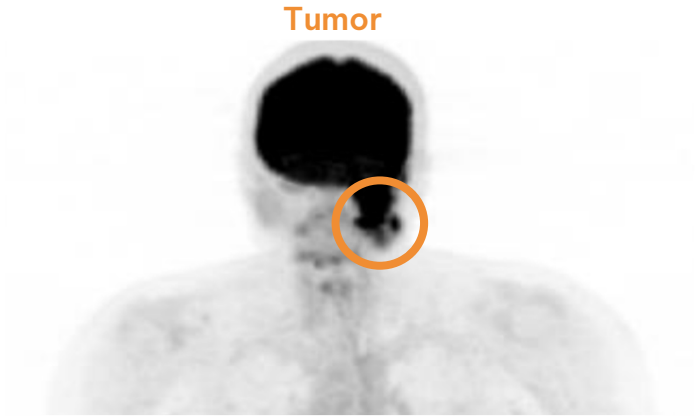
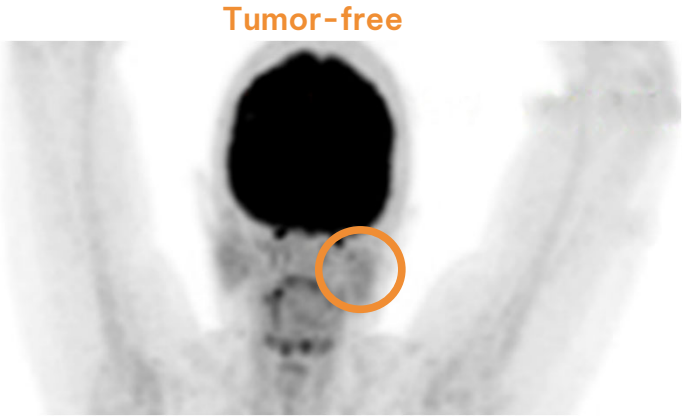
- 47 year old female, first diagnosed with high-grade B-cell lymphoma (HGBCL), stage IV in July 2022.
- Prior to azer-cel, patient failed 4 prior lines of therapy: R-CHOP; R-DHAP, Yescarta, and prednisone
- Good initial response to Yescarta (CR) but short duration of response (relapsed ~7 months later)
- Response: CR @ D28. Remains in CR at greater than 22 months and ongoing




Baseline




Day 365

# Robust CAR T-cell Expansion in CAR T relapsed patients

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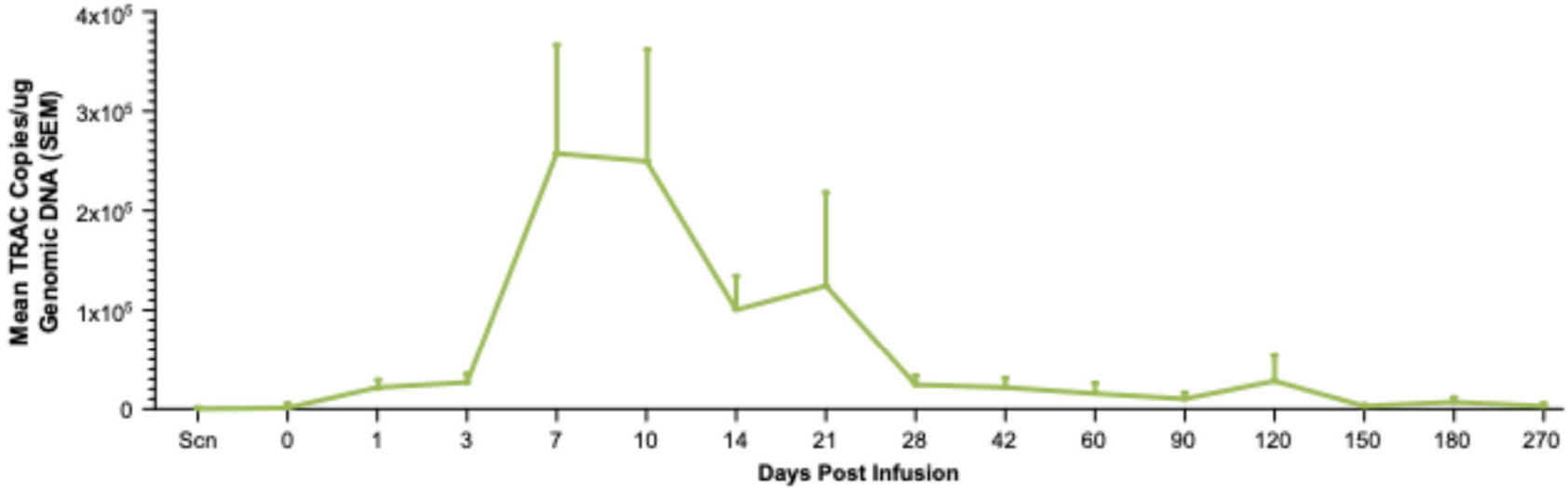


