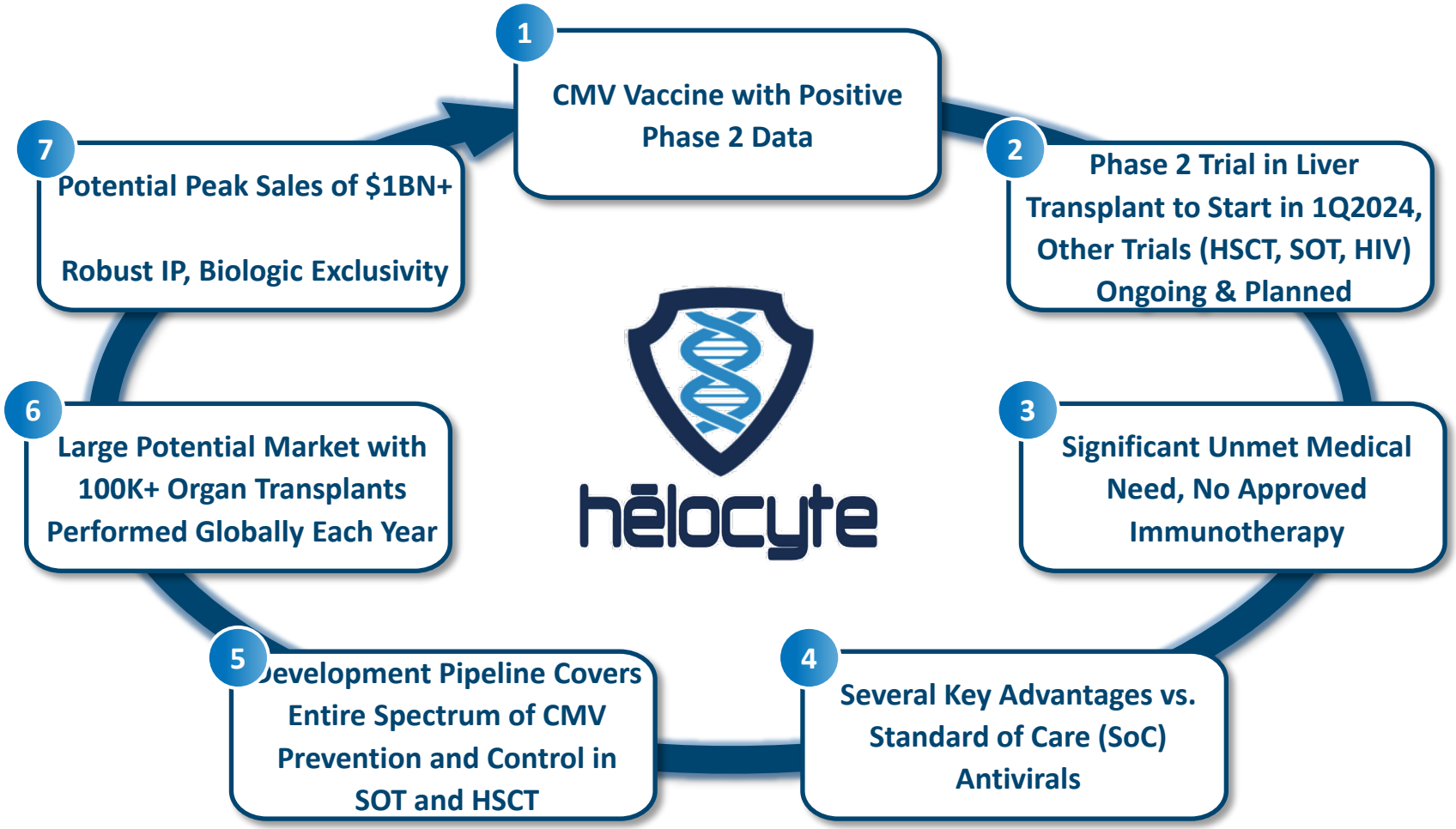
February 2024

Investment Highlights



Company Overview

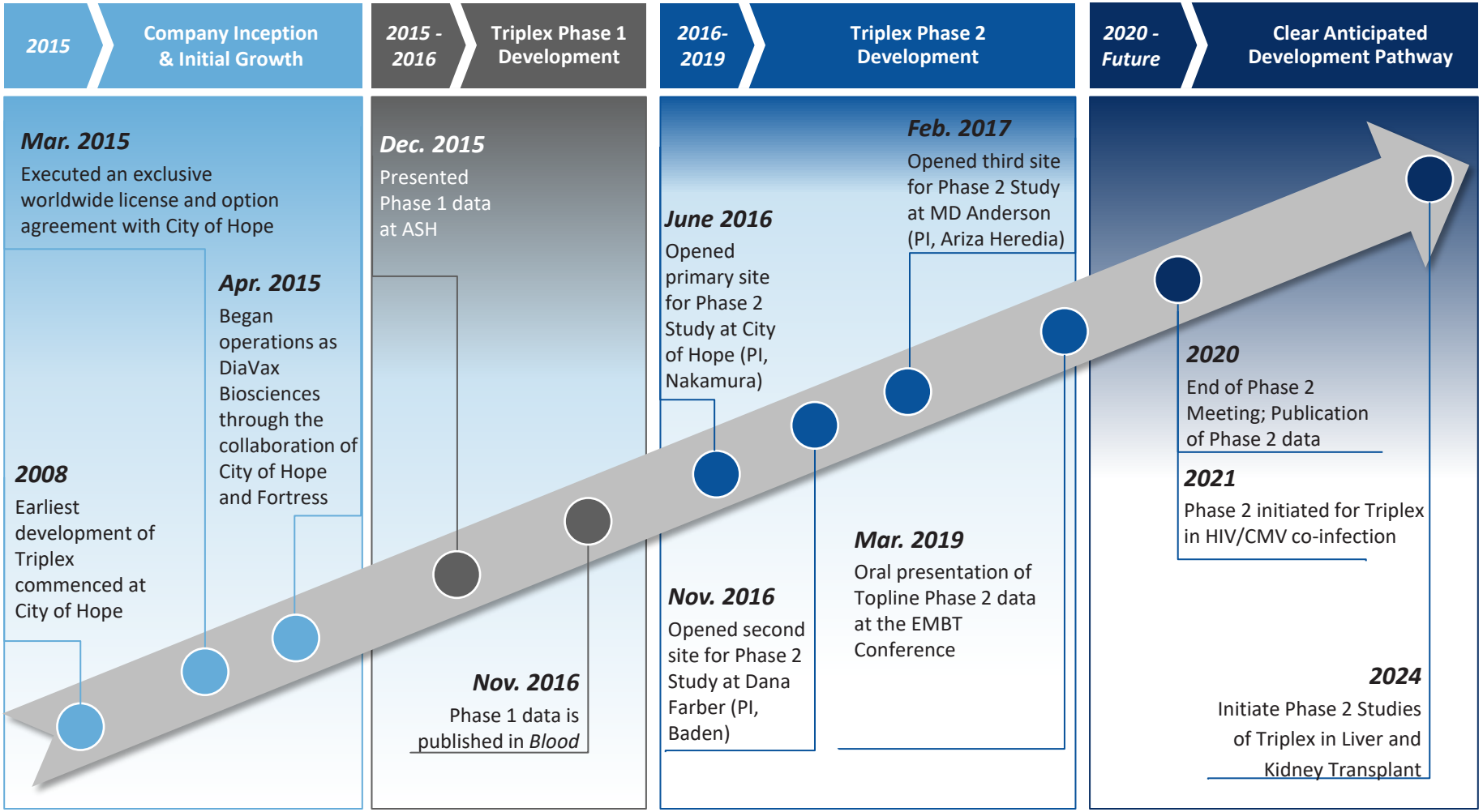
Helocyte is developing novel immunotherapies for the prevention and treatment of cytomegalovirus ("CMV")

Clinically Advanced	Phase 2 Study	2024	2024	2026	$1BN+
CMV Vaccine	*Met Primary Endpoint in difficult-to-treat allogeneic HSCT*	*Initiation of Phase 2 in Liver Transplant*	*Initiation of Phase 2 in Kidney Transplant*	*Topline Data in Liver Transplant*	*Potential Peak US/EU Sales in SOT alone*

- Helocyte (or the "Company") is a private, late-stage biotech company that addresses the unmet need in CMV prevention and control
  - CDC estimates 50-80% of individuals are infected with CMV by age 40
    - Asymptomatic in healthy individuals
    - Life-threating disease in those undergoing allogeneic stem cell and solid organ transplantation
- Current Standard of Care (SoC): antivirals with significant limitations
  - Includes severe toxicity (Black Box), delayed immune reconstitution, late CMV, drug resistance, and inconvenient dosing
- Our lead therapy, Triplex, for CMV control in Transplant
  - Allogeneic hematopoietic stem cell transplant (HSCT): met primary endpoint in first-in patient Phase 2 study
    - Results: Triplex safe, well-tolerated, highly immunogenic and efficacious
    - End-of-Phase 2 Meeting with FDA completed (1Q2020)
  - Solid Organ Transplant (SOT): kidney and liver; significantly larger markets, less competition, lower bar than HSCT
  - Potential for significantly better safety, enhanced immune recovery, and limited dosing versus SoC

