

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): October 2, 2019

Precision BioSciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38841
(Commission
File Number)

20-4206017
(IRS Employer
Identification No.)

302 East Pettigrew St., Suite A-100, Durham, North Carolina 27701
(Address of principal executive offices) (Zip Code)

(919) 314-5512
(Registrant's telephone number, include area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common stock, par value \$0.000005 per share	DTIL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

Precision BioSciences, Inc. (the "Company") will be participating in meetings with investors and analysts, and a copy of the Company's presentation materials being used at these meetings is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. These presentation materials are also available on the Investor Relations page of the Company's website at <https://investor.precisionbiosciences.com>.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Precision BioSciences, Inc. Presentation as of October 2, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PRECISION BIOSCIENCES, INC.

Date: October 2, 2019

By: /s/ Dario Scimeca
Dario Scimeca
General Counsel

Dedicated to Improving Life.

DTIL

Overcome cancer.
Cure genetic disease.
Feed the planet.



Forward Looking Statement



This presentation (together with any other statements or information that we may make in connection herewith) may contain forward-looking statements. All statements other than statements of present and historical facts contained in this prospectus, including without limitation, statements regarding our future results of operations and financial position, business strategy, prospective products, planned preclinical or greenhouse studies and clinical or field trials, regulatory approvals, research and development costs, and timing and likelihood of success, as well as plans and objectives of management for future operations, may be forward-looking statements. Without limiting the foregoing, the words “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate,” “target,” “may,” “will,” “would,” “potential,” the negative thereof and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements reflect various assumptions of Precision’s management that may or may not prove to be correct. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to us. Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, our ability to become profitable; our ability to procure sufficient funding; our limited operating history; our ability to identify, develop and commercialize our product candidates; our dependence on our ARCUS technology; the initiation, cost, timing, progress and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; our or our collaborators’ ability to identify, develop and commercialize product candidates; our or our collaborators’ ability to advance product candidates into, and successfully complete, clinical or field trials; our or our collaborators’ ability to obtain and maintain regulatory approval of future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the regulatory landscape that will apply to our and our collaborators’ development of product candidates; our ability to achieve our anticipated operating efficiencies as we commence manufacturing operations at our new facility; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; the potential for off-target editing or other adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates; the success of our existing collaboration agreements; our ability to enter into new collaboration arrangements; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; potential manufacturing problems associated with any of our product candidates; potential liability lawsuits and penalties related to our technology, our product candidates and our current and future relationships with third parties; and other important factors discussed under the caption “Risk Factors” in our quarterly report on Form 10-Q filed with the SEC on August 14, 2019, as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC’s website at www.sec.gov

All forward-looking statements speak only as of the date of this presentation, and except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

This presentation may also contain estimates, projections, and/or other information regarding our industry, our business and the markets for certain of our product candidates, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, clinical trials, studies and similar data prepared by market research firms and other third parties, from industry, medical and general publications, and from government data and similar sources. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

Dedicated To Improving Life



Overcome Cancer.



Cure Genetic Disease.



Feed the Planet.



Delivering on the Promise of Genome Editing to Address Core Challenges of Human Health



Proprietary **ARCUS genome editing platform** built for translation with full freedom to operate

Scaled and cell phenotype-optimized **allogeneic CAR T platform** in the clinic for R/R NHL and ALL. Second program entering clinic Q4 2019



World class team of **Precisioneers** that includes the **pioneers** in genome editing



Industry leading **in vivo gene correction platform** first to publish in non-human primates



Wholly integrated **food editing platform** focused on human wellness and food security



Our Near-Term Development Strategy



PRECISION
BIOSCIENCES

Indication: NHL and ALL
Target: CD19 (PBCAR0191)
Clinical Phase 1/2a



Focusing on validated targets

Building out fully scaled
in-house manufacturing

Leveraging partnerships to
access additive capabilities

Positioning follow-on programs to
advance rapidly upon PoC



Indication: Hepatitis B
Target: cccDNA and
integrated DNA

IND 2020



Indication: NHL, CLL, SLL
Target: CD20 (PBCAR20A)
IND accepted, trial start Q4 2019
Orphan designation (MCL)



Product: Ultra-low sat canola oil

Target: Saturate pathways

Greenhouse 2019





ARCUS

Nature's Genome Editing System





Industry's Approach to Genome Editing

- ⊖ Ease of design
- ⊖ Speed of manufacture
- ⊖ Density of targeting
- ⊖ Open source

Precision BioSciences' Approach to Genome Editing

- ✓ Safety
- ✓ Delivery
- ✓ Control of edits
- ✓ Proprietary

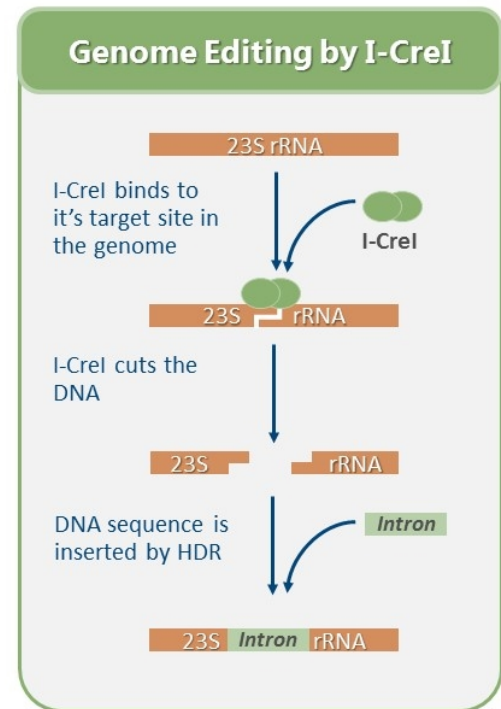
ARCUS: Engineering Nature's Genome Editing System



ARCUS is derived from I-CreI, a homing endonuclease naturally evolved for highly precise genome editing

Four Key Attributes

- 1. Safety:** Self-inactivates to prevent off-target editing
- 2. Delivery:** Small size (364 amino acids) maximizes delivery
- 3. Control of edits:** 3' "sticky ends" enable all forms of edits
- 4. Proprietary:** Complete control of platform and freedom to operate





Overcoming Cancer

Off-the-shelf CAR T



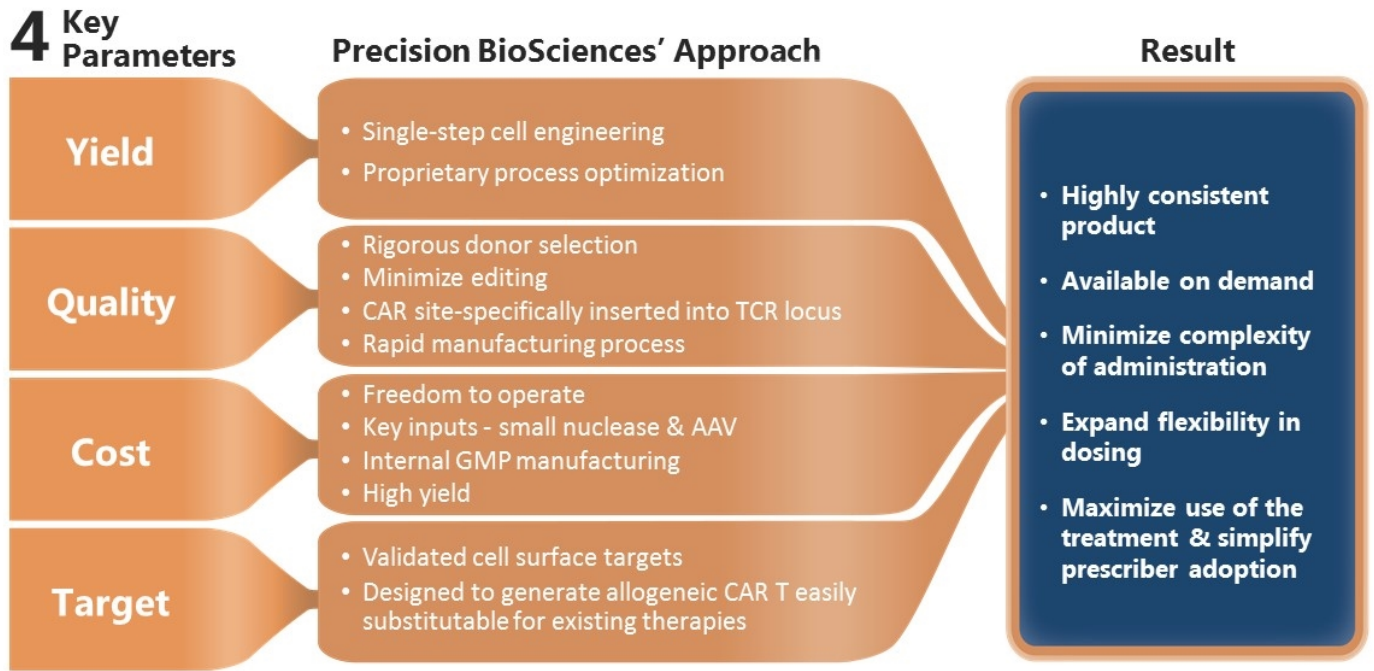
Off-the-shelf CAR T Immunotherapy Pipeline

