
# First anniversary of PRIME: experience so far

## KTE-C19 Experience

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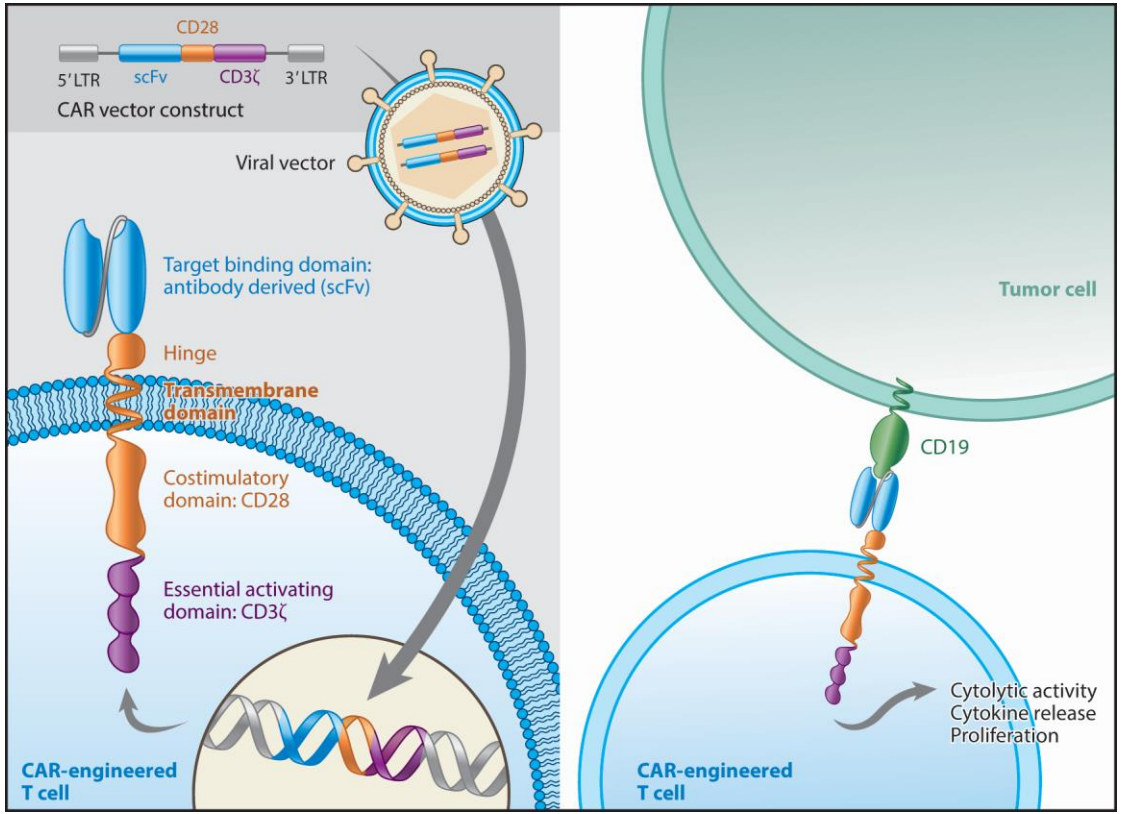
Diamond BioPharm Limited
REGULATORY CONSULTANTS