Evolution Since Inception: Groundwork Completed

Helocyte has consistently met critical developmental milestones, paving the way for pivotal studies and approval…



Triplex: Addresses Significant Unmet Medical Need in CMV Control

Prior to approval of Merck's Letermovir (Prevymis) in HSCT[(1)] ($370MM in 2021 sales), last CMV antiviral approved 15+ years ago

Current Standard of Care (Antivirals)		Triplex (Immunotherapy)
Four of five approved CMV antivirals carry Black Box warnings for severe toxicity; newly-approved Prevymis[(1)] caused diarrhea, nausea, fever and/or rash in >20%	Safety	Safe and well-tolerated in Phase 2
Antivirals delay reconstitution of immunity to CMV	Immune Response	Rapid, robust and durable CD4 and CD8 virus-specific global T Cell reconstitution in Phase 2 (key objective post-transplant)
Prophylactic antivirals (like newly-approved Prevymis approved for HSCT) have demonstrated efficacy in the range of ~40% (see Prevymis Phase 3 primary endpoint)	Efficacy	Equal or better efficacy than antivirals (50% reduction in CMV events versus placebo in Phase 2)
CMV events often occur after Day 100 post-transplant and/or following use of preemptive or prophylactic antivirals	Late CMV	Reduced rate of late CMV in Phase 2
Prophylactic antivirals must be administered daily for up to 200 days (Prevymis for 180 days in SOT)	Dosing	More convenient, less frequent dosing
All antivirals are susceptible to CMV resistance, particularly following extended use; recent data suggests Prevymis at greater risk (see Helou 2019)	Resistance	Immunotherapy, thus not susceptible to resistance (or anti-vector immunity)

(1) Not approved for use in SOT patients

Triplex: Market & Commercial Opportunity

Triplex targets CMV control in SOT and HSCT; well-defined markets with significant unmet need and no approved immunotherapy

Solid Organ Transplant (SOT)

Procedure	US Incidence	EU Incidence	Peak Sales
Kidney Transplant	~25,000	~25,000	**$1BN+**
Liver Transplant	~9,000	~9,000	

- Standard of Care: Antivirals
  - Preemptive: initiated upon evidence of CMV
    - Used in low-to-moderate risk patients
  - Prophylactic Antivirals: initiated prior to transplant, >180 days
    - Used in higher risk patients
    - Merck's Prevymis approved in SOT as of 06/2023
      - Prophylaxis in high-risk kidney transplant (D+R-)
      - Phase 3 (n=589): randomized (1:1), non-inferiority to Valganciclovir (10% vs. 12%)

- Substantially larger market, treating both CMV(+) and (-) recipients

Hematopoietic Stem Cell Transplant (HSCT)

Procedure	US Incidence	EU Incidence	Peak Sales
Allogeneic Stem Cell Transplant	~9,000	~15,000	**~$340MM**

- Standard of Care: Antivirals
  - Similar to Solid Organ Transplant, but greater preemptive use
    - Preemptive: used in matched related/unrelated donors
  - Merck's Prevymis approved for prophylactic use in HSCT
    - 2019 Sales: ~$165M
    - 2020 Sales: ~$281M
    - 2021 Sales: ~$370M
    - 2022 Sales: ~428M
    - 2023 Sales: >$500M (projected based on ~$273M 1H Sales)
    - Trend towards prophylactic use in haploidentical donors, mismatches, cord blood

Triplex: Universal Multi-Antigen MVA-based CMV Vaccine

Triplex's unique clinical profile positions it to potentially be a leading treatment for CMV control in SOT and HSCT recipients

Triplex Overview:

- **Mechanism**
- **Indications**
- **Administration**
- **Safety / Side Effects**

Mechanism: Cellular Immunity to Primary CMV Proteins

- CD4 & CD8 T Cell Response to: pp65 + IE1 + IE2
  - **CD8 T Cell Responses:** exert rapid antiviral effects against CMV (Feuchtinger, 2010)
    - Triplex induced robust, durable CD8 T cells in HSCTs early post transplant in Phase 2
  - **CD4 T Cell Responses:** provide physiological, sustained immune response to CMV (Feuchtinger, 2010);
    - Triplex induced robust, durable CD4 T cells in HSCTs early post transplant in Phase 2
    - HOOKIPA's HB101 failed to show any appreciable CD4 T cell responses
- Vector: Modified Vaccinia Ankara (MVA), dosed safely in over 120,000 (elderly, children included), demonstrated safety and immunogenicity in HSCTs with rapid, robust and durable CD4 & CD8 T cell responses observed

Indication

- Prophylactic control of CMV in solid organ transplantation (SOT) and allogeneic hematopoietic stem cell transplant (HSCT)

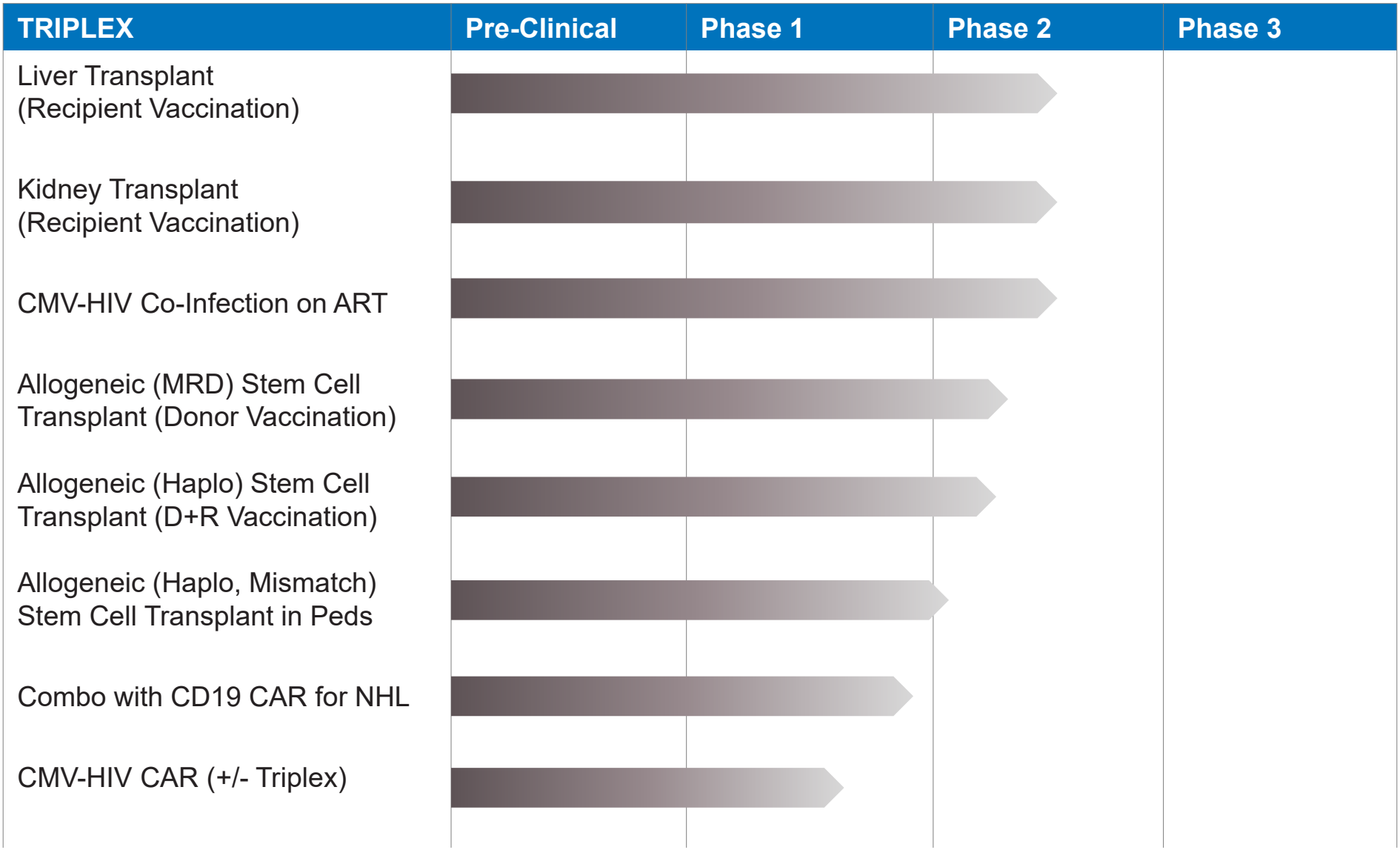
Administration

- Intramuscular administration prophylactically as a single agent to recipient
- If CMV exceeding threshold detected after Triplex vaccination, antivirals given per institutional guidelines

Safety / Side Effects

- Triplex has proven to be safe and well tolerated in clinical trials with no Grade 3 or 4 side effects probably or definitely related to the vaccine and no anti-vector immunity observed
- Most common Grade 1 and 2 side effects include fatigue, myalgia, transient headaches at the time of injection
- No cases of secondary transmission of MVA have occurred and MVA not integrated into host DNA
- Triplex can be used alone and following discontinuation of prophylactic antivirals