| Mean (± SEM) | N=16 |
|---|---|
| Peak CAR T-cell, copies/ug of gDNA | $4.2x10^5$ ($\pm 1.3x10^5$) |
| $AUC_{D0-28}$ CAR T-cell, copies/ug of gDNA | $3.2x10^6$ ($\pm 1.0x10^6$) |
| Time to peak, days | 14.4 (±7.15) |

# Sustained MRD negativity in complete responders

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| | Day 21/28 | Day 60 | Day 90 | Day 120 | Day 150/180 | Day 270 | Day 360 |
|---|---|---|---|---|---|---|---|
| Patient 1 | PR | CR | CR | CR | CR | CR | CR |
| Patient 2 | CR | CR | CR | CR | CR | CR | |
| Patient 3 | PR | PR | CR | CR | | | |
| Patient 4 | CR | CR | CR | | | | |
| Patient 5 | PR | CR | CR | | | | |

MRD negative  MRD positive  Positive below LOD  Not done/data unavailable

LOD: Limit of detection

- MRD was assessed using the ClonoSEQ assay (Adaptive Biotechnologies)
- Dominant tumor cell clone for each subject is calibrated at screening using tumor tissue

# Manageable safety profile with no new safety signals

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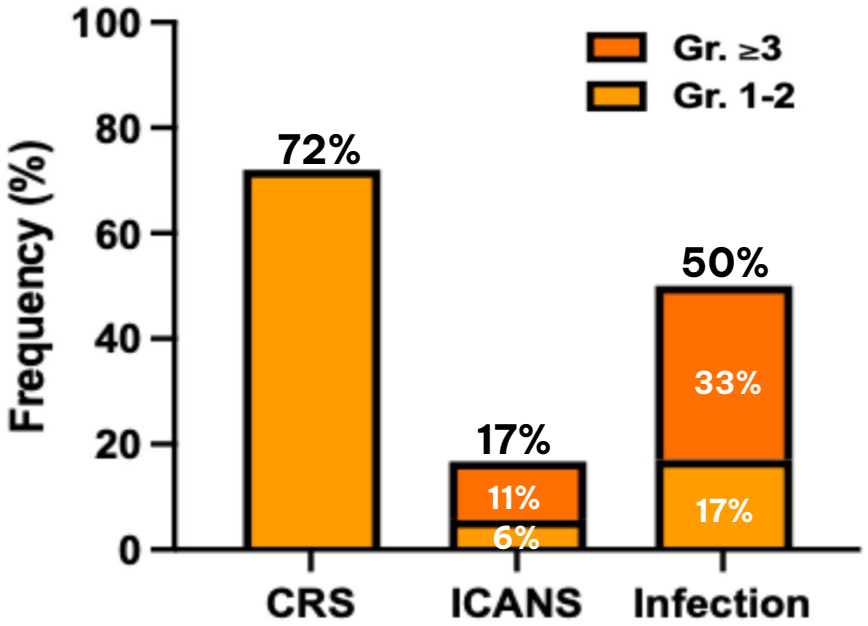
## No Evidence of GvHD or Gr. ≥3 CRS

| Adverse Event, n (%) | Any Grade | Grade ≥ 3 |
|---|---|---|
| Any | 18 (100) | 14 (78) |
| Serious | 6 (33) | 3 (22) |
| Cardiac Disorders | 4 (22) | 0 |
| Neutropenia | 18 (100) | 18 (100) |
| Anemia | 18 (100) | 7 (39) |
| Thrombocytopenia | 18 (100) | 9 (50) |




Safety Evaluable population (n = 18)
Both Gr. ≥3 ICANS events (n = 2) were Gr. 3. No Gr. 4 or 5 ICANS events have been observed to date.