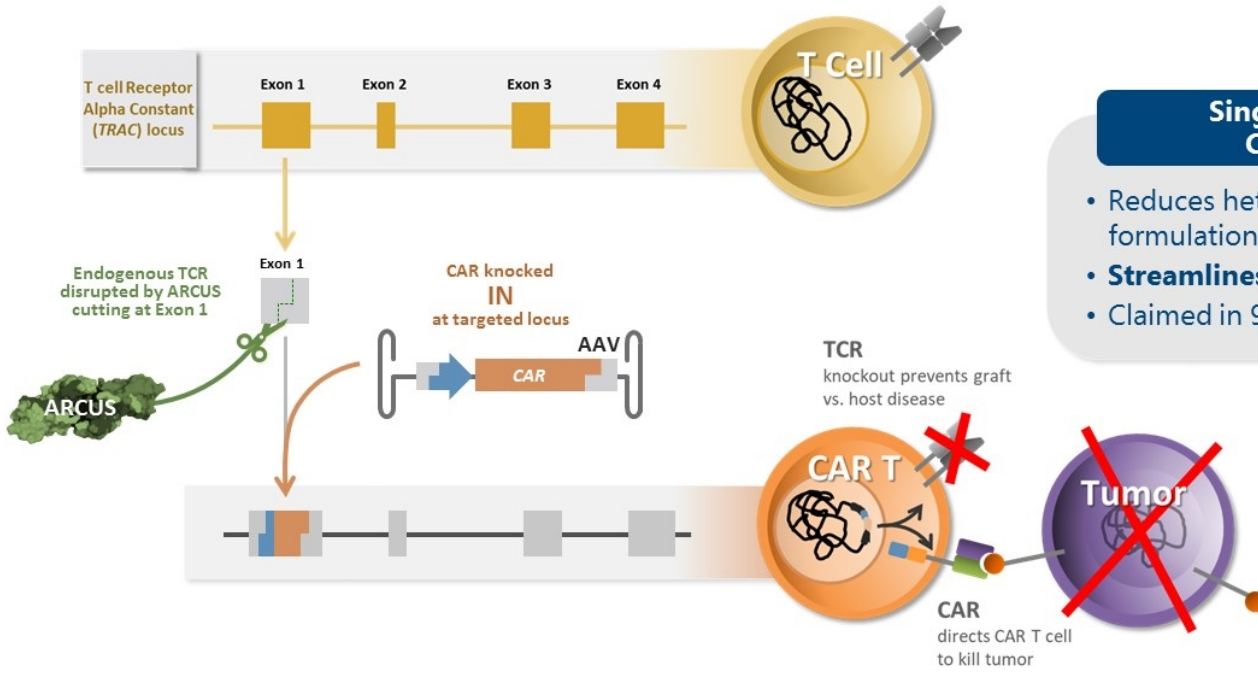


An Allogeneic CAR T Platform Designed to Overcome Cancer



Allogeneic CAR T requires a traditional drug development approach to compete with traditional biologics





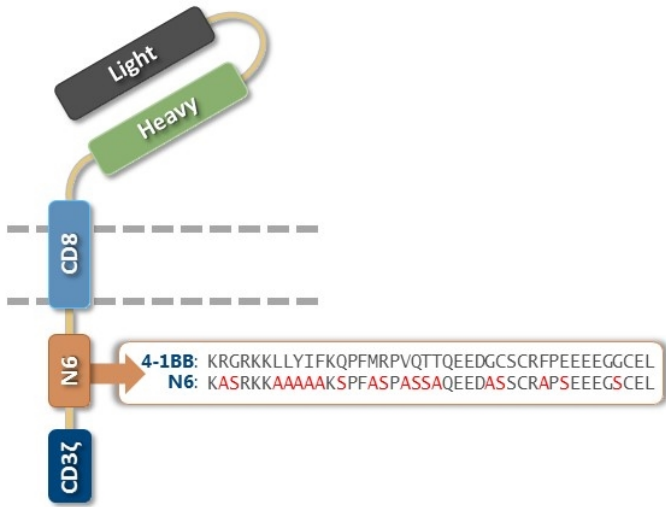
Single-step CAR T

- Reduces heterogeneity in cell formulation
- **Streamlines manufacturing**
- Claimed in 9 issued US patents

Novel Costimulatory Domain Preserves Cell Phenotype

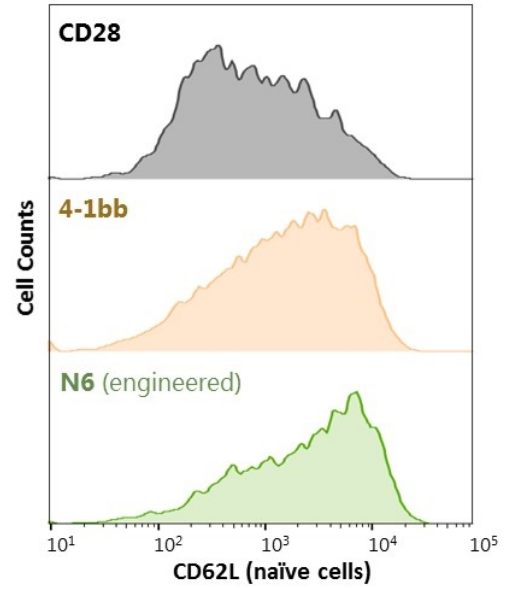


- Precision CARs incorporate a novel proprietary costimulatory domain called "N6"
- N6 promotes cell expansion while maintaining naïve cell phenotype



N6 maintains a greater percentage of naïve cells

- N6 preserves naïve phenotype and expansion potential better than CD28 and 4-1BB following exposure to target cells



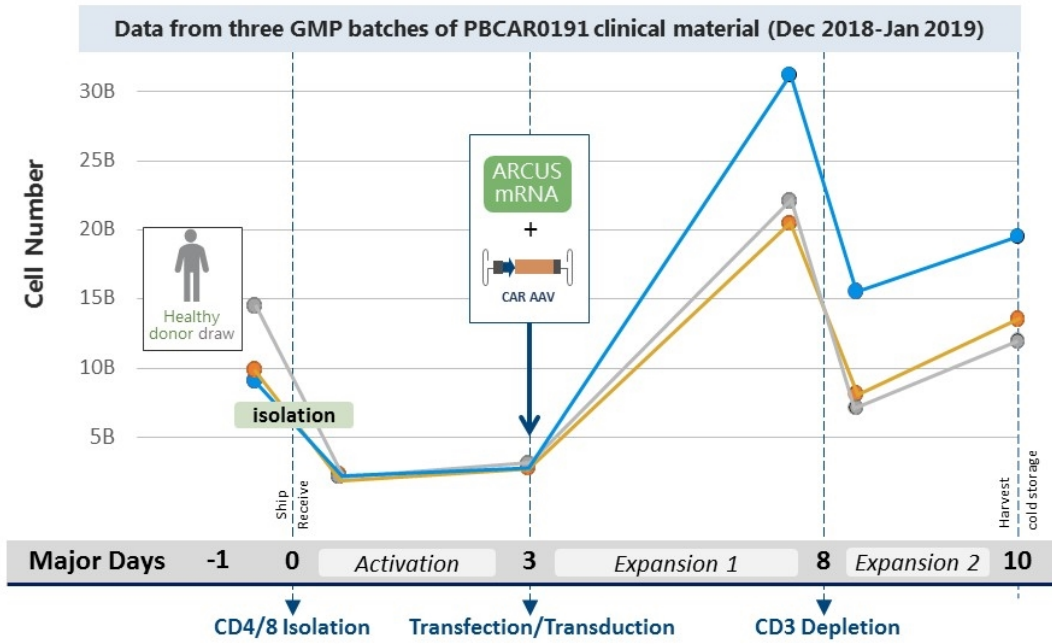
First In-House cGMP Manufacturing Facility for Genome Edited Allogeneic CAR T in the U.S.



- Precision's Manufacturing Center for Advanced Therapeutics (MCAT) is a 17,300 square foot cGMP clinical manufacturing facility
- Allogeneic CAR T Cells, mRNA (10g scale) and rAAV (400L scale) vectors for *in-vivo* and *ex-vivo* uses
- Close proximity to RDU airport and Precision R&D facility (<10 min)
- Second phase expansion for commercial application (>10,000 CAR T doses / treatments per year)



Scaled CAR T Manufacturing: Optimizes Yield and Quality



Final Yield CD19 Drug Product
(64M CAR T cells/vial)

Batch	Vial Count
1	130
2	114
3	100

CD3- >99%
CAR+ 65% - 75%
 $T_{N/SCM}$ & T_{CM} >50%
1.25 CD4:1 CD8 (Batch2)

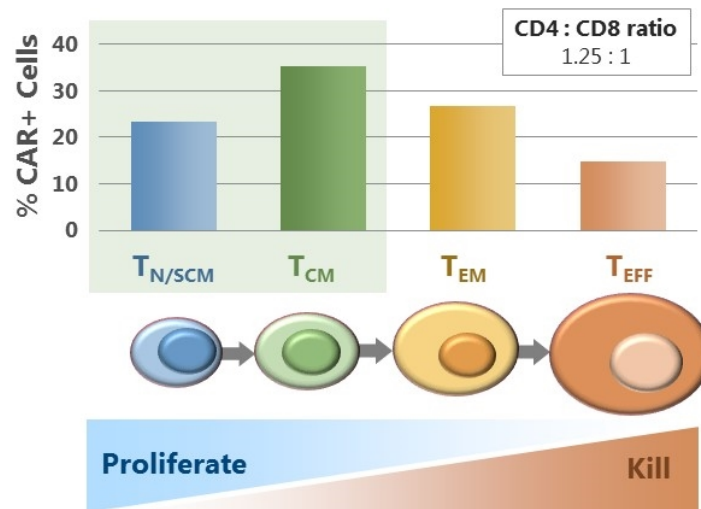
$T_{N/SCM}$ = Naïve; T_{CM} = Central Memory