Pipeline


TRIPLEX
Pre-Clinical
Phase 1
Phase 2
Phase 3
Liver Transplant (Recipient Vaccination)
Kidney Transplant (Recipient Vaccination)
CMV-HIV Co-Infection on ART
Allogeneic (MRD) Stem Cell Transplant (Donor Vaccination)
Allogeneic (Haplo) Stem Cell Transplant (D+R Vaccination)
Allogeneic (Haplo, Mismatch) Stem Cell Transplant in Peds
Combo with CD19 CAR for NHL
CMV-HIV CAR (+/- Triplex)

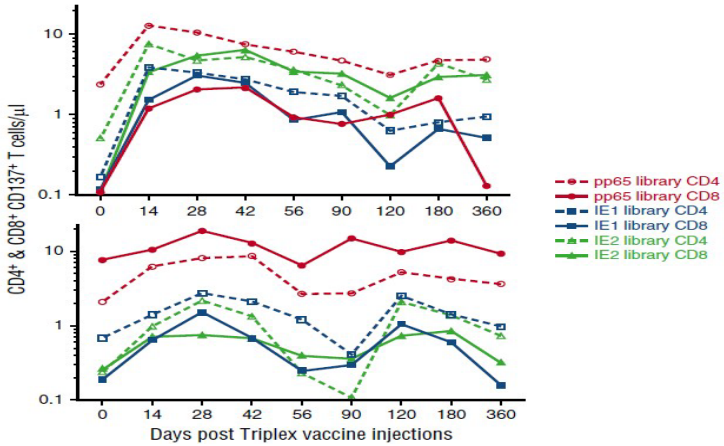
Completed Studies of Triplex (4)

Completed Studies of Triplex

Four Completed Trials Demonstrate Triplex Safety, Immunogenicity and Efficacy

Phase 1 (Completed)

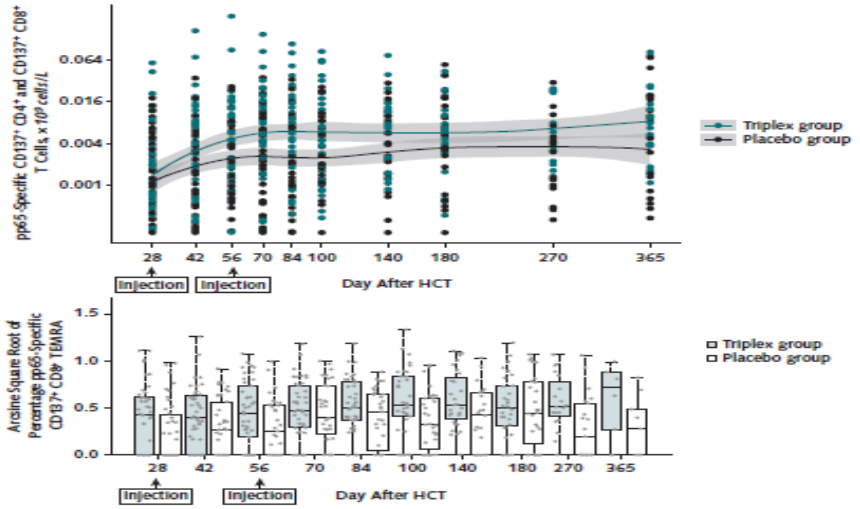
- Design: open-label, single-arm, single-center, dose-escalation (three levels)
- Patient Population: CMV+ and CMV- healthy volunteers
- Enrollment: 24 adult volunteers, eight in each dose cohort
- **Data**
  - **Safety:** well-tolerated, no SAE or dose-limiting toxicities
  - **Immunogenicity:** rapid, robust, durable CD4 and CD8 T-cell responses to each of the three antigens
  - Presented at **ASH (12/2015)** and published in ***Blood*** **(11/2016)**



Representative(1) CD4 & CD8 T-cell responses of two healthy volunteers to each of three CMV proteins targeted by Triplex, durable to 360 days

Phase 2 in HSCT (Completed)

- Design: multicenter, double-blind, randomized (1:1), placebo-control
  - Top Transplant Centers: City of Hope, Dana Farber, MD Anderson
- Patient Population: R+ matched related, unrelated allogeneic HSCT
- Enrollment: 102 adult subjects
- **Safety**
  - Safe, well-tolerated; no grade 3-4 adverse events related to vaccine
  - No adverse impact on transplant (GvHD, relapse, or survival)
- **Immunogenicity**
  - Rapid, robust, durable CD4 and CD8 T-cell responses
- **Efficacy**
  - *Comparable to Prevymis and other SoC antivirals*
  - *Met Primary Endpoint:* 50% reduction in CMV events through Day 100
    - 5 CMV Events in Vaccine Arm (9.8%) vs 10 in Placebo (19.6%) (p=0.08)
- Presented at **EBMT (03/2019),** Published in ***Annals of Internal Medicine*** **(02/2020)**



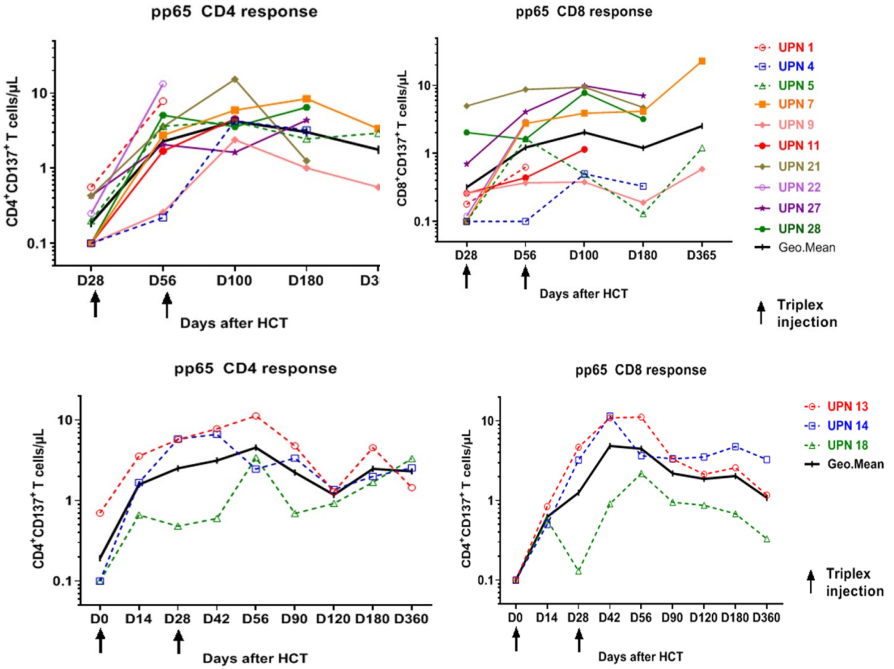
(1) Data published in Blood

Completed Studies of Triplex (cont.)

Four Completed Trials Demonstrate Triplex Safety, Immunogenicity and Efficacy (cont.)

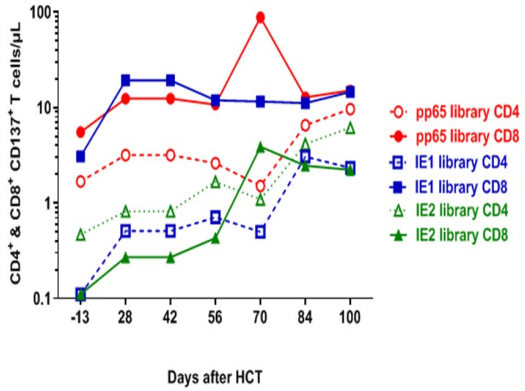
Phase 1 in Auto-HSCT (Completed)

- Design: open-label, single-center (University of Minnesota)
- Patient Population: 20 autologous HSCT recipients (10 CMV+, 10 CMV-)
- Rationale: increase adaptive NK cells after transplant, reduce relapse in MM
- Data
  - **Safety:** safe, well-tolerated, no SAE or dose-limiting toxicities
  - **Immunogenicity:** CD4, CD8 T-cell responses in both R+ and R-
  - Adaptive NK Cells: significant increase (p=0.02 versus unvaccinated control)
- Published in Transplantation and Cellular Therapy (03/2022)



Phase 1: Donor Vaccination in Allo-HSCT (Completed)

- Design: open-label, single-center (City of Hope)
- Patient Population: R+ with matched related adult allogeneic HSCT donors
- Enrollment: 17 adult donor-recipient pairs; 16 with CMV+ donors
- Data
  - On Day 28 Post HSCT, significantly higher CD137+CD8 T Cells (p=0.017 and for pp65 alone, p=0.0001)
  - Reduced number of CMV events (18%) vs cohorts receiving prophylactic antiviral Prevymis (37%)
  - Strong immunity in recipient derived from vaccination of donor
  - CMV Events (requiring antiviral intervention): 18% vs. 37% in cohort treated prophylactically with Prevymis
- Presented at 2023 Tandem Meetings, Published in American J. Hematology
- Funded by City of Hope, other non-dilutive sources



Ongoing Studies of Triplex (4)

