## Allogene: <br> Leading the Next Revolution in Cell Therapy

March 2019

## Forward-Looking Statements

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## Autologous CAR T: Learning from the First Revolution



## Allogeneic CAR T Therapy: The Next Potential Breakthrough



## Allogene: Leading the Future of AlloCAR $\top^{\text {TM }}$ Cell Therapy



## Allogene Today: Creating the Future of AlloCAR $T^{T M}$ Cell Therapy



## The Allogene Leadership Team

$\left.\begin{array}{lc}\text { Arie Belldegrun, M.D., FACS } & \text { Kite } \\ \text { Executive Chairman \& Co-Founder }\end{array}\right)$

| Barbra Sasu, Ph.D. Chief Scientific Officer | Pfizer AMGEN |
| :---: | :---: |
| Susie Jun, M.D., Ph.D. Chief Development Officer | abbvie |
|  | AMGEN \/J GILEAD |
| Veer Bhavnagri General Counsel | Kite Cooley |
|  | SULIVAN \& Cromwell llp |
| David Tillett, Ph.D. Head of Quality | AMGEN |

## Allogene's Strategy: Focused Development of AlloCAR $T^{\text {TM }}$ Cell Therapy

| DIFFERENTIATION |
| :---: |
| Build state-of-the-art <br> gene engineering and <br> cell manufacturing <br> capabilities |
| (Sustainability) |


| NEAR-TERM |
| :---: |
| Capitalize |
| on validated target |
| and first-mover |
| advantage in anti- |
| CD19 AlloCAR T |
| candidates |
| (Leadership) |


| FAST-FOLLOW |
| :---: |
| Expand leadership |
| position within |
| hematologic |
| indications including |
| Multiple Myeloma |
| and AML |
| (Advantage) |

LONG-TERM

Leverage next generation technologies and expand into solid tumor indications with high unmet need
(Innovation)

## Current Manufacturing Capabilities \& Planned Expansion

## Current South San Francisco Facility

- Manufacturing process development \& optimization
- Analytic methods for in-process characterization \& improvement
- Quality Assurance and Quality Control support

Planned East Bay Area Facility (Newark, CA)


## Current CMO Support

- Dedicated purpose built GMP suite
- Clinical supply manufacturing, formulation \& release


## AlloCAR $T^{\text {TM }}$ Cells Will Be Available On Demand



## Allogene

## Deep AlloCAR $T^{\text {TM }}$ Pipeline Targeting Vast Array of Tumor Types

| CATEGORY | PROGRAM | PRE-CLINICAL | PHASE 1 | PHASE 2/31 |
| :---: | :---: | :---: | :---: | :---: |
| Hematological Malignancies | UCART19 (CD19/ALL) (Servier Sponsored) ${ }^{2}$ |  |  |  |
|  | ALLO-501 (CD19/NHL) ${ }^{2}$ |  |  |  |
|  | ALLO-715 (BCMA/MM) |  |  |  |
|  | ALLO-819 (FLT3/AML) |  |  |  |
|  | CD70 (NHL) |  |  |  |
| Solid Tumors | CD70 (RCC) |  |  |  |
|  | DLL3 (SCLC) |  |  |  |
| Lymphodepletion <br> Agent ${ }^{3}$ | ALLO-647 (Anti-CD52 mAb) |  |  |  |

[^0]
## UCART19: The First AlloCAR T TM in Clinical Development



## Controlling Graft-vs-Host Disease (GvHD) Reaction

| GvHD with TCR |
| :---: |
| present |


| No GvHD with TCR |
| :---: |
| knocked out |



- GvHD: a potentially serious complication where allogeneic cells ("the graft") attack the patient's healthy cells ("the host")
- Risk of GvHD can be reduced by inactivating T cell receptors (TCR)
- Mild cases of Grade 1 acute GvHD reactions limited to skin observed with UCART19 in ongoing clinical studies (ASH 2018)


## Creating a Window of Persistence



Allogeneic CAR T cells lacking CD52 will not be eliminated by ALLO-647 (anti-CD52 mAb)

Anti-CD52 mAb (ALLO-647) intended to reduce the likelihood of the patient's immune system from rejecting AlloCAR $T^{\text {TM }}$ cells


BCMA CAR T cells knocked out for CD52 are resistant to ALLO-647 in a complement-dependent cytotoxicity assay