Naïve and Central Memory CAR T cells are understood to be responsible for robust *in vivo* CAR T expansion

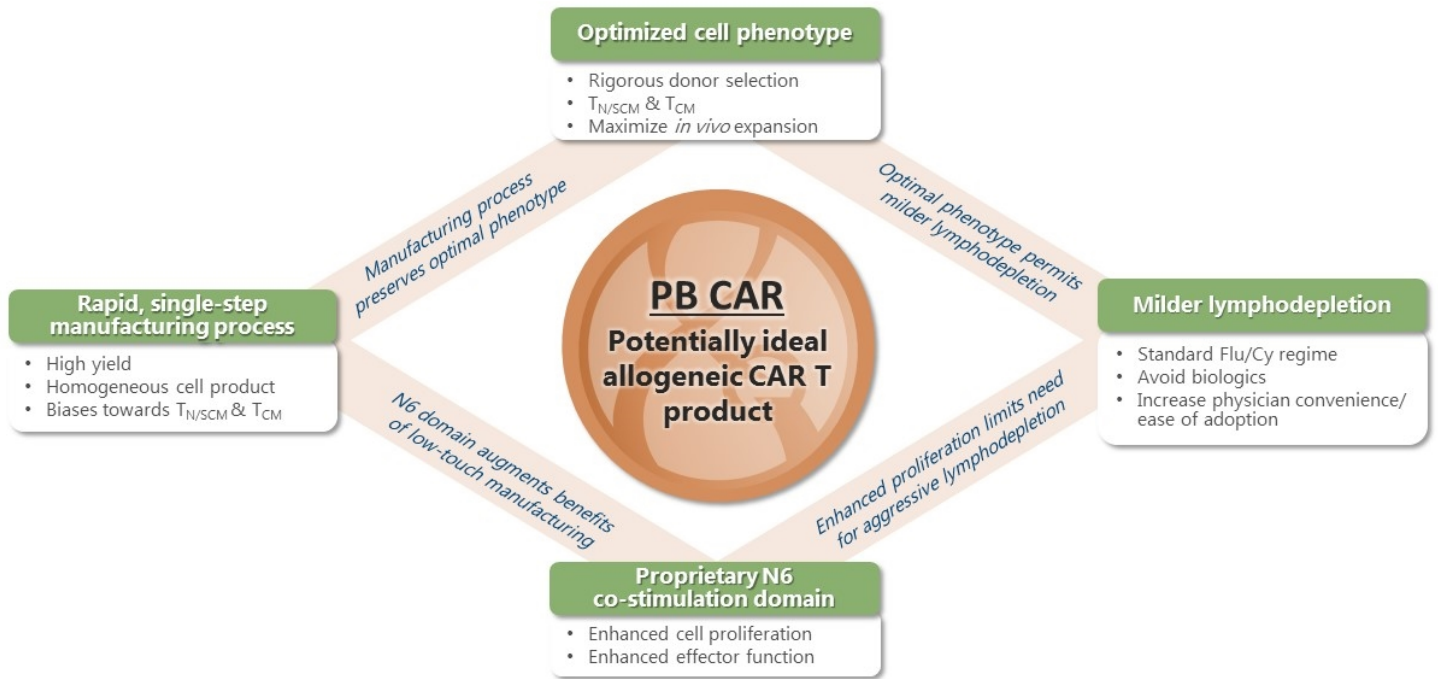
- Donor selection and proprietary, streamlined manufacturing **maximizes naïve and central memory T cells**
- Lengthy and/or complex manufacturing processes result in primarily effector memory (T_{EM}) and effector (T_{EFF}) T cells

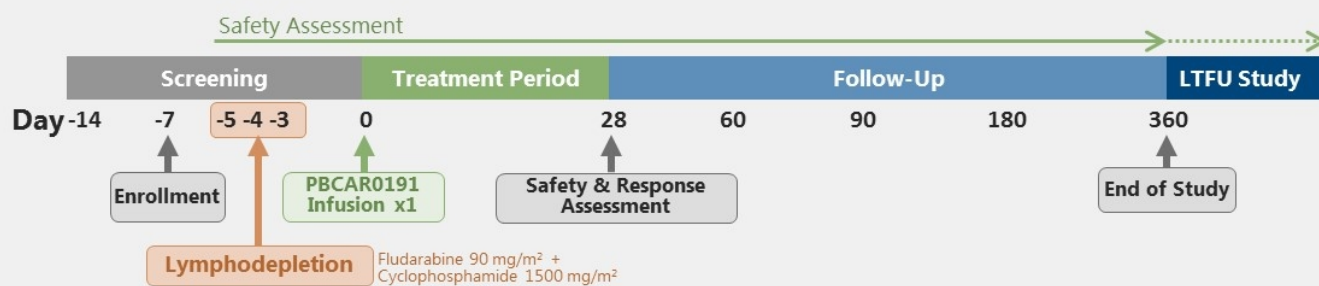
PBCAR0191 has a high proportion of Naïve and Central Memory CAR T cells.



Cell phenotype data from PBCAR0191 clinical trial drug product

Unique Approach to Allogeneic CAR T Positions for Potential Best-in-Class Product Profile





First patient dosed April 2019

Eligibility

- Adult patients with R/R B-NHL or R/R B-ALL

Clinical Sites

- Moffitt (Bijal Shah)
- City of Hope (Anthony Stein / Alex Herrera)
- Dana Farber (Caron Jacobson)
- MD Anderson (Nitin Jain)

Objectives

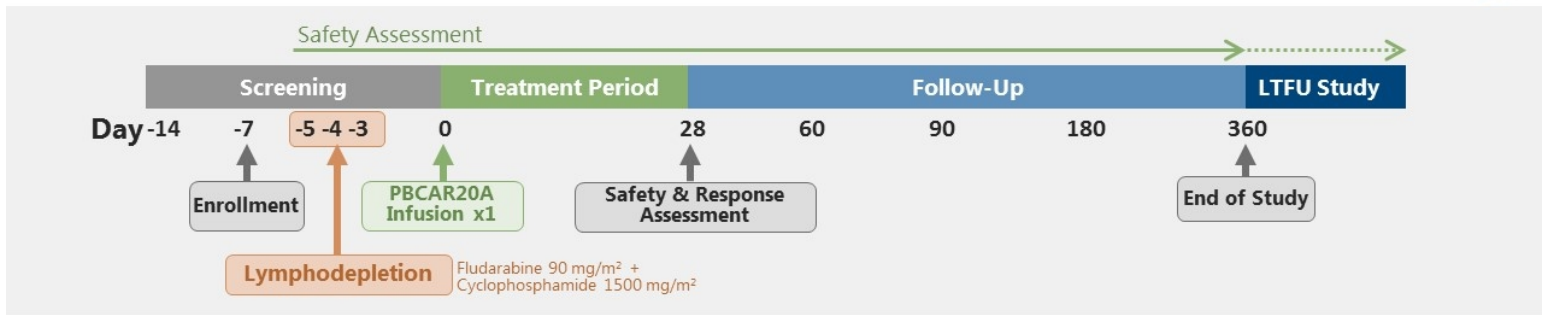
- Primary: safety and tolerability
- Secondary: anti-tumor activity
- Exploratory: expansion, trafficking, and persistence

Dose Escalation (standard 3+3)

- DL1 = 3.0 x 10⁵/kg
- DL2 = 1.0 x 10⁶/kg
- DL3 = 3.0 x 10⁶/kg

Interim data expected no later than Q1 2020

PBCAR20A (CD20): Phase 1/2a Clinical Plan



Ph 1/2a to begin Q4 2019; ODD granted for MCL

Eligibility

- Adult patients with R/R NHL (including MCL) or R/R CLL or SLL

Projected Clinical Sites

- MD Anderson
- Memorial Sloan Kettering
- Cleveland Clinic
- Stanford University

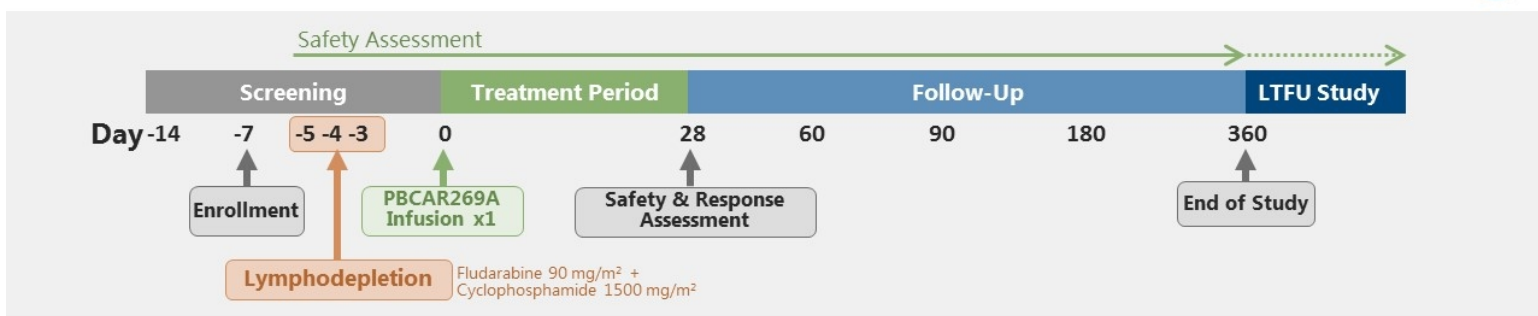
Objectives

- Primary: safety and tolerability
- Secondary: clinical (anti-tumor) activity
- Exploratory: expansion, trafficking, and persistence

