Forward Looking Statements/Safe Harbor

To the extent statements contained in this presentation are not descriptions of historical facts regarding Kite Pharma, Inc. (“Kite,” “we,” “us,” or “our”), they are forward-looking statements reflecting management’s current beliefs and expectations. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance, or achievements to be materially different from those anticipated by such statements. You can identify forward-looking statements by words, such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” or the negative of those terms, and similar expressions, that convey uncertainty of future events or outcomes. Forward-looking statements contained in this presentation include, but are not limited to, statements regarding: (i) the success and timing of our product development activities and clinical trials; (ii) the ability and willingness of the National Cancer Institute (NCI) to continue research and development activities relating to our product candidates; (iii) our ability to obtain and maintain regulatory approval of axicabtagene ciloleucel (“axi-cel”) and any other product candidates; (iv) our ability to further develop and commercialize our product candidates; (v) our plans to research, discover, and develop additional product candidates and next-generation product candidates, including a next-generation CAR with an “on/off” or “control” switch; (vi) our and our partners’ ability to develop, manufacture and commercialize our product candidates and to improve the manufacturing process; (vii) the size and growth potential of the markets for our product candidates, and our ability to serve those markets; (viii) the rate and degree of market acceptance of our product candidates; (ix) our ability to attract and retain key scientific or management personnel; (x) the anticipated timing of clinical data availability; (xi) the anticipated timing of submitting a Biologics License Application for axi-cel and commercially launching axi-cel; (xii) our plans to expand geographically; (xiii) our ability to meet the milestones set forth herein; and (xiv) our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

Various factors may cause differences between Kite’s expectations and actual results as discussed in greater detail in Kite’s filings with the Securities and Exchange Commission (SEC), including without limitation in its Quarterly Report on Form 10-Q filed with the SEC for the quarter ended March 31, 2017. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy securities, nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.
Outline

• Background on Kite
  – Axicabtagene ciloleucel (axi-cel)
• Background on Comparability
• Experience at Kite with Comparability
The Science of CAR T and TCR
Axi-cel Production: Harnessing the Power of Patients’ Own T Cells

- T cell stimulation, growth, and formulation are critical to an efficient manufacturing process
- Patients depend on a robust and efficient manufacturing process
- Continuous process with no downstream purification steps
Potential to Transform the Treatment of B-Cell Malignancy

62-Year-Old Man With Refractory DLBCL

- Prior therapies
  - R-CHOP
  - R-GDP
  - R-ICE
  - R-lenalidomide

DLBCL, diffuse large B-cell lymphoma; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone; R-GDP, rituximab, gemcitabine, dexamethasone, cisplatin; R-ICE, rituximab, ifosfamide, carboplatin, etoposide.
Ongoing Response in Pivotal ZUMA-1 CAR T Trial Illustrates Promise of CAR T Cell Therapy

<2 Years + 22 Clinical Trial Sites + 101 Patients with Aggressive NHL = 82% ORR
54% CR
44% in ongoing response
39% in ongoing CR

Axi-cel Maintained Ongoing Responses at Median Follow-up of 8.7 Months
Commercial Manufacturing Ready in 2017 for **Axi-cel**

In-house clinical manufacturing in full operation

Commercial facility within close proximity to LAX airport

Capacity to produce 4,000+ patient therapies per year

Modular design – scalable, cost effective, and can be quickly replicated to meet increased demand if needed

Site to produce **axi-cel**/KTE-C19, CAR, and all TCR products

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CAR, chimeric antigen receptor; TCR, T cell receptor.
Overview of the Manufacturing Process

Clinical Center → Apheresis product → Ship for Manufacturing

Manufacturing Site

- Enrich for T cells
- T cell Activation
- Retroviral Transduction
- T cell Expansion
- Harvest / Freeze

Clinical Center → Final Product → Ship to Patient

- Ficoll separation of PBMC
- Gentle simulation with anti-CD3 Ab
- Natural co-stimulatory signals from Monocytes and B cells
- Introduce CAR gene
- Achieve dose
- Prepare KTE-C19
Regulatory Guidance on Comparability

- CBER/CDER Guidance: Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products - April, 1996

- ICH Q5E: Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process (2005)

- EMEA Guideline (2006) and EMA Q&A on Post approval change management protocols (10/2012)

- CBER/CDER Draft Guidance for Industry: Comparability Protocols-Protein Drug Products and Biological Products - Chemistry, Manufacturing, and Controls Information, April, 2016

- ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
A determination that a product is “Comparable” indicates that products before and after a manufacturing change are highly similar and that no adverse impact on the quality, safety or efficacy of the drug product has occurred.