## ALLO-501 ALPHA Study Targeting CD19 in R/R NHL

## ALLO-501 and ALLO-647 Phase 1 Study Overview (Allogene-Sponsored)

- Eligible patients with relapsed/refractory large B-cell lymphoma or follicular lymphoma and:
- Failed at least two prior lines of therapy
- No prior anti-CD19 therapy
- Absence of pre-existing donor (product)-specific anti-HLA antibodies
- Objectives:
- Primary: Safety, tolerability and recommended P2 doses for ALLO-501 and ALLO-647
- Secondary: Anti-tumor activity, ALLO-501 cellular kinetics, ALLO-647 PK, immunogenicity and host lymphocyte reconstitution
- Dose-escalation of ALLO-501: 40 to $360 \times 10^{6}$ CAR+ cells in $3+3$ design
- Up to 24 patients


Treatment:

- Starting cell dose: $40 \times 10^{6} \mathrm{CAR}+$ cells

Lymphodepletion:

- ALLO-647: $13 \mathrm{mg} / \mathrm{d} \times 3$ days
- Fludarabine: $30 \mathrm{mg} / \mathrm{m}^{2} / \mathrm{d} \times 3$ days
- Cyclophosphamide: $300 \mathrm{mg} / \mathrm{m}^{2} / \mathrm{d} \times 3$ days


## UCART19 PALL \& CALM Studies Targeting CD19 R/R ALL

## UCART19 ALL Pediatric (PALL) and Adults (CALM) Study Overview Servier Sponsored

- Eligible patients with CD19+ B-ALL and:
- Morphological or MRD+
- Failed previous treatment options
- Objectives:
- Primary: Safety and tolerability
- Secondary: Anti-leukemic activity
- Exploratory: UCART19 expansion and persistence
- PALL ongoing:
$\checkmark \mathrm{n}=7$ treated with $2 \times 10^{7}$ total cells
- CALM dose escalation ongoing:
$\checkmark n=6$ treated at DL1 ( $6 \times 10^{6}$ total cells)
$\checkmark \mathrm{n}=6$ treated at DL2 ( 6 to $8 \times 10^{7}$ total cells)
$\rightarrow$ DL3 ( 1.8 to $2.4 \times 10^{8}$ total cells) ongoing

- Fludarabine: $\quad 90 \mathrm{mg} / \mathrm{m}^{2}$ for adults; $150 \mathrm{mg} / \mathrm{m}^{2}$ for pediatrics
- Cyclophosphamide: $1500 \mathrm{mg} / \mathrm{m}^{2}$ for adults; $120 \mathrm{mg} / \mathrm{kg}$ for pediatrics
- Anti-CD52 mAb: $1 \mathrm{mg} / \mathrm{kg}$ both adults and pediatrics


## UCART19: Manageable AE Profile in Phase 1 Studies

| N=21 | $\begin{gathered} \mathrm{G} 1 \\ \mathrm{n}(\%) \end{gathered}$ | $\begin{gathered} \mathrm{G} 2 \\ \mathrm{n}(\%) \end{gathered}$ | $\begin{gathered} \text { G3 } \\ \mathrm{n}(\%) \end{gathered}$ | $\begin{gathered} \text { G4 } \\ \mathrm{n}(\%) \end{gathered}$ | $\begin{gathered} \mathrm{G} 5 \\ \mathrm{n}(\%) \end{gathered}$ | All grades n (\%) |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| AEs related to UCART19 |  |  |  |  |  |  |
| Cytokine release syndrome | 4 (19.0) | 12 (57.1) | 2 (9.5) | 1* (4.8) | - | 19 (90.5) |
| Neurotoxicity events | 7 (33.3) | 1 (4.8) | - | - | - | 8 (38.1) |
| Acute skin graft-versus-host disease ** | 2 (9.5) | - | - | - | - | 2 (9.5) |
| AEs related to lymphodepletion and/or UCART19 |  |  |  |  |  |  |
| Viral infections † | 1 (4.8) | 2 (9.5) | 4 (19.0) | 1 (4.8) | - | 8 (38.1) |
| Prolonged cytopenia*** | - | - | - | $6 \ddagger(28.5)$ | - | 6 (28.5) |
| Neutropenic sepsis |  |  |  | 1 (4.8) | 1* (4.8) | 2 (9.5) |
| Febrile neutropenia/ septic shock |  |  |  |  | 1 (4.8) | 1 (4.8) |
| Pulmonary hemorrhage |  |  |  |  | $1 \ddagger(4.8)$ | 1 (4.8) |