Dose Escalation (standard 3+3)

- DL1 = 3×10^5 /kg
- DL2 = 1×10^6 /kg
- DL3 = 3×10^6 /kg

Interim data expected in 2020



Eligibility

- Adult patients with r/r Multiple Myeloma

Objectives

- Primary: safety and tolerability
- Secondary: clinical (anti-tumor) activity
- Exploratory: expansion, trafficking, and persistence

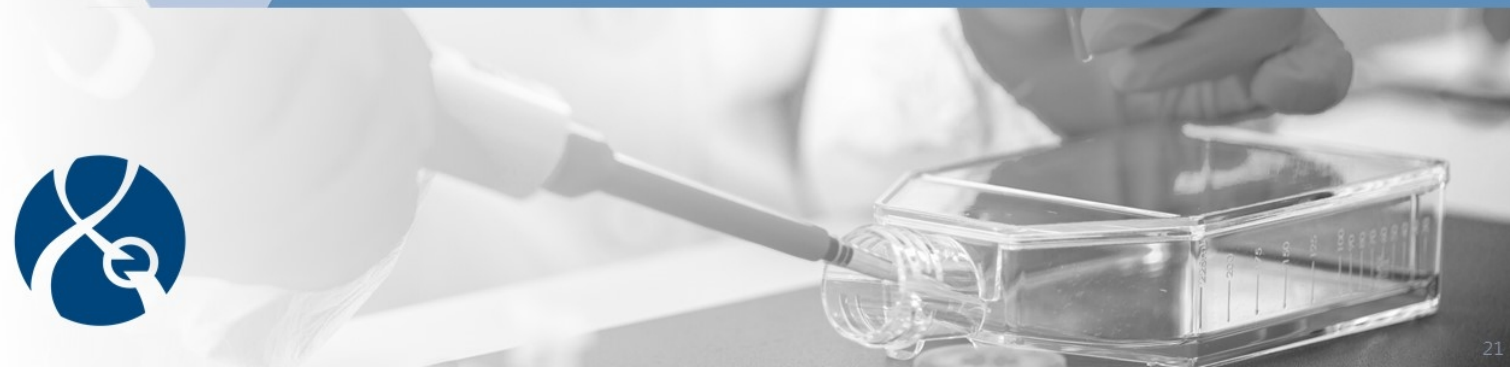
Dose Escalation (standard 3+3)

- DL1 = 6 × 10⁵/kg
- DL2 = 2 × 10⁶/kg
- DL3 = 6 × 10⁶/kg



Curing Genetic Disease

In Vivo Gene Correction



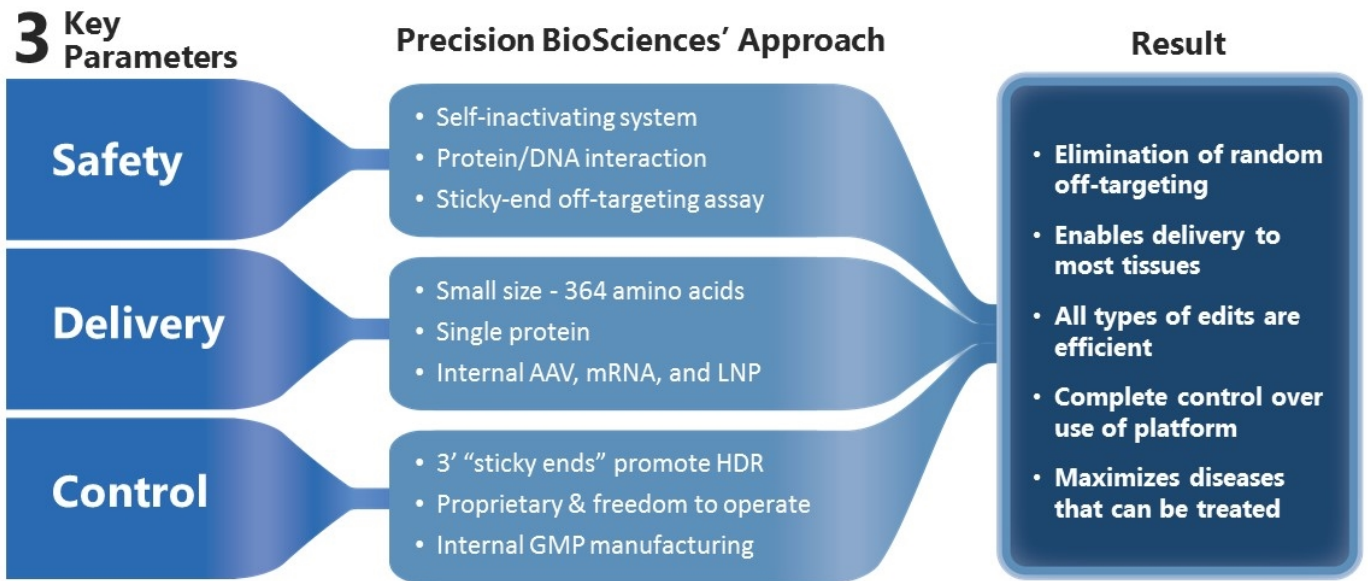


Product Candidate	Program Area	Discovery	Pre-clinical	Clinical	Rights
HBV	Chronic Hepatitis B – IND 2020				GILEAD
Transthyretin	Familial amyloid polyneuropathy	<p>Candidate selection for lead gene correction (2H19)</p>			
HAO1	Primary hyperoxaluria				
FVIII (Intron 22 inversion)	Hemophilia A				
P23H RHO	Retinitis pigmentosa				
ApoC3	Lipoprotein lipase deficiency				
PCSK9	Familial hypercholesterolemia				

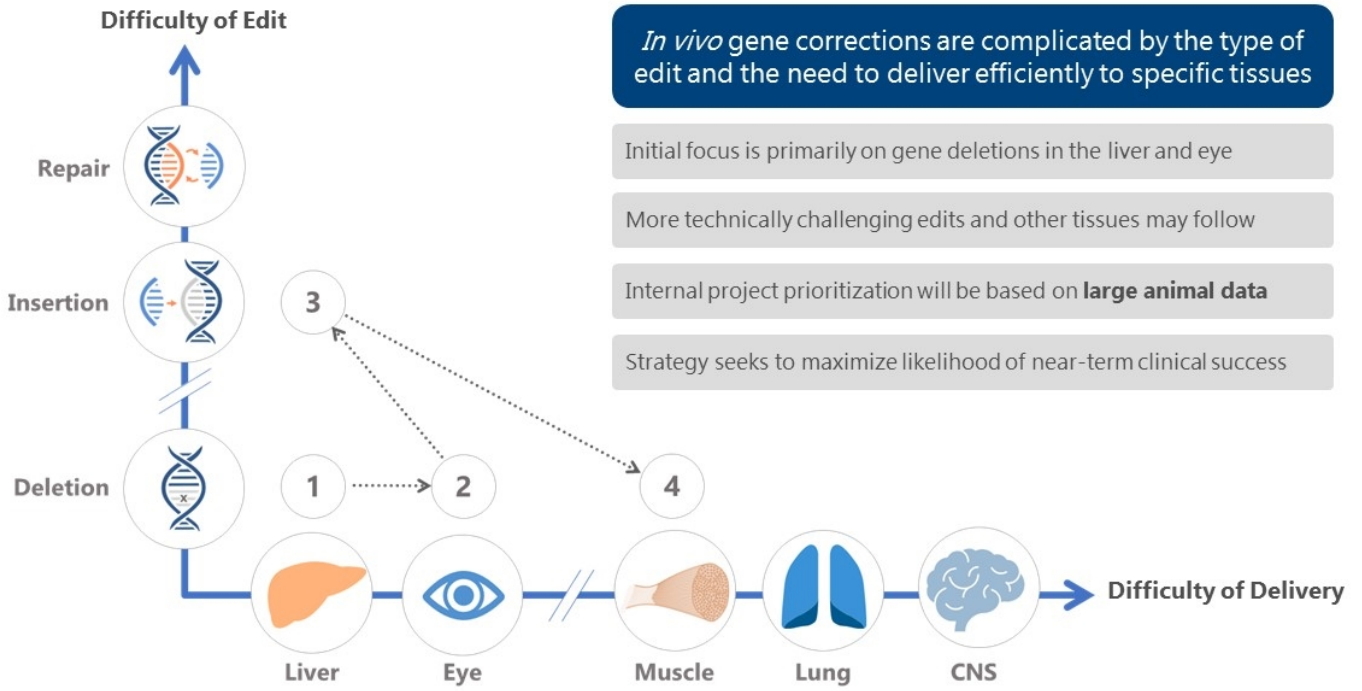
An *In Vivo* Gene Correction Platform to Cure Genetic Disease