It does not mean that pre- and post-change products are identical or indistinguishable.
Comparability strategy depends on the complexity of change

- Type and extent of Change
- Stage of product lifecycle
- Availability and robustness of analytical procedures
- Extent of product and process knowledge
- Outcome of risk assessment - impact on quality, safety and efficacy
- Agency recommendation (EMEA, FDA, etc)
Fundamental challenge for autologous products

- Complex, often labor intensive, multi-step process
- Inherent variability from many sources
  - Raw materials and supplies
  - Patient cells (e.g., apheresis product)
  - Production process
  - Analytical methods depend on bioassay and FACS
- Limited data available on range and nature of variation
- Variation for some parameters is relatively large compared to others (e.g. Patient source)
Two approaches commonly used to demonstrate comparability in autologous cell therapy

1. Expectation Approach
2. Equivalence Approach
Expectation Approach

• Comparability is demonstrated by comparing performance of test sample to pre-specified acceptance criteria calculated from reference sample data
• Tolerance interval is commonly used to calculate the acceptance criteria
• Easy to execute
• Less powerful
• Large data set needed for setting meaningful acceptance criteria
Equivalence Approach

- Comparability is demonstrated by performing pre- and post-change studies concurrently using split starting material
- Powerful approach since it reduces variability caused by the starting material
- Two one-sided t-test (TOST) is commonly used to show comparability
- Difficult to execute, especially if the study has to conducted at sites located in different countries
- Estimation of equivalence interval and sample size is challenging
Equivalence Approach: Sample Size and Power Calculations

<table>
<thead>
<tr>
<th>Range of Observed Standard Deviation (SD)</th>
<th>Total sample size (Number of donors)</th>
<th>Minimum Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 or smaller</td>
<td>4</td>
<td>83%</td>
</tr>
<tr>
<td>2.6 – 3.1</td>
<td>5</td>
<td>81%</td>
</tr>
<tr>
<td>3.2 – 3.5</td>
<td>6</td>
<td>82%</td>
</tr>
<tr>
<td>3.6 – 3.9</td>
<td>7</td>
<td>82%</td>
</tr>
<tr>
<td>4.0 – 4.3</td>
<td>8</td>
<td>81%</td>
</tr>
</tbody>
</table>

Important to estimate standard deviation right
Kite Pharma has successfully performed several comparability studies

1. Early research site vs CMO making clinical material
2. CMO vs internal clinical manufacturing site
3. Internal clinical manufacturing site vs Internal commercial site
4. Before and after a major process change
5. Process transfer of Phase II pipeline process from clinical site to commercial site
Criteria to Assess Comparability

• Risk assessment was performed to determine which Critical Quality Attributes should be considered for comparability
  – Percent transduction is used to calculate dose and is highly dependent on the starting apheresis material
  – Potency (IFNγ production) demonstrates that T cells are functional
  – Impurity clearance demonstrates process capability
  – Safety (sterility) demonstrates process integrity

• Additional process performance criteria
  – Wash recovery
  – Viability at selected process steps and harvest
  – Fold expansion
Growth data from a Equivalence Approach study

<table>
<thead>
<tr>
<th>Lot</th>
<th>D % CAR: Site A vs. B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>2</td>
<td>5.4</td>
</tr>
<tr>
<td>3</td>
<td>3.1</td>
</tr>
<tr>
<td>4</td>
<td>-1</td>
</tr>
</tbody>
</table>
TOST results from Site-Site Comparability Study

<table>
<thead>
<tr>
<th>Acceptance Difference (%)</th>
<th>Calculated Power</th>
<th>% Transduction Mean Difference</th>
<th>90% Confidence Interval for Mean Difference</th>
<th>Equivalence Test P Value</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>±X1</td>
<td>89%</td>
<td>y</td>
<td>(−3.93, 7.43)</td>
<td>0.0142</td>
<td>Equivalent</td>
</tr>
<tr>
<td>±X2</td>
<td>&gt;99%</td>
<td>y</td>
<td>(−3.93, 7.43)</td>
<td>0.0015</td>
<td>Equivalent</td>
</tr>
<tr>
<td>±X3</td>
<td>&gt;99%</td>
<td>y</td>
<td>(−3.93, 7.43)</td>
<td>0.0002</td>
<td>Equivalent</td>
</tr>
</tbody>
</table>

**Distribution of Difference**

With 90% CI and Equivalence Bounds for Mean

TOST (Two One-Sided Test) Equivalence Analysis for 8 Paired Runs
## Risk matrix to define comparability approach during product lifecycle

<table>
<thead>
<tr>
<th>Product Lifecycle Stage</th>
<th>Minor Change</th>
<th>Major Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Phase 2 Pivotal</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>Commercial</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>
Summary

- Assessing comparability for autologous products is confounded by
  - Intrinsic variability in donor starting material
  - Availability of appropriate analytical methods and method variability

- Two approaches commonly used
  - Expectation approach is easy to execute but requires large data set
  - Equivalence approach using split starting material is more powerful and relevant

- Careful planning and execution of studies required

- Clear company policy required to manage comparability during product lifecycle
Thank you!