Ongoing Studies of Triplex

Expanding Dataset in Cancer Setting

Phase 1/2: Pediatric Allo-HSCT (Ongoing)

- Design: open-label, single-center (City of Hope) dose escalation followed by efficacy
- Patient Population: aged 1-21 seropositive recipients of matched, mis-matched, haplo- HSCT
- Enrollment: up to 80 pediatric subjects
- Administration: Days 0 and 28 post-HSCT
- Primary Endpoints
  - Evaluate safety profile in pediatric patients
  - Determine optimal dose for pediatric patients
- Secondary Endpoints
  - Immunogenicity
  - CMV reactivation and disease
  - Time to reactivation, duration, recurrence
  - Impact on transplant-related outcomes
- Follow-Up: 365 days post-HSCT
- Funded by City of Hope, other non-dilutive sources

Pilot Study: Triplex + CD19 CAR T for NHL (ongoing)

- Design: open-label, single-center (City of Hope)
- Patient Population: adults with intermediate or high Grade B-lineage NHL indicated for autologous HSCT in first relapse after complete remission
- Enrollment: 12-15 adults
- Administration: single infusion of CD19 CAR in combo with Triplex
- Primary Endpoints
  - Safety of CD19-CAR T Cells alone and in combo with Triplex
- Secondary Endpoints
  - Feasibility of autologous cell manufacturing
  - Short- and longer-term CMV specific CD19 CAR T cell in vivo expansion and persistence
  - Assessment as to whether CMV specific CAR T cells respond to Triplex
  - Rate of CMV reactivation after CAR T cell infusion
  - Rate of progression free survival (PFS) and median overall survival (OS) at 12 months after autologous HSCT
- Follow-Up: 1 year (primary endpoint), 3 year (secondary endpoints)
- Funded by City of Hope, other non-dilutive sources

Ongoing Studies of Triplex (cont.)

Expanding Dataset in Other Indications

Phase 2: Adults Co-Infected with CMV & HIV (Ongoing)

- Design: randomized, multicenter, placebo-controlled trial
- Patient Population: adults aged 18-65 co-infected with HIV and CMV
- Enrollment: 90 subjects (fully enrolled as of 10/2023)
  - 60 participants randomized to receive Triplex
  - 30 participants randomized to receive placebo
- Administration: Days 0 and 28 after enrollment
- Primary Endpoints (through Week 48)
  - Safety
  - Change in pp65-secific CD137+ CD8+ T Cells
- Secondary Endpoints (through Week 96)
  - Reduction in viral shedding (CMV replication)
  - Change in IL-6, sCD163, IP-10, sTNFRII, D-Dimers
  - Change in IE1-, IE2-specific CD137+ CD8 T Cells
- Follow-Up: 96 weeks following enrollment
- Funded by National Institutes of Health ($3.22M)

Phase 1: Triplex + Bispecific CMV-HIV CAR (ongoing)

- Design: open-label, Phase 1 dose-finding trial at single-center (City of Hope)
- Patient Population: adults living with HIV-1 on stable ART who have maintained viral suppression
- Enrollment: ~12-18 adults (TBD)
- Administration: single infusion of Bi-Specific CMV/HIV CAR, optionally followed by administration of Triplex to drive proliferation of CAR
- Primary Endpoints
  - Safety of Bi-Specific CMV/HIV CAR T cells (+/- Triplex)
  - Dose Limiting toxicities
- Secondary Endpoints
  - CD4+ T cell count and HIV RNA levels in peripheral blood
  - Number of EGFR+ CD3+ T cells in peripheral blood
  - Time to viral rebound (HIV RNA > 1,000 copies/mL for 4 weeks
  - HIV reservoir analysis (total HIV DNA in CD4+ T cells)
- Follow-Up: 1 year (TBD)
- Preclinical data published in Molecular Therapy: long-term durability, eradication of latent viral T cell reservoirs in immune cells
- Phase 1 Funded by $11.3M grant from California Institute of Regenerative Medicine (CIRM), other non-dilutive sources

Planned Studies of Triplex (4)

Planned Studies of Triplex

Targeting Largest Segments of Solid Organ Transplant: Liver and Kidney

Phase 2: Liver Transplant (2024)

- Design: randomized, double-blind, placebo-control
- Patient Population: seronegative liver transplant candidates receiving a transplant from a CMV positive donor within 2-12 months (D+R-) with preemptive antiviral therapy strategy
- Enrollment: ~420 adult subjects (D+R-)
- Randomization: 2:1 between vaccine and placebo
- Administration: Days 0 and 28 after enrollment
- Sites: 15 U.S.-based (CAPSIL consortium)
- Primary Endpoints
  - Safety
    - Solicited AEs within seven days of each dose
    - Unsolicited AEs within 28 days of each dose
    - Anti-vector immunity (none in Phase 2)
  - Immunogenicity
    - Proportion of Responders
    - Robustness & Duration of vaccine-induced CMV-specific immunity
  - Efficacy
    - Impact on days of CMV antiviral therapy within 100 days post-Tx
    - CMV infection, reactivation 12-mos post-transplant
    - CMV viremia requiring treatment (duration of treatment, etc.)
  - Funded by up to $20M from National Institutes of Health

Phase 2: Kidney Transplant (2024)

- Design: randomized, double-blind, placebo-control
- Patient Population: seronegative kidney transplant candidates receiving a transplant from a CMV positive donor within 2-12 months
- Enrollment: 176 adult subjects (at least 88 to receive transplant)
- Randomization: 1:1 between vaccine and placebo
- Administration: Days 0 and 28 after enrollment
- Sites: ~10 U.S.-based
- Primary Endpoints
  - Safety
    - Solicited AEs within seven days of each dose
    - Unsolicited AEs within 28 days of each dose
    - Anti-vector immunity (none in Phase 2)
  - Immunogenicity
    - Proportion of Responders
    - Robustness & Duration of vaccine-induced CMV-specific immunity
  - Efficacy
    - Vaccine impact on CMV infection, reactivation 12-mos post-transplant
    - CMV viremia requiring treatment (duration of treatment, etc.)

Planned Studies of Triplex (cont.)

Expanding Dataset in HSCT via Vaccination of HSC Donor

Phase 2: Donor Vaccination in Matched Related Donor (MRD) Allo-HSCT (2023)

- Design: randomized, double-blind, placebo-control
- Patient Population: haploidentical transplant recipients from CMV+ donor
- Enrollment: ~108 adult subjects
- Randomization: 1:1 between vaccine and placebo
- Administration
  - MRD Donor vaccinated -60 to -10 days
  - MRD Recipient not vaccinated
  - No antiviral prophylaxis (preemptive therapy)
- Sites: ~3 clinical sites
- Primary Endpoints
  - Safety
    - Solicited AEs within seven days of each dose
    - Unsolicited AEs within 28 days of each dose
    - Anti-vector immunity (none in Phase 2)
  - Immunogenicity
    - Proportion of Responders
    - Robustness & Duration of vaccine-induced CMV-specific immunity
  - Efficacy
    - Vaccine impact on CMV infection, reactivation
    - CMV viremia requiring treatment (duration of treatment, etc.)
- Funded by $3.22M grant from National Institutes of Health

Phase 1b: Donor + Recipient Vaccination in High-Risk Haploidentical Allo-HSCT (2024)

- Design: single arm, open label trial
- Patient Population: haploidentical transplant from CMV+
- Enrollment: ~18 adult subjects
- Randomization: 1:1 between vaccine and placebo
- Administration
  - Haploidentical Donor vaccinated: single dose, -60- to -10 days
  - Haploidentical Recipient vaccinated: three doses, D28, D56, D100
  - Three Cohorts (+/- Prevymis): no prophy, D7-D28 prophy, D7-D100 prophy
- Sites: TBD
- Primary Endpoints
  - Safety
    - Solicited AEs within seven days of each dose
    - Unsolicited AEs within 28 days of each dose
    - Anti-vector immunity (none in Phase 2)
  - Immunogenicity
    - Proportion of Responders
    - Robustness & Duration of vaccine-induced CMV-specific immunity
  - Efficacy
    - Vaccine impact on CMV infection, reactivation
    - CMV viremia requiring treatment (duration of treatment, etc.)
- Funded by City of Hope, National Institutes of Health

Robust IP Protection & Orphan Market Exclusivity

Regulatory

- Orphan Exclusivity: 7 Years (US), 10 Years (EU)
- Biologic Exclusivity: 12 Years (US), 11 Years (EU)

Triplex IP

- HCMV Antigens Expressed in MVA, Methods (7,163,685), expires 2024
- rMVA Vaccines and Methods of Prep Thereof (8,580,276), expires 2031
- rMVA Vaccines and Methods of Prep Thereof (9,675,689), expires 2033
- Patent Term Adjustment, Patent Term Extension possible(1)
- De Facto market exclusivity may extend well beyond patent life as Triplex is a complex biologic associated with significant manufacturing know-how

Biologic exclusivity for 12 years from initial launch in the U.S. provides high barrier to entry and minimizes risk of generic or biosimilar competition

(1) Up to 5 years for Patent Term Extension (based on any regulatory delays), but in no event more than 14 years from product's approval date