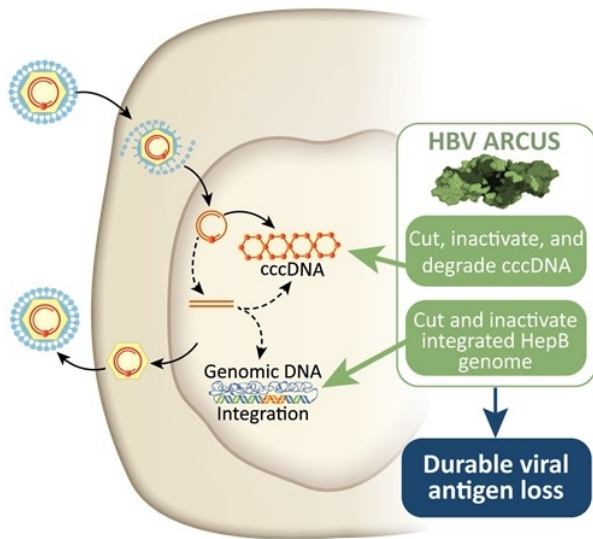
In vivo gene corrections are permanent and require a therapeutic-grade genome editing approach



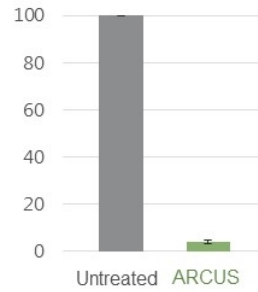
Precision's *In Vivo* Gene Correction Strategy



ARCUS can target and destroy HBV cccDNA



A) ARCUS reduces HBV S-antigen in infected human hepatocytes



B) ARCUS reduces cccDNA in infected human hepatocytes



Development of a potential cure

We are working with Gilead to develop a drug formulation for curing chronic HBV infection

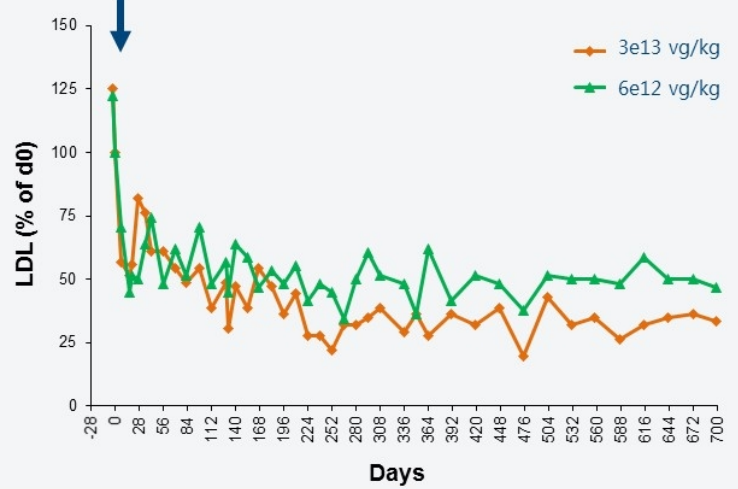
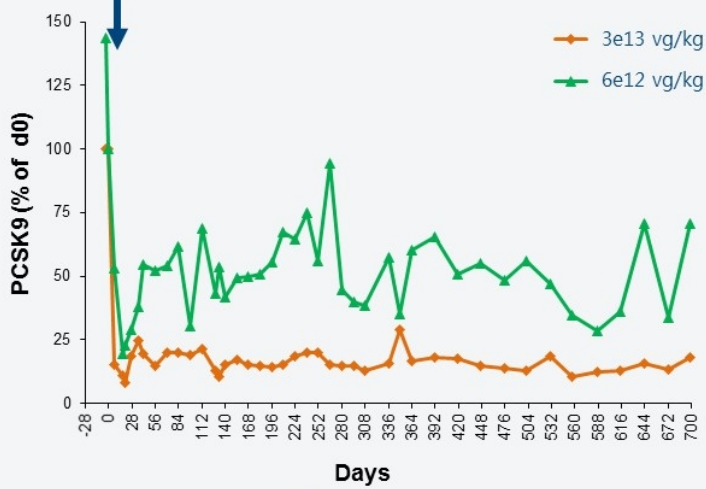
- mRNA-based drug
- Lipid nanoparticle (LNP) delivery
- Large-scale in-house mRNA manufacturing process
- Preclinical data collection underway
- **IND expected in 2020**

Familial Hypercholesterolemia: Reduce 'Bad' Cholesterol



Rhesus macaques treated with ARCUS show reductions in PCSK9 and LDL levels, sustained since 2017

- First peer-reviewed data demonstrating *in vivo* gene correction in a non-human primate model
- Animals tolerated treatment, no obvious AEs and appear healthy two years after dosing
- Similar results obtained with 4 additional treated animals at 2 years+



LDL levels are stably reduced by roughly 50% or more following one-time AAV delivery of an ARCUS nuclease

Autosomal Dominant Retinitis Pigmentosa: Restore Vision



ARCUS can be used to selectively eliminate the P23H *RHO* gene associated with adRP

leave WT allele intact

>wild-type rhodopsin
ACGGGTGTGGTACGCAGCCCT

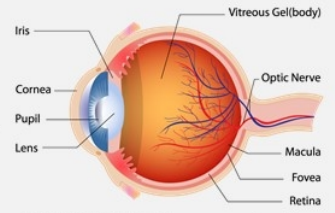
eliminate mutant allele

>RHO C68A (P23H) mutant
~~ACGGGTGTGGTACGCAGCCACT~~



Inject P3-P7
(one eye)

Electroretinogram (ERG)

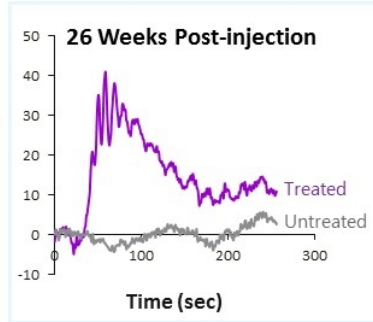
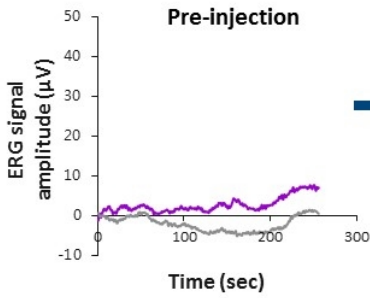


hP23H *RHO* Transgenic Pig

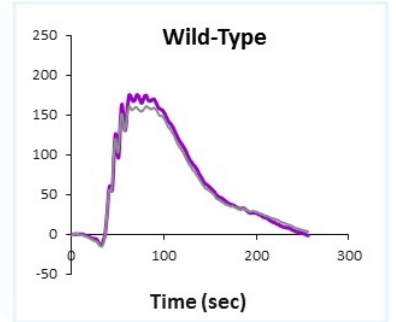
ARCUS treatment restores vision in a humanized pig model of P23H adRP

Measuring ERG in treated animals demonstrates correction of retinal electrical activity in response to light stimulus