# Successful FDA Type C Meeting

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## Establishing a Registrational Path in 3L+ DLBCL

- FDA Type C Meeting held in Nov 2025
- FDA alignment on the following:
  - Recommended Ph. 2 Regimen (Aug/Cy conditioning, azer-cel dose of 500M cells, low-dose SC IL-2)
  - 3L+ DLBCL patient population (CAR T-naïve, as well as CAR T-exposed)
  - Single randomized Ph. 3 trial with dual endpoints to potentially achieve accelerated and full approval with 1 clinical trial
  - Comparator arm
  - Endpoints (ORR with durability for accelerated approval, PFS for conversion to full approval)
  - CMC plans for registrational readiness

# Cohort 2: CAR-T naïve patients show strong overall response rate of 83%

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## Azer-cel 83% Overall Response Rate (N=6) in several indications

### Cohort 2: Evaluates azer-cel in CAR-T naïve patients across rare and niche lymphomas

| Date of Release | Evaluable patients | N | Overall Response Rate (ORR) |
|---|---|---|---|
| October Update | CAR-T Naïve Lymphomas | 6 | 5 (83%) 5/6 |

*CR rate assessment requires longer patient follow-up: for approved, autologous CD19 CAR-T products, the average time to best response is 2-3 months with some patients taking up to 6 months to achieve their best response*

### KEY TAKEAWAYS

- No approved CAR-T therapies in several of these indications
- Clear opportunity to expand into high-value niche populations
- Expands the potential registrational pathway
- **Potential for single arm pivotal study with low number of patients for Fast to Market**

### RESULTS

- 83% Overall Response Rate (ORR) in six evaluable heavily pretreated CAR-T naïve patients (5/6 responders, with results from the sixth patient pending)
- 50% Complete Response (CR) rate (3/6 patients)
- **Enrolling across multiple CD19+ B-cell malignancies including DLBCL, FL, CLL/SLL, MZL, WM and PCNSL**
- Enrolment progressing significantly faster than the CAR-T relapsed DLBCL cohort, supporting a potential expedited clinical path

# BTKi's AS A Pharmacological "gene editing" TOOL

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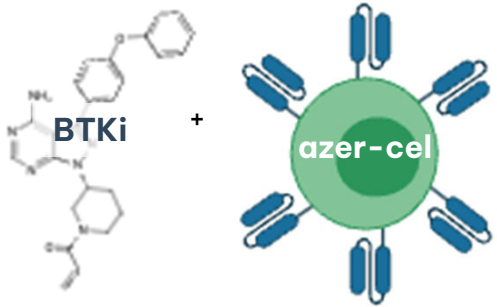
1. Skew T-cells to a more naïve-like state, enhancing CART proliferation and persistence[1]
2. Enhance metabolic fitness, increasing effector function[1]
3. Attenuate CART exhaustion[2]
4. Remodel TME to be less immunosuppressive[2,3]
5. Potential to reduce CART-associated toxicity[4]
6. Reverse endogenous T-cell dysfunction[5]




- Ph. 2 TARMAC trial of Ibrutinib + CTL019 (research version of Kymriah) in R/R MCL[6]
  - ORR: 85%, CR: 80%
- TRANSCEND-CLL 004: Liso-cel + Ibrutinib Cohort[7]
  - N = 51 (DL2 expansion cohort): ORR 86%, CR/Cri: 45%

1. Yao et al., ASH 2025c 2. Luo et al., Cytotherapy (2023), 3. Frost et al., ASH 2024, 4. Roschewski et al., Sci Immunol (2020) 5. Long et al., JCI (2017), 6. Minson et al., Blood (2024), 7. Wierda et al., ASH (2024)

# BTKi Market is Large and Growing

*Combination with existing BTKi's to increase registrational and commercial opportunity*

