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): June 4, 2020

Cue Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38327**	**47-3324577**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

21 Erie St., Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (617) 949-2680

(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 (see General Instruction A.2. below):

☐ 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 Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**CUE**	**The Nasdaq Stock Market LLC**

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

On June 4, 2020, Cue Biopharma Inc. presented at the Jefferies Virtual Healthcare Conference. The materials for this presentation are furnished as Exhibit 99 to this Current Report on Form 8-K.

The information contained in this Item 7.01 of this report is being furnished and 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. The information in this Item 7.01 shall not be deemed incorporated by reference in any filing 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

Exhibit No.	Description
99	*Cue Biopharma Corporate Presentation*, Jefferies Virtual Healthcare Conference, June 4, 2020, furnished herewith

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 thereunto duly authorized.

Cue Biopharma, Inc.

Date: June 5, 2020

By: /s/ Daniel R. Passeri
Name: Daniel R. Passeri
Title: Chief Executive Officer

Corporate Presentation

Immune Responses, On Cue™

Nasdaq: CUE

Forward-Looking Statements

This presentation has been prepared by Cue Biopharma, Inc. ("we," "us," "our," "Cue" or the "Company") and is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities, nor shall there be any sale of any 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. The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this presentation unless stated otherwise, and neither this presentation, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This presentation contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely" or other comparable terms. All statements other than statements of historical facts included in this press release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding anticipated results of our drug development efforts, including study results, our expectations regarding the timing of milestone events, regulatory developments and expected future operating results. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, our limited operating history, limited cash and a history of losses; our ability to achieve profitability; our ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for our product candidates and the breadth of any approved indication; negative or inconclusive results from our clinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; our reliance on third parties to conduct our clinical trails as well as licensors, collaborations and strategic alliances; our ability to obtain adequate financing to fund our business operations in the future; uncertainties associated with COVID-19 or coronavirus, including its possible effects on our operations and clinical trial; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and any subsequently filed Quarterly Report(s) on Form 10-Q. Any forward-looking statement made by us in this presentation is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Corporate Highlights

Disruptive Platform for T Cell Modulation *In Vivo*

- Distinct mechanism of action for selective modulation of disease-relevant T cells directly in a patient's body
- Modular therapeutic frameworks targeting cancer and autoimmune disease
- Industry-standard manufacturing, without need for ex vivo manipulation

Focused Execution Against Platform Validation

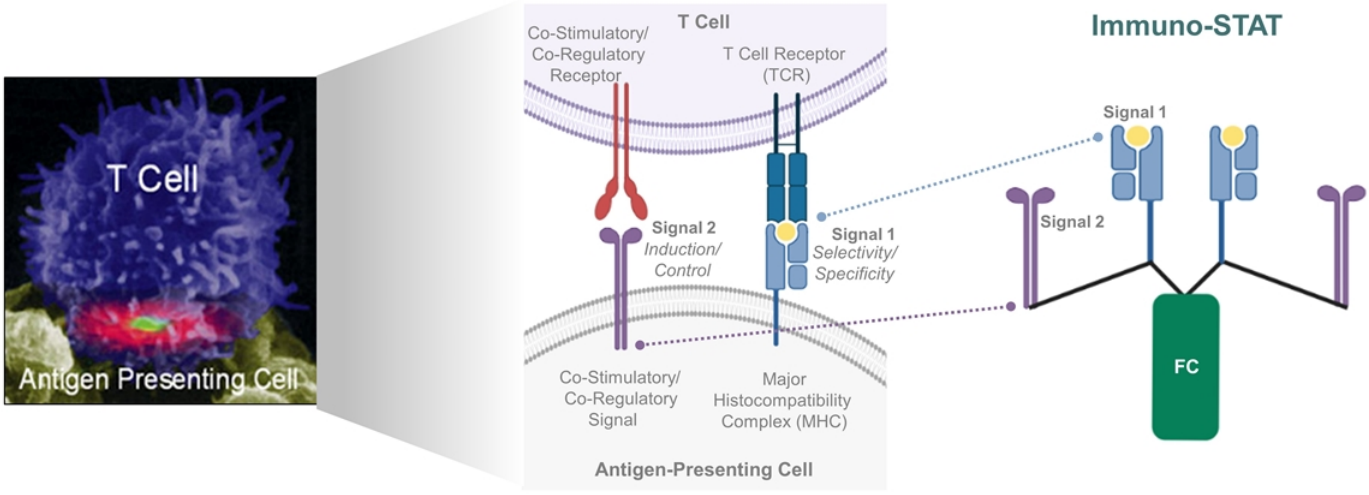
- CUE-101 in Phase 1 for R/M HPV+ head and neck cancer with initial data in 1H 2020
- Platform modularity demonstrated through CUE-102 for WT1-associated cancers as well as targeting KRAS with Immuno-STAT framework
- Neo-STAT capability enhances R&D efficiency and expands the landscape of clinical utility