## ASH 2018

n : number of patients with at least one AE by worst grade

* 1 DLT at DL1 related to UCART19: G4 CRS associated with G5 neutropenic sepsis (death at D15 post-infusion)
** GvHD confirmed by biopsy in 1 out of 2 cases
*** Persistent Grade 4 neutropenia and/or thombocytopenia beyond Day 42 post UCART19 infusion, except if $>5 \%$ bone marrow blasts
$\ddagger 1$ DLT at DL2 related both to UCART19 and LD: G4 prolonged cytopenia associated with infection and pulmonary hemorrhage (death at D82 moimigitusighlon $\dagger$ Viral infections: CMV, ADV, BK virus, metapneumovirus


## UCART19: 82\% CR/CRi with FCA Lymphodepletion Regimen

| Trial | Patients Enrolled \& Treated | CR/CRi with FCA | CR/CRi with FC only | CR/CR Overall |
| :---: | :---: | :---: | :---: | :---: |
| PALL | 7 | $\begin{gathered} 100 \% \\ (6 / 6) \end{gathered}$ | $\begin{gathered} 0 \% \\ (0 / 1) \end{gathered}$ | $\begin{aligned} & 86 \% \\ & (6 / 7) \end{aligned}$ |
| CALM | 14 | $\begin{gathered} 73 \% \\ (8 / 11) \end{gathered}$ | $\begin{gathered} 0 \% \\ (0 / 3) \end{gathered}$ | $\begin{gathered} 57 \% \\ (8 / 14) \end{gathered}$ |
| Pooled | 21 | $\begin{gathered} 82 \% \\ (14 / 17) \end{gathered}$ | $\begin{gathered} 0 \% \\ (0 / 4) \end{gathered}$ | $\begin{gathered} 67 \% \\ (14 / 21) \end{gathered}$ |

[^1]- UCART19 expansion observed in $15 / 17$ patients with FCA and $0 / 4$ patients with FC only
- Allogene will use its Proprietary anti-CD52 mAb (ALLO-647) for AlloCAR T ${ }^{\text {TM }}$ Programs


## ALLO-715: BCMA AlloCAR $T^{\text {TM }}$ for Multiple Myeloma




ALLO-715 showed activity in vitro against myeloma cell lines and in vivo in xenograft models

- Plan to initiate a Phase 1 clinical trial in 2019
- Expected Phase 1 clinical trial will be an open label, multi-center, dose escalation study in $r / r$ Multiple Myeloma


## CD70 for Renal Cell Carcinoma (RCC)

CD70 Expression High in RCC and Low in Normal Tissues
CD70 is the ligand for the co-stimulatory receptor CD27

- Normal CD70 expression is limited to activated lymphocytes and APCs

CD70 expression ${ }^{1}$ :

- RCC tumor samples (80-100\%)
- AML (96\%)
- DLBCL (71\%), MM (63\%), CLL (50\%),
- GBM (35\%)

Lead CARs chosen from several Abs targeting different regions of the protein

- Candidates screened to show long-lived activity in low-expressing cell lines similar to disease level expression


> CD70-Low Cell Line Models Match Median Expression in Tumors


## DLL3 for Small Cell Lung Cancer (SCLC)

## DLL3 reported to have a role in tumorigenesis

- Outside of the developing embryo, minimal to no surface expression in normal tissue
DLL3 expression ${ }^{1}$ :
- Small cell lung cancer (80\%)
- Low grade gliomas (90\%) \& GBM (70\%)
- Bladder (57\%) \& Prostate (24\%)
- Testicular cancer (90\%)

Candidate CARs chosen from several Abs targeting different regions of the protein

- Two protein domains identified with superior CAR T activity


## Toxicology program ongoing

DLL3 RNA Expression High in Tumor and Normal Tissue


- Investigating toxicity using mouse crossreactive CARs


## Engineering a Future for AlloCAR TTM in Solid Tumors



The 2019 Path Forward: Allogene-Sponsored Program Milestones



[^0]:    ${ }^{1}$ Phase 3 may not be required if Phase 2 is registrational
    ${ }^{2}$ Servier holds ex-US commercial rights
    ${ }^{3}$ ALLO-647 intended to enable expansion and persistence of allogeneic CAR $T$ product candidates

[^1]:    ASH 2018 ; FCA: Fludarabine, cyclophosphamide \& alemtuzumab (anti-CD52 mAb); FC: Fludarabine \& cyclophosphamide