Kite Pharma
FOCUSED ON THE CURE

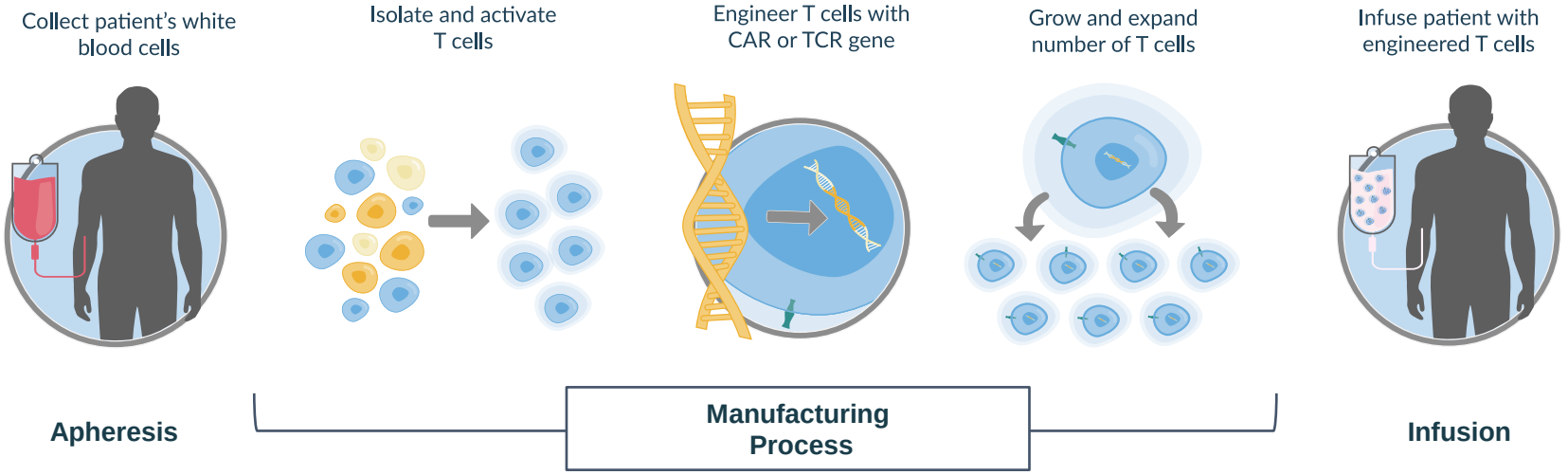
# KTE-C19: anti-CD19 CAR T Cell Therapy

- KTE-C19 is an autologous chimeric antigen receptor (CAR) T cell therapy with a CD3ζ/CD28-based signaling that recognizes and eliminates CD19-expressing cells on normal and malignant cells



# Kite is Developing Personalized Cancer Immunotherapies

## CHIMERIC ANITGEN RECEPTOR (CAR) T CELL TECHNOLOGY



# PRIME Candidate – Eligibility Criteria

- ✓Must address an area of ‘unmet medical need’
- ✓Must have preliminary clinical evidence
- ✓Has the potential to bring a major therapeutic advantage to patients
- SMEs and Academic applicants may apply earlier with compelling non-clinical data and tolerability data from initial clinical trials

# PRIME Benefits

- ✓Early appointment of Rapporteur
- ✓Kick-off meeting to provide guidance on the development plan and regulatory strategy
- ✓Early review of eligibility for accelerated assessment
- ✓Dedicated contact person at EMA
- ✓Additional support from EMA, SAWP/CHMP and other relevant scientific committees (PDCO, COMP, CAT, ATMP) and stakeholders
- Early support for clinical trial design

# KTE-C19: Eligible Candidate for DLBCL condition

- Non-Hodgkin Lymphoma (NHL) is the most common hematologic malignancy
- DLBCL is the most common type of aggressive B-cell NHL in adults
- Outcomes in refractory, aggressive DLBCL are poor
- No therapies are approved in this setting
- These patients have no curative options and there is a clear unmet medical need
- KTE-C19 is being developed as an option for patients with highly chemotherapy-refractory lymphoma - namely DLBCL, PMBCL and TFL

# KTE-C19 Experience

- Scientific Advice previously sought on development program prior to obtaining PRIME
- Pivotal study ongoing at time of receiving PRIME designation
- First oncology product to receive PRIME status
- Very new process when we entered; unsure of expectations
- PRIME Coordinator very approachable, knowledgeable and helpful
- Kickoff meeting agenda driven largely by PRIME team – discussions top level
- Knowing Rapporteur early was a positive factor
- Strong drive to help orientate a development towards accelerated assessment

# Feedback

- High reliance on following scientific advice/protocol assistance procedure
  - Could impact timelines and EMA's mission for expediting development for patients with unmet medical need
  - Different focus needed for late stage versus early phase products
- Key concerns could be highlighted by the Rapporteur/EMA and some top level advice provided at the kick-off meeting
  - Rapporteur could provide feedback on briefing document prior to the meeting
  - Similar follow up meetings to kick-off could be helpful for Sponsor/SMEs
- Provide opportunities for direct interactions with CHMP/CAT Rapporteur for non-significant issues
  - EMA PM to facilitate or propose interactions