Strategic Partnerships to Accelerate Expansion

- LG Chem collaboration to expand IL-2 based CUE-100 series in immuno-oncology
- Merck collaboration to establish proof of mechanism for Immuno-STAT platform in autoimmune disease

Strong financial position supports key readouts from ongoing CUE-101 clinical study and further expansion of Immuno-STAT platform

Emulating Nature's Cues to Selectively Modulate T Cells



Rationally engineered Immuno-STAT biologics selectively target and modulate the activity of disease-relevant T cells

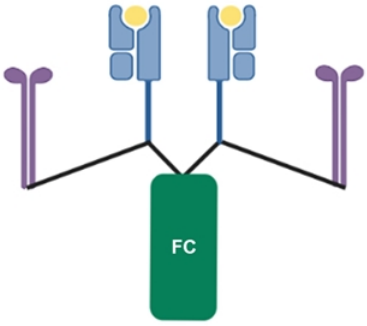
Immuno-STAT Modularity

Peptide

Peptide epitopes to target different diseases

MHC

Different HLA alleles to address global patient populations



Co-stim/Co-reg

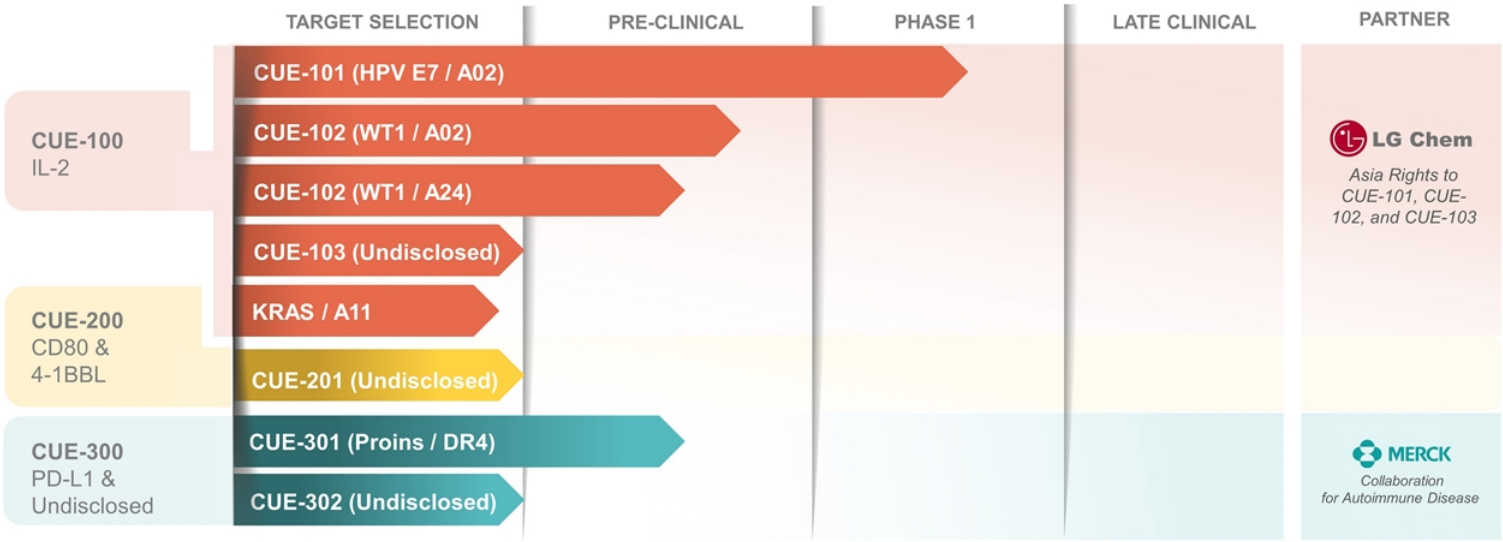
Distinct biological signals, including cytokines; cell-surface receptors; and/or other targeting modalities (e.g., scFv, etc.)