Experienced Management Team with Proven Track Record

Key Management	Tenor Overview	Prior Experience
Lindsay A. Rosenwald, M.D. Co-Founder and Executive Chairman	20+ years experience	Life Sciences Entrepreneur and Investor
Frank Taffy, J.D. Co-Founder & Strategic Advisor	20+ years experience	Forest Laboratories, Inc. P&G ThermoFisher SCIENTIFIC

Board of Directors

Lindsay A. Rosenwald, M.D.
Executive Chairman

Michael S. Weiss, J.D.
Director

Frank Taffy, J.D.
Director

World-Class Key Opinion Leaders

Helocyte has partnered with a distinguished group of key opinion leaders

Key Opinion Leaders	Tenor	Overview
 **Don J. Diamond, PhD** *Scientific Founder & Chair of SAB*	35+ years of experience	▪ Professor in the Department of Hematology & Hematopoietic Cell Transplantation at City of Hope ▪ Research includes developing vaccines to combat hematologic malignancies, solid tumors, and infectious pathogens such as the herpesvirus, cytomegalovirus (CMV) and HIV
 **Ajit Limaye, MD** *CMV in SOT Expert*	25+ years of experience	▪ Board certified physician at the Infectious Diseases & Tropical Medicine Clinic and Kidney Care and Transplantation Services at University of Washington (UW) Medical Center ▪ UW professor of Medicine and Allergy and Infectious Diseases
 **Michael Boeckh, MD, PhD** *CMV in HSCT Expert*	30+ years of experience	▪ Head of the Infectious Disease Sciences Program within the Vaccine and Infectious Disease Division at Fred Hutch ▪ Clinical expertise focuses on infections in the immunocompromised host, especially diagnosis, prevention and treatment of CMV, VZV, BK virus, and respiratory virus infections
 **Krishna Komanduri, MD** *HSCT Clinical Expert*	20+ years of experience	▪ Professor of Medicine, Transplantation and Cellular Therapy at University of Miami ▪ Research interest includes immune reconstitution after stem cell transplantation (SCT); human T cell immunity to pathogenic viruses and fungi; graft-versus-host disease (GvHD) and graft engineering
 **Ryo Nakamura, MD** *PI at City of Hope for Phase 2 Trial*	15+ years of experience	▪ Professor in the Department of Hematology & Hematopoietic Cell Transplantation at City of Hope ▪ Research is focused on stem cell transplantation and development of cancer vaccines
 **Lindsey Baden, MD** *PI at Dana Farber for Phase 2 Trial*	30+ years of experience	▪ Associate Professor of Medicine at Harvard Medical School ▪ Research is focused on transplant / oncology infectious diseases, HIV vaccines, and novel diagnostics for invasive fungal disease
 **Ella Ariza Heredia, MD** *PI at MD Anderson for Phase 2 Trial*	15+ years of experience	▪ Associate Professor in the Department of Infectious Diseases, Division of Internal Medicine, Baylor College of Medicine, Houston, TX ▪ Research is focused on stem cell transplant

Source: Company websites

CMV Market Overview and Unmet Need

CMV Overview

CMV infection is ubiquitous and usually benign, but is a major cause of morbidity and mortality in immunosuppressed patients

CMV Overview

- CMV is a member of the herpes virus family and the largest among known human viruses
- Once infected, an individual carries the virus for life, typically in a latent state
  - Prevalence of infection is strongly correlated with age
  - CDC estimates 50-80% infected with CMV by age 40
- CMV can lead to severe disease and increased mortality in immunocompromised individuals
  - High risk individuals include HSCT and SOT recipients, as well as developing fetus or newborn children
  - CMV infection can predispose patients to transplant rejection/failure, CMV-related infections, other opportunistic infections, and increased mortality risk
  - Most common infectious complication in HSCT & SOT
- Current Standard of Care: moderately effective antivirals, often associated with toxicity, resistance, delayed immune reconstitution, late CMV and/or extended dosing
  - No approved vaccine for CMV prevention or control
- Helocyte currently progressing novel biologic (Triplex)
  - Induces CMV-specific T cell immunity to control reactivation in post-transplant (HSCT, SOT)
- Triplex Advantages vs. SoC Antivirals: safety, immune reconstitution, dosing, and no likelihood of resistance

Effects of CMV

CMV is easily transmitted and is associated with a life-long latency… → **…with the ability to become active (reactivation) in those with weakened immune systems…** → **…and progress to CMV disease and create significant risk for morbidity and mortality**

CMV in Hematopoietic Stem Cell & Solid Organ Transplantation

Direct Effects

- Direct clinical effects include CMV viral syndrome and end-organ disease
- CMV disease: pneumonitis, gastrointestinal disease, hepatitis, pancreatitis, nephritis, cystitis, myocarditis, retinitis, CNS diseases, thrombocytopenia, hemolytic anemia, adrenalitis, disseminated disease
- CMV syndrome
- Tissue-invasive CMV/end-organ disease (GI tract most common)

Indirect Effects

- Indirect effects include opportunistic infections:
  - Caused by bacteria, fungi or other virus
  - More commonly, it is these indirect effects that contribute to mortality with CMV infection
- Include graft rejection, graft failure, opportunistic infections, atherosclerosis and heart disease, obliterative bronchiolitis, new onset diabetes, lung transplantation, higher mortality

Market Overview & Opportunity: Solid Organ Transplant (SOT)

The number of solid organ transplants, specifically kidney and liver, has risen year-over-year

Observations

- **40K+ Solid Organ Transplants in the US per year**
- **37K+ Solid Organ Transplants in the EU per year**
- **CMV occurs in ~50% of SOT and Represents the Most Common Infectious Complication**
- **Recent Executive Order Aimed at Doubling the Number of Kidneys available in the US by 2030**
- **Prevymis Approved in Kidney Transplant as of 06/2023, Currently No Approved Immunotherapy or Vaccine in SOT**

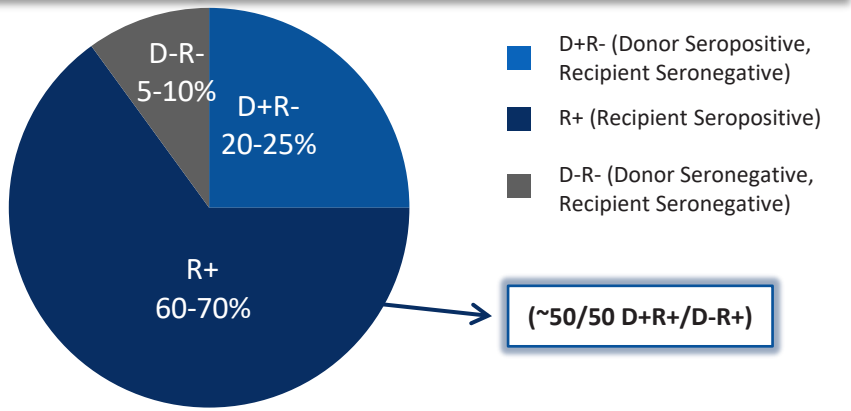
2019 Transplants by Organ & Region

Organ	U.S.	Europe	Globally
Kidney	25,490	23,593	92,532
Liver	9,236	9,333	34,694
Heart	3,863	2,350	8,409
Lung	2,569	1,964	6,470
Pancreas	963	609	2,025
Small Bowel	96	46	172
Total Organ Transplants	42,217	37,895	144,302

Represents Triplex's target patient population for SOT

Kidney & Liver Transplant Patient Stratification

Planned Phase 2 studies of Triplex in Kidney and Liver Transplant To Target D+R- and R+ groups (80%+ of market)(1)



Source: Transplant Observatory
(1) Market research indicated KOLs strongly supported vaccination in D+R- and R+ groups

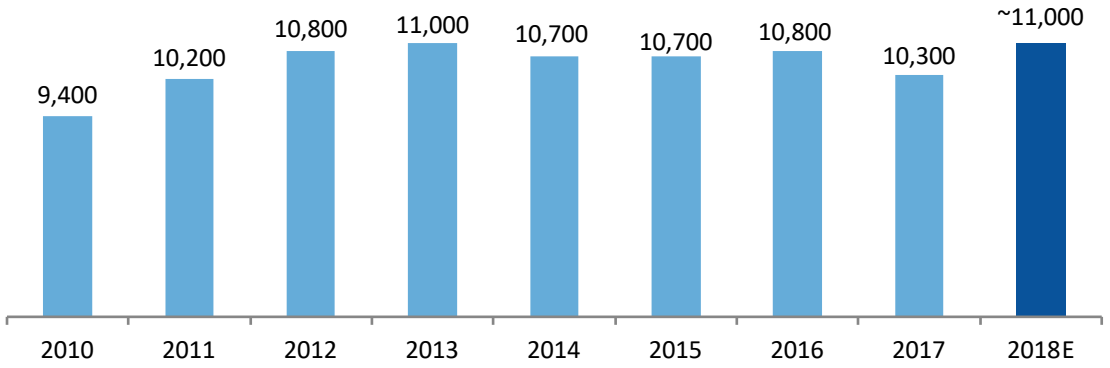
Market Overview & Opportunity: Hematopoietic Stem Cell Transplant (HSCT)