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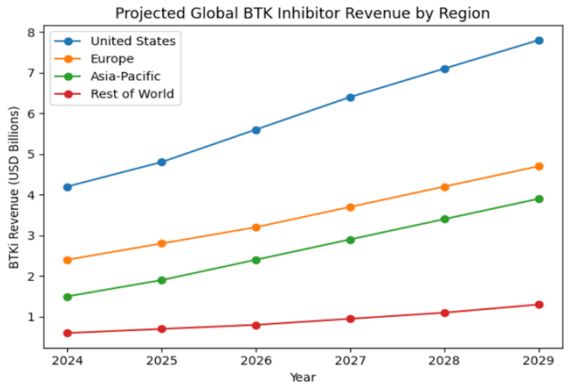
- BTK inhibitors are an established standard of care across multiple B-cell malignancies with >US$10bn in annual global sales
- Combining azer-cel with an approved BTKi has the potential to expand addressable patient populations beyond current CAR-T settings
- Leverages an existing commercial drug class with significant physician adoption
- BTKi are currently approved in Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), Waldenström macroglobulinemia (WM) and other B-cell malignancies and auto immune diseases




Total annual BTKi market[1]: USD ~$10-11.5B (2024-2025) and growing; Forecast to grow to USD 13.1B in 2026

[1]Global market for BTKi: GlobalData 18 Jan 2024, the Business Research Company, February 2026

| BTKi Drug | 1st Line | 2nd Line | 3rd Line | Annual Revenue |
|---|---|---|---|---|
| Ibrutinib | CLL, WM, MCL[1] | CLL, MCL[1] | | ~$4-6B |
| Acalabrutinib | CLL, MCL | MCL, CLL, MZL[1] | | ~$1-2B |
| Zanubrutinib | CLL, MCL[1] | CLL, MCL, MZL | FL | ~$1-2B |
| Pirtobrutinib | CLL[2] | CLL | CLL, MCL | Several hundred million, expanding |

[1]Recommended per NCCN Guidelines
[2]sBLA submission anticipated in 2026

# Proposed Clinical Pathway: Azer-cel Allogeneic CD19 CAR-T

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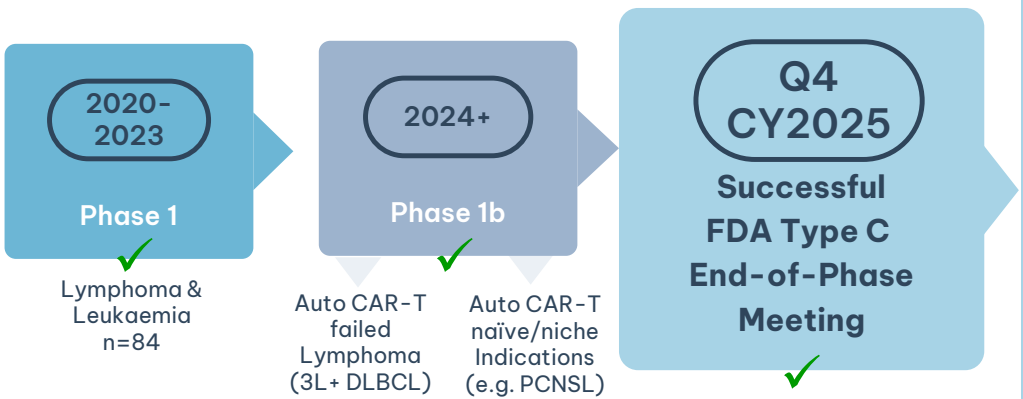
## 2026 Provides Opportunity to Progress Toward Registrational Strategy

- Continue advancement of azer-cel incorporating expansion into CAR-T naïve rare and niche indications
- Advance BTKi + azer-cel combination and CAR-T naïve lymphoma cohorts to support expanded Registrational Path
- Leverage FDA-aligned single randomized study design




## 2026 Execution

### Clinical

- Continued enrollment and data maturation for:
  - **CAR-T naïve/ niche cohorts**
  - **BTKi + azer-cel combination cohorts**
- Additional data presentation at ASCO, EHA, ASH 2026

### Manufacturing & Supply

- Scale-up and validation of registrational manufacturing
- Readiness for one-to-many allogeneic supply model
- **Continue to align our CMC activity with FDA**

### Regulatory

- Continued FDA engagement to support:
  - **Accelerated approval pathway**
  - Label expansion into additional niche indications
- Potential regulatory designations to de-risk development timeline

### Business Development

- Partnering / out-licensing discussion for:
  - Azer-cel (regional or indication-specific)
  - **BTKi combination strategy (major pharmaceutical blockbuster drug)**
- onCARIytics collaboration execution (JW Therapeutics)

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