Fc Backbone

Fc engineering to dial in or out biological and effector functions

Combinatorial diversity presents potential to generate therapeutic molecules for a broad set of diseases and patient populations

Pipeline



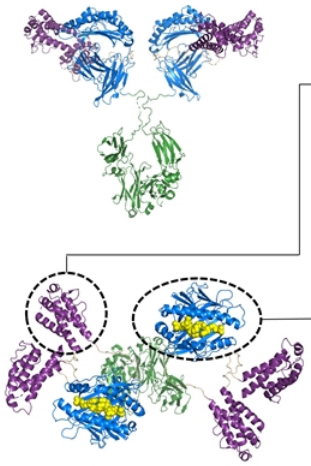
CUE BIOPHARMA

CUE-100 Series: Exploiting IL-2 via Rational Protein Design

CUE-100 Series

Side View

Top View



Modified IL-2

Tumor-Peptide Loaded HLA

Immune Signaling Components

Affinity modified IL-2:

- **Minimize Treg activation**
- **Selective activity on tumor-specific T cells, while sparing activation of irrelevant T cells**
- **Differentiated MoA over "not-alpha" IL-2s**

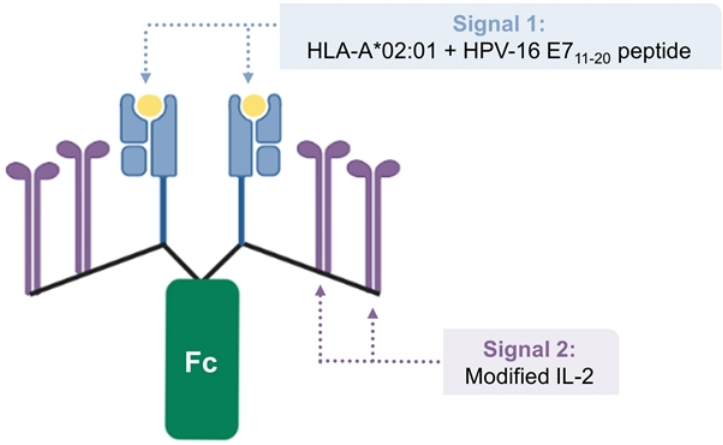
"Signal 1" engagement of T cells via TCR:

- **Selective delivery of IL-2 to tumor-specific T cells**
- **Enables priming and expansion from naïve or pre-existing T cell repertoire**

Therapeutic framework is not dependent on barriers of antigen processing & presentation, and is designed to avoid systemic immune activation