The number of stem cell transplants worldwide has grown steadily year-over-year, and correlates with an increased CMV burden

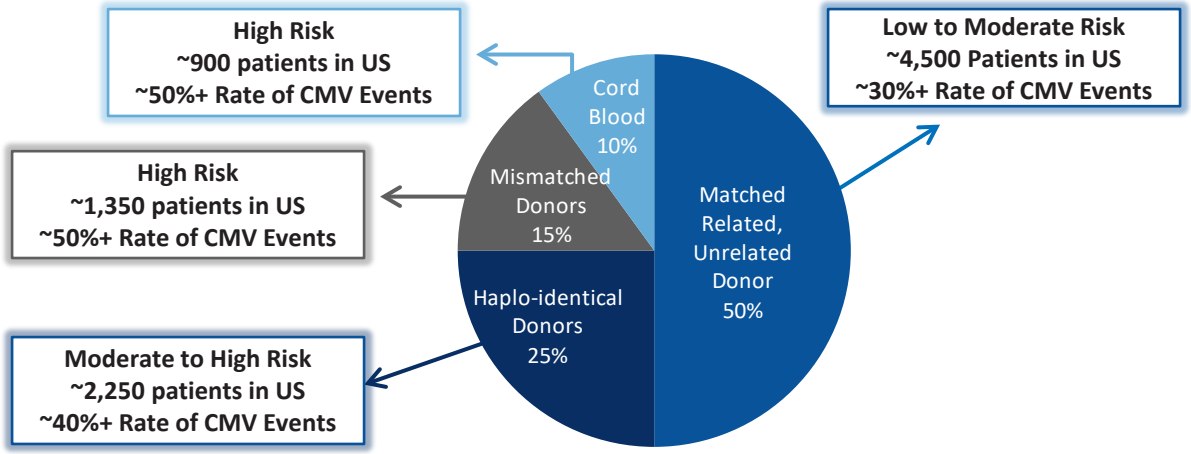
Observations

- 10K+ Allogeneic Stem Cell Transplants in US per year
- 17K+ Allogeneic Stem Cell Transplants in EU per year
- CMV occurs early after HSCT (Day ~40) or after Day 100 ("Late CMV")
- CMV occurs in 30%-60%+ of CMV(+) HSCT Patients and is the most common infectious complication
- Recently Approved Antiviral Prevymis with Better Toxicity Profile, but Extended Dosing (up to 180 days)[1]

Stability in Number of Allo-HSCT Transplants in the U.S.



Estimated HSCT Patient Stratification & Rate of Infection



Source: Center for International Blood & Marrow Transplant Research

(1) Extended dosing not only creates compliance issues, but gives rise to resistance

Limitations of Current Standard of Care…

Preemptive and Prophylactic Antivirals (most with Black Box Warnings)

Prophylactic vs. Preemptive

Prophylaxis:

- Commence treatment at the time of or immediately following transplant (regardless of viremia) and continue for 100 – 200 days
- Monitoring may still be recommended
- Historically, toxicity and/or low efficacy of antivirals has limited use of this strategy

Preemptive:

- Commence treatment when CMV viremia exceeds institutional threshold (monitored weekly as part of standard of care)
- Therapy given two weeks or until viremia reduced (discontinued with negative qPCR)
- Shorter duration of use has enabled use of this strategy despite severe toxicities associated with most approved antivirals

FDA Approved Antivirals for CMV

Drug	Label	Admin / Dosing	Black Box Warning
Ganciclovir	Prophylactic; preemptive (1L or 2L)	IV, Oral (up to 200 daily doses)	Hematologic Toxicity, Impairment of Fertility, Teratogenicity, and Carcinogenicity
Foscarnet	Preemptive (1L or 2L)	IV	Renal Impairment
Cidofovir	Preemptive (2L or 3L)	IV	Hematologic Toxicity, Impairment of Fertility, Fetal toxicity, Mutagenesis, and Carcinogenesis
Valganciclovir	Prophylactic & Preemptive	Oral (up to 200 daily doses)	Hematologic Toxicity, Carcinogenicity, Teratogenicity, and Impairment of Fertility
Letermovir(2)	Prophylactic (R+ all-HSCT)	IV, Oral (up to 100 daily doses)	No Black Box, but Diarrhea, Nausea Fever, Rash observed in 20%+ (Phase 3)

- Prevymis (Letermovir) - newest antiviral approved for CMV Prophylaxis in Allo-HSCT (November 2017)
  - 1st new agent for CMV infection in 15 years
  - Efficacy: reduced rate of CMV to 38% vs. 61% in placebo
  - Late CMV still occurs (nearly 20% in Phase 3)
  - Daily administration through Day 100 post-transplant
  - WAC price of $19,500 oral or $27,000 injectable for 14-week (100-day) course of therapy (partially subsidized)
  - 2023 Annual Sales (Projected) >$500M

Source: Company websites
(1) Prevymis sales are based on actual growth from Q1 to Q2 2019 and annualized estimated Q3 2019
(2) Not approved for use in SOT

Triplex: Addresses Significant Unmet Medical Need in CMV Control

Prior to approval of Merck's Letermovir (Prevymis) in HSCT[1] ($370MM in 2021 sales), last CMV antiviral approved 15+ years ago

Current Standard of Care (Antivirals)		Triplex (Immunotherapy)
Four of five approved CMV antivirals carry Black Box warnings for severe toxicity; newly-approved Prevymis[1] caused diarrhea, nausea, fever and/or rash in >20%	Safety	Safe and well-tolerated in Phase 2
Antivirals delay reconstitution of immunity to CMV	Immune Response	Rapid, robust and durable CD4 and CD8 virus-specific global T Cell reconstitution in Phase 2 (key objective post-transplant)
Prophylactic antivirals (like newly-approved Prevymis approved for HSCT) have demonstrated efficacy in the range of ~40% (see Prevymis Phase 3 primary endpoint)	Efficacy	Equal or better efficacy than antivirals (50% reduction in CMV events versus placebo in Phase 2)
CMV events often occur after Day 100 post-transplant and/or following use of preemptive or prophylactic antivirals	Late CMV	Reduced rate of late CMV in Phase 2
Prophylactic antivirals must be administered daily for up to 200 days (Prevymis for 180 days in SOT)	Dosing	More convenient, less frequent dosing
All antivirals are susceptible to CMV resistance, particularly following extended use; recent data suggests Prevymis at greater risk (see Helou 2019)	Resistance	Immunotherapy, thus not susceptible to resistance (or anti-vector immunity)

(1) Not approved for use in SOT patients

Triplex Clinical Trials (Detailed)

Triplex: CMV Immunotherapy with Best-in-Class Potential

Differentiated Product Profile Addresses Significant Limitations of Standard of Care Antivirals

Indication	▪ Indicated for prophylactic control of CMV in post allogeneic hematopoietic stem cell transplant (HSCT) in oncology
Description / Mechanism of Action	▪ Universal (off-the-shelf, broadly-recognized) vaccine engineered to induce a rapid, robust and durable virus-specific T-cell response to control CMV in recipients of allogeneic HSCT ▪ Consists of a recombinant Modified Vaccinia Ankara (MVA) vector incorporating genes expressing three immuno-dominant proteins linked to CMV events in the post-transplant setting, UL83 (pp65), UL123 (IE1), and UL122 (IE2)
Administration	▪ Two Intramuscular injections administered prophylactically 28 days apart (optional third injection in HSCT)
Safety / Side Effects	▪ MVA dosed safely in over 120,000 individuals in Germany (adults, children, high risk subjects) ▪ Triplex has proven to be safe and well tolerated in clinical trials with no Grade 3 or 4 side effects related to vaccine ▪ Most common Grade 1 and 2 side effects include fatigue, myalgia, and transient headaches at the time of injection ▪ No cases of secondary transmission of MVA have occurred, and MVA not integrated into host DNA ▪ Triplex can be used in conjunction with (and after discontinuation of) antivirals
Efficacy Summary	▪ **Immunogenicity**: Triplex demonstrated rapid, robust and durable CD4 and CD8 T Cell responses in both healthy subjects (Phase 1, n=24) and immuno-compromised allogeneic HSCT recipients (Phase 2, n=102) ○ Initial data from donor vaccination and autologous HSCT trials further demonstrate robust, durable immunity ▪ **Efficacy**: Triplex demonstrated efficacy comparable to Prevymis and other SoC antivirals (Phase 2) ○ Primary Endpoint (Met): pre-specified, one-sided 0.10 test (appropriate for Phase 2 trial) ○ 50% reduction in CMV events versus placebo through Day 100 ○ 5 CMV events in Vaccine Arm (9.8%) vs 10 in Placebo Arm (19.6%) (p=0.08)

(1) Protocol still in process of being finalized and subject to review by FDA during EOP2

Triplex: Phase 1 Safety and Tolerability Study

Phase 1 data confirms safety, tolerability and immunogenicity of Triplex

Phase 1 Trial (Completed)

Design

- Open-label, single arm, dose-escalating trial to assess safety and immunogenicity of Triplex
- Sample size of 24 healthy volunteers
- 3 Dose Levels (DL) / cohorts with 8 subjects per cohort
  - DL1: 10Xe7 plaque forming units (PFU)
  - DL2: 5X10e7 PFU
  - DL3: 5X10e8 PFU