— Treated eye
— Untreated eye



Treated eye
mirrors
wild-type





Feed the Planet

Elo Life Systems

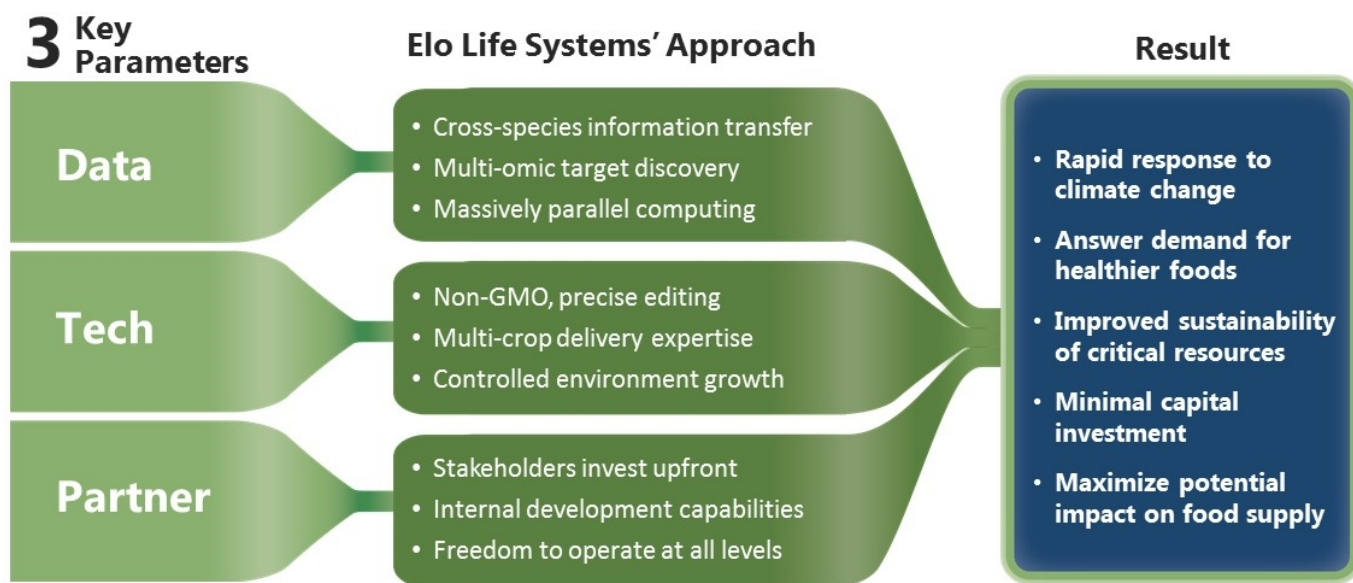




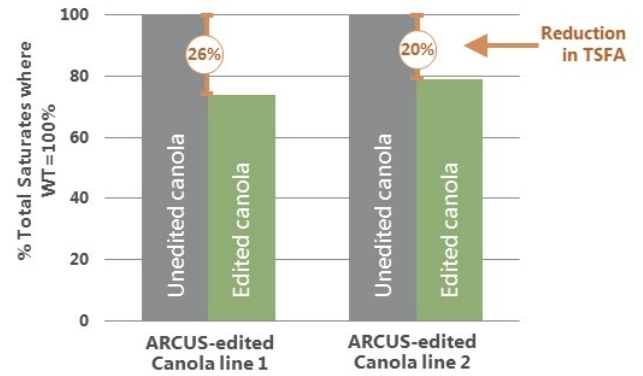
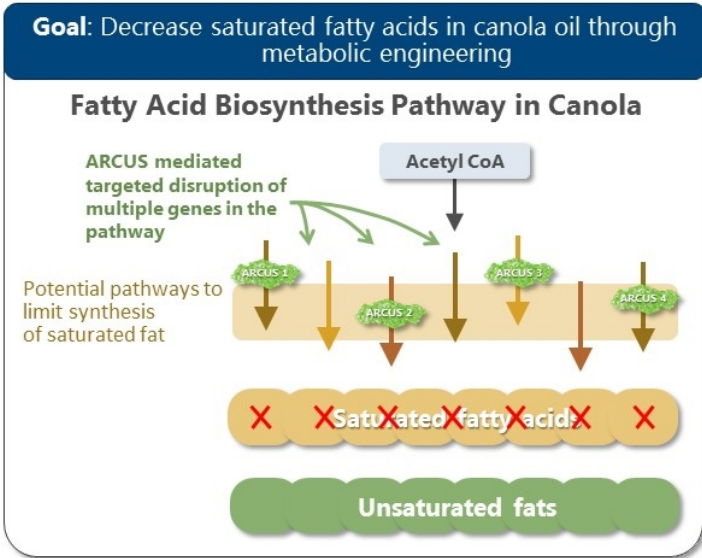
Product	Discovery	Greenhouse	Field	Program Lead
Ultra-low Saturate Canola Oil				
Scaled, Zero Calorie Watermelon Sweetener				
Self-Breeding Stevia				
High Protein Chickpea				

A Food Editing Platform Built to Deliver Healthy Nutrition

Elo Life Systems, a subsidiary of Precision BioSciences, seeks to improve human health through food



Cargill is one of the world's largest producers of cooking oil. We are collaborating with Cargill to develop ultra-low saturate "heart healthy" canola oil



Edited canola plants produce significantly lower levels of saturated fat relative to current low-saturate canola lines

Source: US patent 2017/0034541 W; TSFA: C18:0/C20:0/C22:0/C24:0; TSFA = Total Saturated Fatty Acid

Mogroside V is an all-natural zero calorie sweetener from Monk Fruit

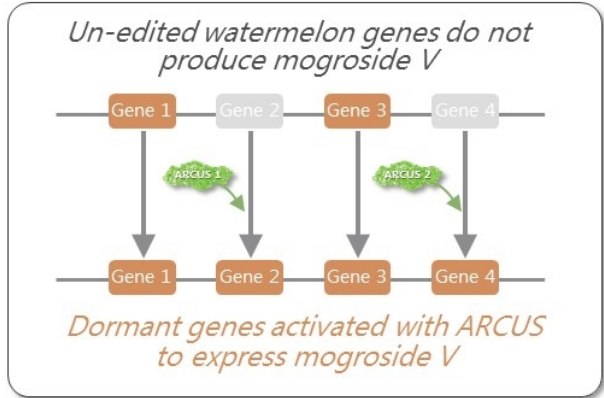
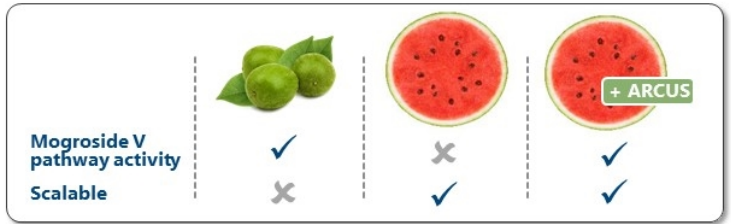
Mogroside V is difficult to source because monk fruit is not scalable

- Grown regionally, long life cycle, small, difficult to cultivate and process

Watermelon has all the genes to make mogroside V, but the pathway is dormant

Elo is using ARCUS to re-activate the dormant mogroside V pathway genes in watermelon

- Watermelon production and processing is already highly optimized
- Production of mogroside V in watermelon would make harvesting this sweetener scalable
- Mogroside V could be produced locally and sustainably, for the global food, beverage and ingredient industry



Significant Near-Term Value Catalysts Expected Through 2019 into 2020



- ✓ Initial Public Offering (Ticker: DTIL) - Q2 2019
- ✓ Clinical dosing of allogeneic CD19 CAR T - Q2 2019
- ✓ Open cGMP manufacturing facility: CAR T, mRNA, AAV – Q3 2019
- ✓ IND acceptance and ODD for wholly owned CD20 CAR T
- CD20 CAR T enters clinic Q4 2019
- Interim data from Ph1/2a CD19 CAR T – no later than Q1 2020
- IND for wholly-owned BCMA CAR T - 2020
- IND for lead *in vivo* gene correction program - 2020

Cash Runway Takes Us Into 2021



Highly experienced team of over 180 Precisioneers includes the pioneers in editing



Proprietary ARCUS genome editing platform with full freedom to operate



Independent cGMP manufacturing capabilities by YE 2019



Multiple allogeneic CAR T programs expected to be in clinical trials by YE 2019



Initial CD19 CAR T clinical data no later than Q1 2020



Strong balance sheet and validating partnerships in each business area



PRECISION
BIOSCIENCES



Overcome Cancer.



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Feed the Planet.



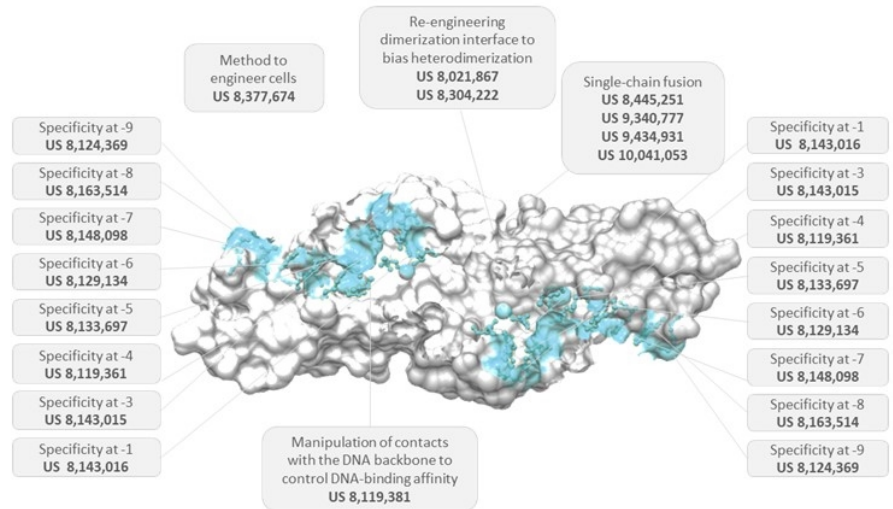
Dedicated To Improving Life



Appendix



- Precision controls more than 45 issued US and foreign patents related to the ARCUS platform and ARCUS nuclease products
- Two core US patents ('867 & '015) have undergone reexamination and were confirmed with no changes
- Each new ARCUS nuclease that generates a novel mutation is a non-obvious entity and patentable, providing extended patent protection on each new drug substance or product

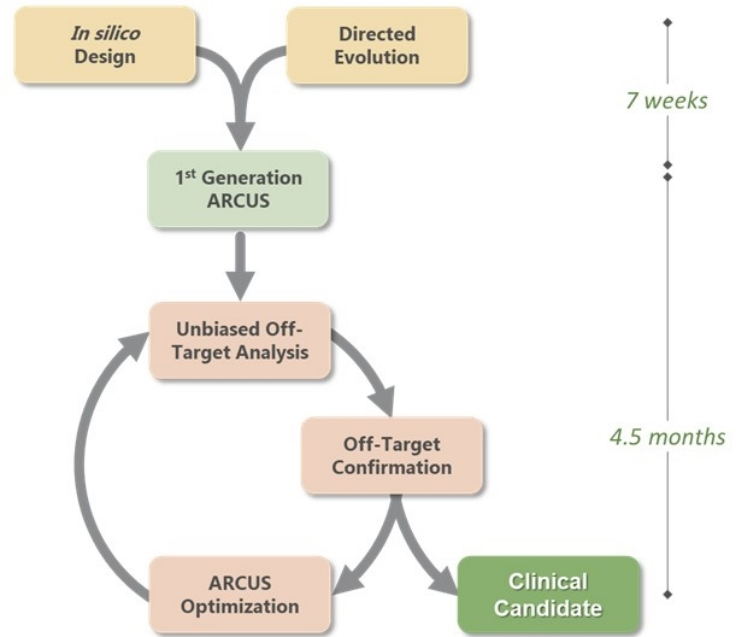
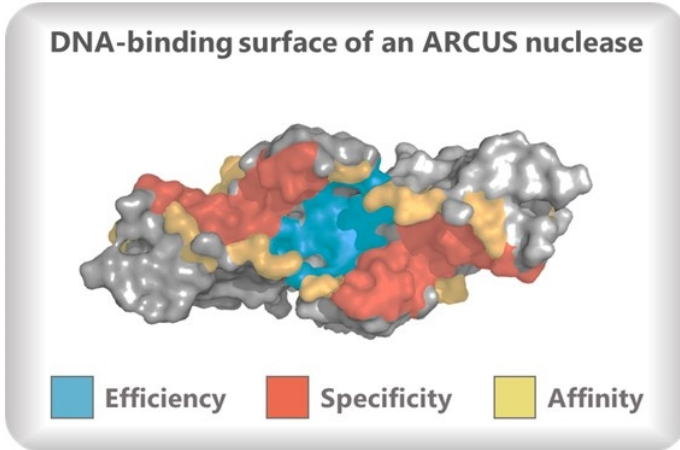


We believe that we have the freedom to operate the ARCUS platform and do not require licenses from third parties for any of our nucleases

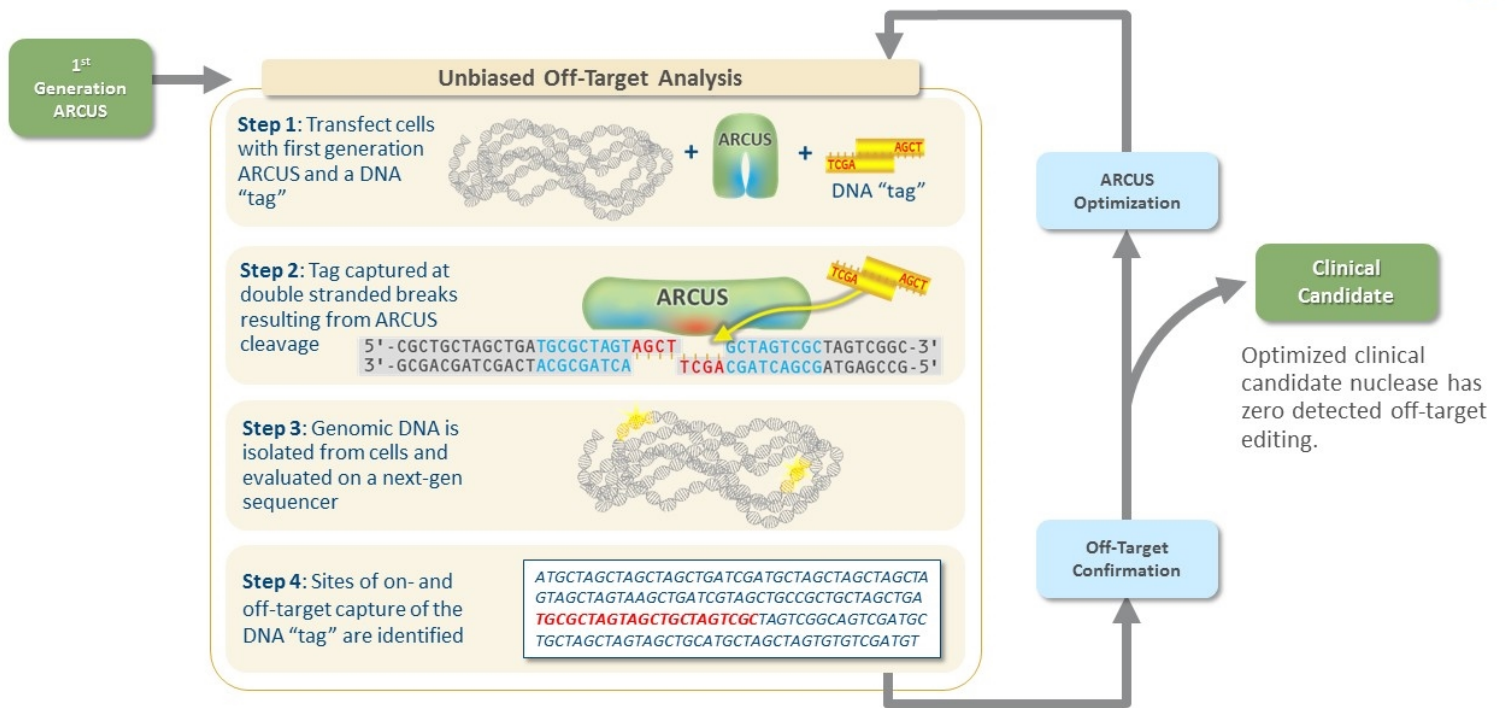
ARCUS: Engineered I-CreI Nucleases



- ARCUS platform – an iterative protein engineering process involving changes to the specificity, affinity, and cleavage efficiency of I-CreI



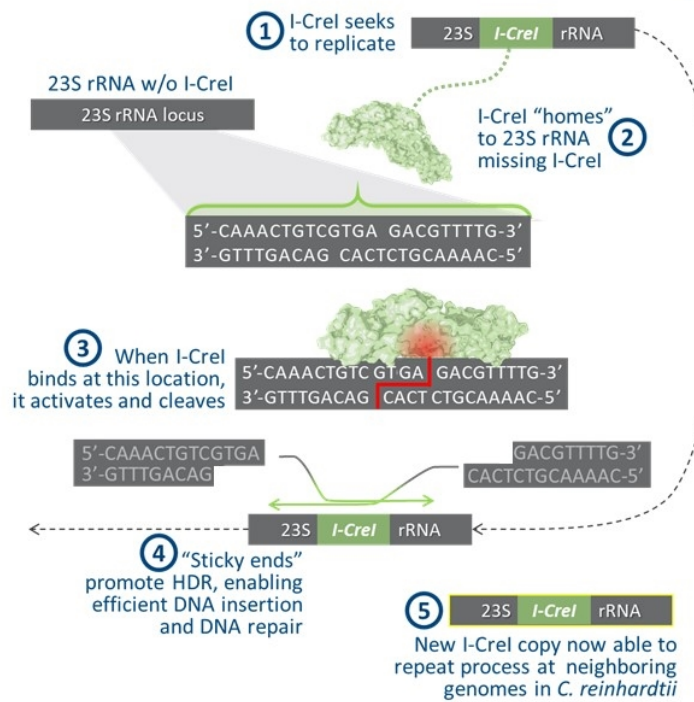
Highly Sensitive Off-Target Detection



I-CreI: A Natural Genome Editing Enzyme



- ARCUS is derived from I-CreI, a genome editing "homing" endonuclease (HE) from the algae *Chlamydomonas reinhardtii*
 - Intron-encoded enzyme in the 23S ribosomal RNA gene
- Member of the LAGLIDADG homing endonuclease family and among the best biochemically understood
- Site-specific recognition and cleavage within a large genome
 - Target homing site represents a 22-bp long pseudo-palindromic DNA sequence
- Cleavage of the homing site generates two, 4 base pair, 3' "sticky ends"

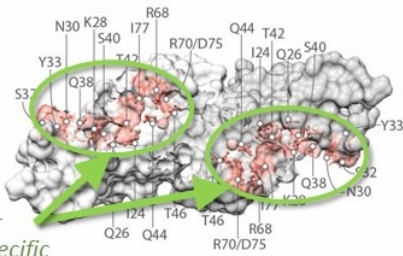


Example: Creating an ARCUS Nuclease from I-CreI



Goal: Create an ARCUS nuclease to knockout the PCSK9 gene while retaining desirable attributes of I-CreI

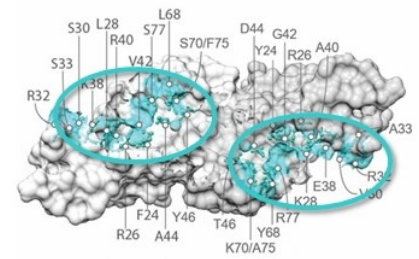
I-CreI



Amino acids responsible for recognizing specific target sequence

Alter the amino acids at these positions so the nuclease now specifically binds to PCSK9 gene

ARC-PCSK9

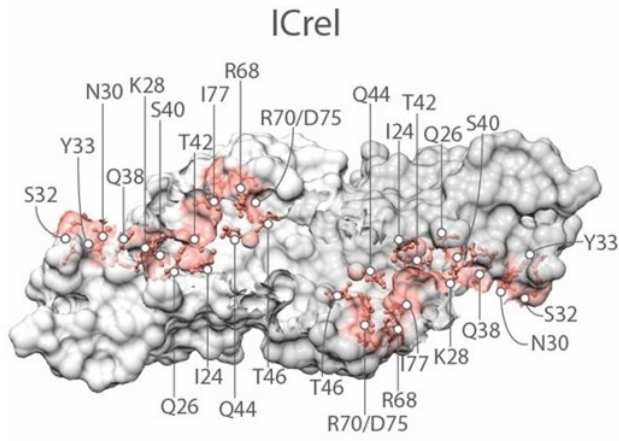


- Low frequency of off-targeting
- Type of cut
- Small size

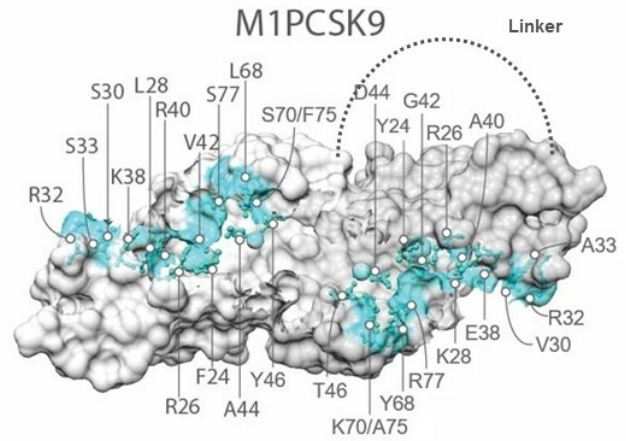


- Specificity for gene target → Recognizes a new sequence
- Affinity for new binding site → Prevents off-targeting
- Efficiency & speed of cut → Optimizes for different delivery strategies