Method

- Eligible Subjects: 18-60 years old, CMV(+) and CMV(-) healthy volunteers
- Administration: 1mL IM injection with identical booster 28 days later
- Primary Endpoint: safety and immunogenicity of Triplex for one year after first injection
- CMV-specific and MVA vector-specific immune responses in PBMC by longitudinally measuring T-cell levels through Day 360

Phase 1 Trial Results

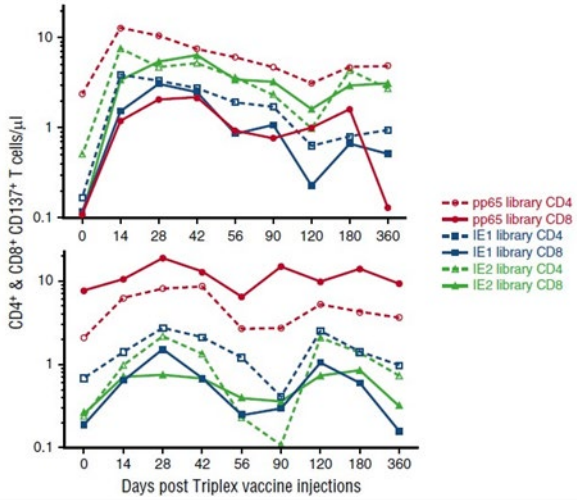
Triplex was safe and well tolerated in all subjects and demonstrated robust and durable CD4 and CD8 T cell responses

Safety

- Well-tolerated in most subjects at all DLs
- Single Grade 3 injection site AE (erythema) resolved in a day reported in one DL3 subject
- Three mild to moderate cutaneous reactions
- Most common systemic reaction: mild fatigue, myalgia, headache

Immunogenicity

- Rapid, robust, durable CD4 and CD8 T-cell responses to each of the three antigens
- Responses observed in both seropositive and seronegative recipients, including those who were previously vaccinated for smallpox
- Responses to pp65 portion of vaccine recorded in >80% and highly significant (P<0.00001)
- Responses to IE1 and IE2 Less Substantial: likely due to nonviremic status of healthy population as IE1 & IE2 among first proteins to be expressed in CMV infection and reactivation



Triplex: Phase 2 Trial in Allogeneic HSCT

Phase 2 data demonstrates Triplex safety, immunogenicity and efficacy

Phase 2 Trial (Completed)

Design

- Multi-Center
  - City of Hope (PI, Nakamura)
  - Dana Farber (PI, Baden)
  - MD Anderson (PI, Ariza-Heredia)
- Double-blind, randomized (1:1) vaccine / placebo
- Sample size of 102 patients

Method

- Eligible Subjects: CMV-seropositive undergoing allogeneic HSCT from matched related and unrelated donors
- Patients enrolled pre-transplant
- Received two post-transplant IM vaccinations (Day 28 and 56)(1)
- Patients received Triplex or placebo injections on Day 28 and Day 56 post-transplant and followed for one year
- Primary endpoint: reduction in CMV Events through Day 100, Day 365

Phase 2 Trial Results

Top-Line Data Presented at European Society for Blood and Marrow Transplantation (EBMT) Conference (March 2019)

Full Dataset Published in Peer-reviewed Annals of Internal Medicine (February 2020)

Safety

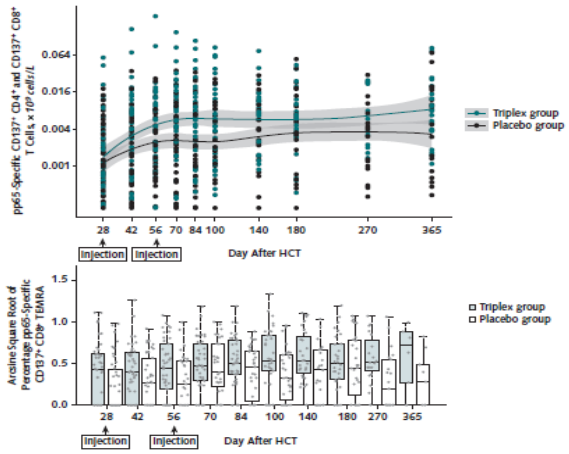
- Independently monitored
- Safe, well-tolerated; no significant difference in grade 3-4 adverse events (AEs) probably or definitely related to vaccine, or serious adverse events (SAEs) between arms
- Balanced patient characteristics
- No adverse impact on any transplant-related outcome (GvHD, relapse, or survival)

Immunogenicity

- Recipients with both CMV(-) and CMV(+) donors showed strong reconstitution of CD4 and CD8 CMV-specific immunity
- Immune response initiated soon after first injection and elevated for 365 days post-HSCT

Efficacy

- Within the range of antivirals
- Primary endpoint met: 50% reduction in CMV Events versus placebo through Day 100
  - 5 CMV Events in Vaccine Arm (9.8%) versus 10 in Placebo Arm (19.6%) (one-sided 0.10 p=0.08)
- Powered by at least 90% at one-sided 0.10 level of significance to detect decrease in events from 30% to 10% or from 40% to 15%
  - Number of CMV Events Anticipated (30 to 40 total) versus Observed (15 total)



(1) To be included in the analysis for Phase 2, subjects must receive at least the first of two planned injections

Triplex for CMV Control in Liver Transplant

Phase 2 Study Anticipated to Commence in 2024

Phase 2 Trial (Planned)

Overview

- Induce the expansion of CMV-pp65, IE1, and IE-2-specific functional T-cells in CMV seronegative and CMV seropositive patients with advanced liver disease who are awaiting liver transplant from a CMV seropositive donor
  - Triplex has the potential to decrease CMV-related complications and need for toxic antiviral therapy in the post-transplant setting

Design

- Prospective, randomized, double-blind, placebo-controlled trial
  - Patient Population: CMV seronegative liver transplant candidates expected to receive transplant from CMV seropositive donor within 2-12 months (D+R-) with preemptive antiviral therapy strategy (no prophylaxis)
- Enrollment of approximately 420 patients
- Randomized 2:1 between vaccine and placebo
- Two planned vaccine administrations on Day 0 and Day 28
- Study will consist of approximately 15 U.S. sites (CAPSIL consortium, others)
- Funded by National Institutes of Health (~$20M)

Objectives

Primary

- Safety
  - Solicited AEs within seven days of each dose
  - Unsolicited AEs within 28 days of each dose
  - SAEs
  - Development of anti-vector immunity (none observed in Phase 2)
- Immunogenicity
  - Determine proportion of responders
  - Determine robustness and duration of CMV-specific immunity
- Efficacy
  - CMV infection or reactivation up to 12-mos post-transplant
  - CMV viremia requiring treatment (duration of treatment, subjects with viremia at any level, time to development of viremia, subjects with recurrent viremia)

Secondary

- Other clinical outcomes up to 12 months post-transplant
  - CMV disease
  - Acute allograft rejection
  - Mortality
  - Re-transplant
  - Non-CMV infections

Triplex for CMV Control in Kidney Transplant

Phase 2 Study Anticipated to Commence in 2024

Phase 2 Trial (Planned)

Overview

- Induce the expansion of CMV-pp65, IE1, and IE-2-specific functional T-cells in CMV seronegative and CMV seropositive patients with advanced kidney disease who are awaiting kidney transplant from a CMV seropositive donor
  - Triplex has the potential to decrease CMV-related complications and need for toxic antiviral therapy in the post-transplant setting

Design

- Prospective, randomized, double-blind, placebo-controlled trial
  - Patient Population: CMV seronegative kidney transplant candidates expected to receive transplant from CMV seropositive donor within 2-12 months (D+R-) with preemptive antiviral strategy (no prophylaxis)
- Enrollment of approximately 176 patients
  - Continues until target of 88 subjects receive kidney transplant from a CMV seropositive donor within 12 months after first dose
- Randomized 1:1 between vaccine and placebo
- Two planned vaccine administrations on Day 0 and Day 28
- Study will consist of approximately 10 sites in the U.S.
- Option to Include Interim Analysis and/or Deploy Adaptive Phase 2/3 Design

Objectives

Primary

- Safety
  - Solicited AEs within seven days of each dose
  - Unsolicited AEs within 28 days of each dose
  - SAEs
  - Development of anti-vector immunity (none observed in Phase 2)
- Immunogenicity
  - Determine proportion of responders
  - Determine robustness and duration of CMV-specific immunity
- Efficacy
  - CMV infection or reactivation up to 12-mos post-transplant
  - CMV viremia requiring treatment (duration of treatment, subjects with viremia at any level, time to development of viremia, subjects with recurrent viremia)

Secondary

- Other clinical outcomes up to 12 months post-transplant
  - CMV disease
  - Acute allograft rejection
  - Mortality
  - Re-transplant
  - Non-CMV infections

Pathway to Approval in HSCT

Generating Additional Data in HSCT to Support Broad Phase 3 Inclusion

Phase 3 Trial Overview

- Phase 3 study for Triplex will be an expanded version of the Phase 2 study with the same endpoint and enrollment criteria, but a larger sample size and interim analysis
- Michael Boeckh, MD, PhD serves as a key internal resource for HSCT
  - World-renowned expert on CMV in HSCT, advised large pharma on antiviral development
- End of Phase 2 Meeting Completed 1Q2020
- FDA confirms proposed Phase 3 trial will be sufficient for registration in lead indication
- Follow post-transplant patients for CMV events from Day 100 to day 365, while also tracking patients' relapse and survival from underlying cancer
- Ongoing studies in HSCT to facilitate integration of donor-vaccination paradigm and/or expansion of patient population to include pediatrics and haploidentical donors
  - Consistent with recent market assessment and survey (Cello Health)

Phase 3 Trial Highlights

Design: Randomized 2:1 between vaccine and placebo

Endpoint: Reduction in CMV events through day 100 (same as in Phase 2)

Total Sites: ~50, likely to include the EU

Total Participants: ~585 patients

Projected Total Cost: ~$30MM

Triplex vs. HOOKIPA's HB101

HOOKIPA's HB101 is a key comparable to Triplex for CMV control in solid organ transplant

	Triplex	HB-101
Clinical Stage	Met Primary Endpoint in Multi-Center Phase 2 in difficult-to-treat allogeneic stem cell transplant (HSCT)	Failed Phase 2 in less difficult-to-treat kidney transplant recipients (more immuno-competent than HSCTs)
Vector	Modified Vaccinia Ankara (MVA), dosed safely in over 120,000 (elderly, children included), demonstrated safety and immunogenicity in HSCTs with rapid, robust and durable CD4 & CD8 T cell responses observed	Lymphocytic choriomeningitis (LCM), rodent-borne viral infectious disease; deaths reported from LCM-infected organ donor (see CDC MMWR 05/2005); LCM vector primarily generates CD8 T cells, but reduced CD4 T cell memory (Flatz, 2010)
Immune Targets	pp65 + IE1 + IE2	pp65 + gB
Relevance of Targets	Prevention of CMV viremia critically dependent on reconstitution of pp65-specific T cells (Walter, 1995); IE gene with decisive role in CMV reactivation, IE2 indispensable to CMV replication (Paulus, 2009)	CMV humoral immunity to gB is not required for control of CMV viremia after HSCT (Bowden, 1991); gB failed to prevent viremia in kidney transplant (Astellas, ASP0113)
CD8 T Cell Responses[(1)]	CD8 T cells exert rapid antiviral effects against CMV (Feuchtinger, 2010); Triplex induced robust, durable CD8 T cells in HSCTs early post-transplant in Phase 2	In CMV(-) healthy volunteers, two injections of Triplex induced rapid, robust pp65-specific CD8 response (max ~2.3%) compared to three injections of HB101 (max ~0.3%)
CD4 T Cell Responses[(1)]	CD4 T cells provide physiological, sustained immune response to CMV (Feuchtinger, 2010); Triplex induced robust, durable CD4 T cells in HSCTs early post-transplant in Phase 2	In CMV(-) healthy volunteers, two injections of Triplex induced rapid, robust pp65-specific CD4 response (max ~2%) compared to three injections of HB-101 (max ~0.02%). Recent immune analysis of HOOK data makes no mention of CD4 or humoral responses, consistent with previous data
Valuation	Privately-Held (No Equity Financing To Date)	Public (NASDAQ: HOOK); Leerink 5/13/19 analyst report values HB101 alone at ~$200M (prior to Phase 2 data)

Helocyte Summary

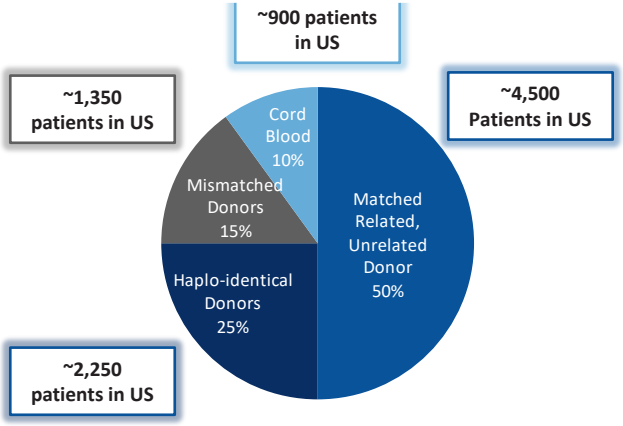
Commercial Opportunity

Well-defined, Orphan disease markets with modest sales and marketing requirement

SOT/HSCT Market Opportunity

Number of SOT by Organ & Region

Organ	U.S.	Europe	Globally
Kidney	25,490	23,593	92,532
Liver	9,236	9,333	34,694
Heart	3,863	2,350	8,409
Lung	2,569	1,964	6,470
Pancreas	963	609	2,025
Small Bowel	96	46	172
Total Organ Transplants	42,217	37,895	144,302



Current Transplant Center Landscape

SOT

- ~200 major transplant centers in US[1] performing 35,000+ solid transplants each year
- ~400 major transplant centers across the US and EU conduct over 75,000 solid organ procedures on an annual basis

HSCT

- 25,000+ total allo-HSCT transplants are performed in the US and EU annually
- Merck's Prevymis >$500M in 2023 Sales Projected (based on 1H2023 Sales)
  - Robust financial performance to date demonstrates need for innovative and efficacious therapies for CMV

Commercial Infrastructure Required

✓ ***Only 20 sales reps with the ability to target growing SOT and HSCT patient populations***

✓ ***Targeting an EU market with higher incidence of CMV and greater number of HSCT and SOT procedures***

(1) United Network for Organ Sharing

Investment Highlights Overview

Key Investment Highlights

1 Two Novel Biologics with Robust Phase 2 Data and Proof of Concept

- Triplex: vaccine engineered to prophylactically reduce the occurrence of early and late CMV after Allogeneic Hematopoietic Stem Cell Transplant (HSCT) and Solid Organ Transplant (SOT)
- Recent **positive Ph. 2 data** for HSCT; met primary endpoint with 50% reduction in CMV events through day 100 (p value based on pre-specified, one-sided 0.10 test = 0.8); no safety issues, no adverse impact on GvHD, relapse, survival
  - **Strong Biomarker data suggest clinical outcomes T cell-mediated and vaccine-driven**
- **Multiple programs ongoing** to evaluate further use in HSCT involving haploidentical donors, donor vaccination and pediatric patients, in addition to kidney and liver transplant

2 Significant Unmet Need for Safe & Effective CMV Immunotherapy

- ~50-80% of population infected with CMV by age 40, life-threatening for immuno-compromised patients
- Limitations of current standard of care:
  - 4 approved antivirals used preemptively, and 3 approved antivirals used prophylactically
  - Generic antivirals are associated with high toxicity with Black Box Warnings for myelotoxicity / nephrotoxicity, as well as late CMV after discontinuation, delayed immune reconstitution, and potential for resistance
  - Newly-approved Prevymis for prophylactic use requires prolonged dosing regimen of up to 100 daily oral or IV doses
  - No approved vaccine or immunotherapy

3 Clear Development and Approval Strategy

- Phase 2 Trial of Triplex in Liver Transplant to commence in 2023
- Phase 2 Trial of Triplex in Kidney Transplant to commence in 2024
- Registrational Study of Triplex in HSCT to commence after donor, pediatric, haploidentical trials
  - Feedback from End of Phase 2 Meeting supports proposed design and endpoints

Investment Highlights Overview (cont'd)

Key Investment Highlights

4 Triplex: Differentiated Clinical Profile

- **Safe** and **well-tolerated** in transplant recipients with no adverse impact on GvHD, relapse, survival
- **Efficacy**: equivalent or better than standard of care antivirals in Phase 2
- **Convenient dosing** of 2-3 IM injections with efficacy in the range of approved antivirals
- **Drives immune reconstitution**: key objective after transplant (delayed by antivirals)
- **Durable effect** following limited administration with potential to address late CMV (after day 100)
- **No drug resistance**: major issue with antivirals, especially with longer duration of use (Prevymis)

5 Attractive Niche Target Market

- ~25k annual allogeneic stem cell transplants in US/EU, ~50k annual kidney transplants in US/EU, and ~20k annual liver transplants in US/EU; Executive Order for kidney health (July 2019) aims to increase kidney transplants per year by 17k
- Highly specialized market with **favorable reimbursement** and pricing dynamics; covered under Medicare
- Ability to effectively detail ~200 transplant centers in US with a cost effective salesforce of **20+ representatives**
- Potential Triplex US & EU peak sales of $1BN+

6 Robust IP Protection and Orphan / Biologic Market Exclusivity

- Robust **patent portfolio** and **BLA status** provides high barriers to entry and minimizes risk of generic / biosimilar competition
- **Orphan Exclusivity** provides 7 years and 10 years of protection in the US and EU, respectively
- **Biologic Exclusivity** provides 12 years and 11 years of protection after first commercial sale in US and EU, respectively
- **BLA** development pathway provides robust protection from future generic biosimilar threat
- Portfolio of three issued patents protecting Triplex through **2033, Biologic Exclusivity for 12 years from First Licensure**