CAAAACGTCGTGAGACAGTTTG
 wild-type I-CreI target site in *Chlamydomonas*



TGGACCTCTTTGCCCCAGGGGA
 M1PCSK9 target site in human *PCSK9* Exon 7

ARCUS Example: PCSK9

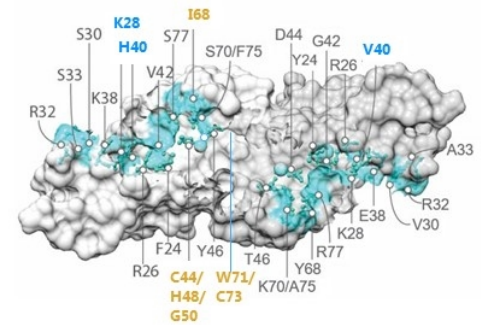
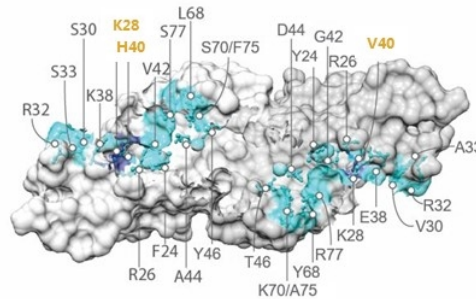
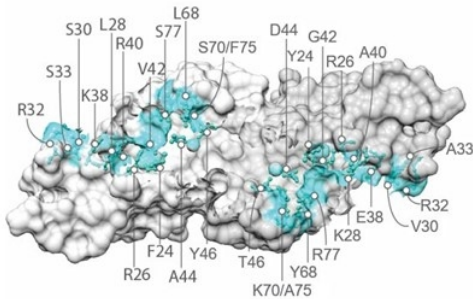


As reported in Wang, *et al* (2018, *Nat. Biotech* **36**:717-725) an ARCUS nuclease was developed to knockout the human/non-human primate *PCSK9* gene. Three generations of the nuclease were produced and tested in non-human primates. Each generation had amino acid substitutions aimed at improving upon the specificity of the previous generation.

M1PCSK9
(generation 1)

M2PCSK9
(generation 2)

M3PCSK9
(generation 3)



TGGACCTCTTTGCCCCAGGGGA
target site in human *PCSK9*

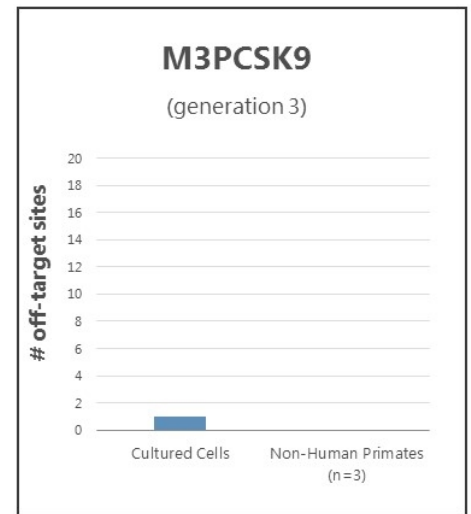
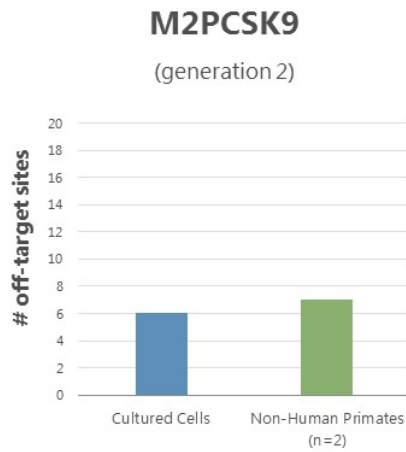
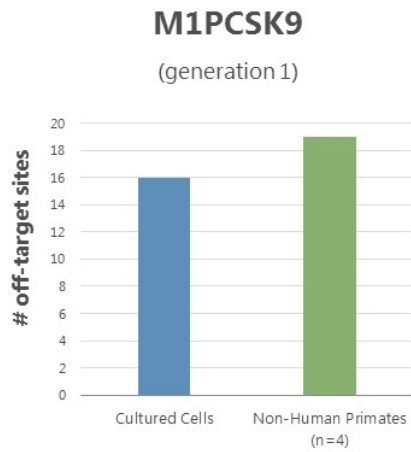
TGG**A**CCTCTTTGCCCCAG**G**GGGA
↑ ↑
specificity improved at these positions

TGGACCT**CTTT**GCCCCAGGGGA
↑ ↑ ↑ ↑
specificity improved at these positions

ARCUS Example: PCSK9



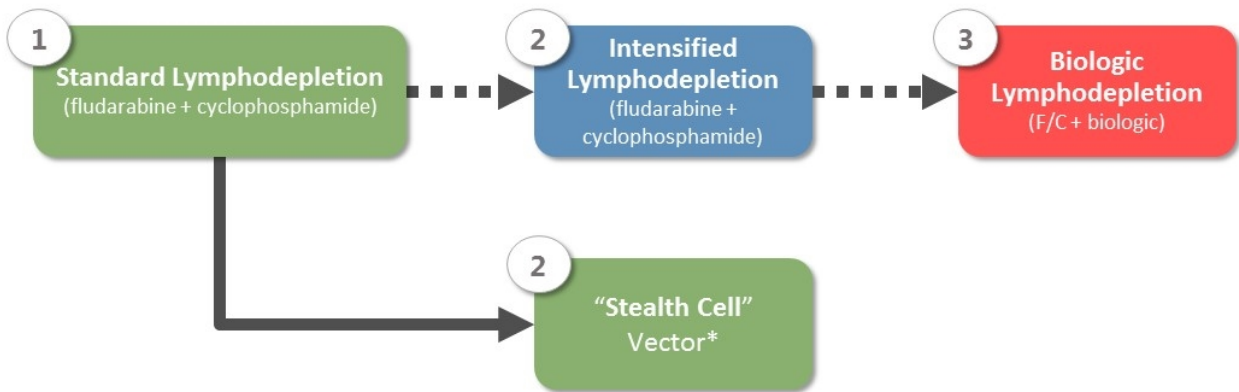
Three generations of a PCSK9 ARCUS nuclease were assayed for off-target editing in human cells and NHP liver biopsies using an advanced method called "Oligo Capture" followed by deep sequencing. It was found that each successive generation had significant reductions in off-target editing. We were unable to detect **any off target editing** in liver biopsies from NHPs transduced with the generation 3 nuclease.



Roadmap for CAR T Clinical Development



- Maximization of naïve and central memory T cells allows for initial exploration with standard flu/cy LD
- Clinical data will direct an expanded LD or the addition of a biologic *only if needed*
- The **“Stealth Cell”** vector will be explored upon completion of initial clinical studies

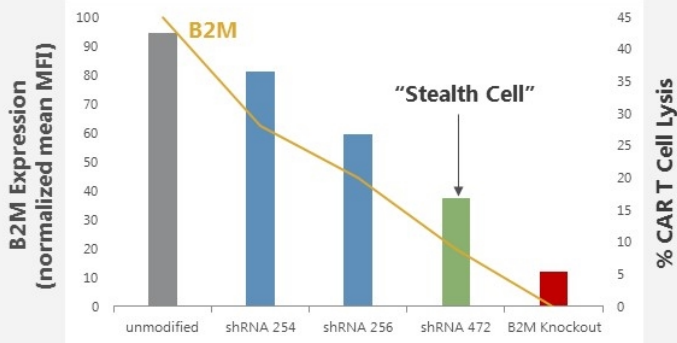
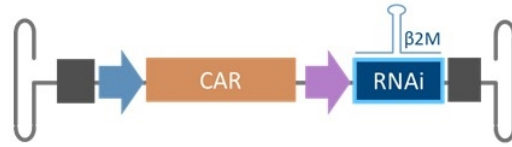


*Novel cell masking strategy that does not require additional editing

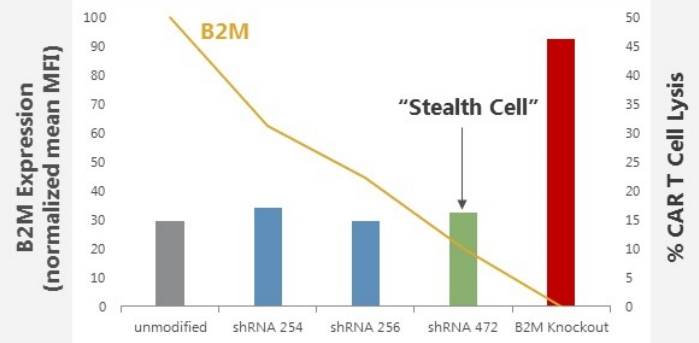
"Stealth Cell" β 2M Knockdown to Extend Cell Persistence



- Completely eliminating MHC-I (knocking out β 2M) results in rapid cell killing by NK cells
- Reducing surface expression of MHC-I to ~10% of wild-type levels reduces cell lysis by T cells or NK



Rejection by T Cells



Rejection by NK Cells

*B2M reduction reduces expression of MHC class 1 on cell surface. MHC-1 mismatch identifies the cell as non-self and triggers rejection by patient immune cells