CUE-101: Lead Clinical Candidate for HPV-Driven Malignancies

CUE-101 Immuno-STAT Design



Clinical Rationale

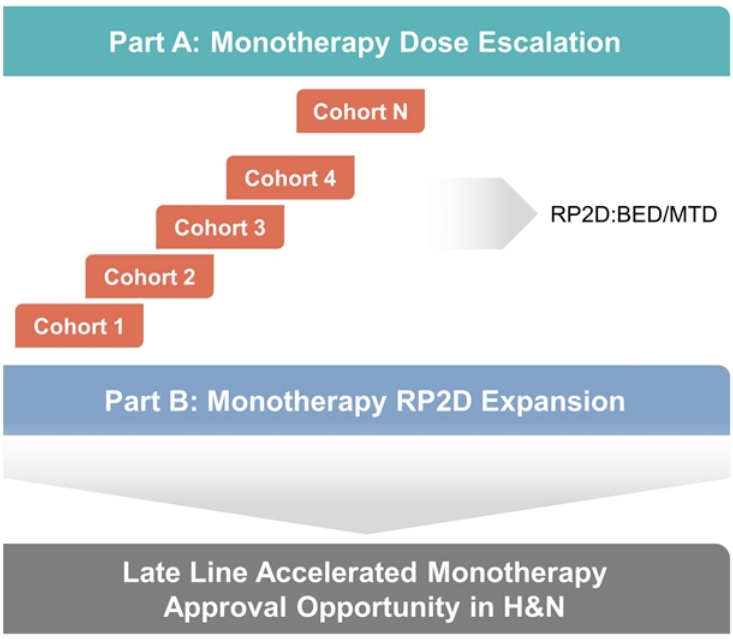
- CUE-101 is designed to selectively prime and expand HPV-specific T cells in vivo
- HPV is recognized as a growing driver of head and neck cancer and is now responsible for over 70% of oropharyngeal cancers in the US and EU
- Despite treatment with current standards of care, more than 50% of patients with advanced disease will experience recurrence with significant quality of life impacts
- The CUE-101 clinical development strategy builds upon robust translational preclinical data and patient stratification

CUE-101: Phase I Clinical Development Network

- **Emory Winship Cancer Institute**: Nabil Saba
- **Karmanos Cancer Institute**: Elizabeth Heath and Ammar Sukari
- **MD Anderson Cancer Center**: Bonnie Glisson
- **MGH/Harvard and Dana Farber Cancer Institute**: Sara Pai and Lori Wirth
- **Moffitt Cancer Center**: Christine Chung
- **Memorial Sloan Kettering Cancer Center**: Lara Dunn
- **Stanford Cancer Center:** A. Dimitrios Colevas
- **University of Arizona Center:** Julie Bauman
- **University of Michigan Rogel Cancer Center:** Frank Worden
- **University of Washington Fred Hutch Cancer Center**: Cristina Rodriguez
- **Vanderbilt-Ingram Cancer Center**: Jill Gilbert and Mike Gibson
- **Washington University Siteman Cancer Center**: Doug Adkins
- **Yale Cancer Center**: Barbara Burtness

Cue has engaged a network of nationally recognized clinical investigators and 13 Phase I sites are now open

CUE-101: Ongoing First-In-Human Study



- **Eligibility**
  - Part A & B: HPV+ H&N Cancer, R/M 2L+
- **Design** (CUE-101 Q3W)
  - Part A: Dose Escalation (3+3 Pts)
  - Part A: PD & Activity Expansion (Up to 9 Pts)
  - Part B: Dose Expansion (10-20 Pts at RP2D)
- **Objectives**
  - Primary: Safety and Tolerability
  - Secondary: PK/PD, Anti-Tumor Activity
- **Biomarkers** (Pre/Post CUE-101 Dose)
  - HPV E7-specific CD8+ T cell counts
  - HPV E7-specific CD8+ T cell functionality
  - Immunophenotyping, cytokine release, and TCR sequencing
- **NCT03978689**

CUE-101: Part A Dose Cohorts

Cohort	CUE-101 Dose	CUE-101 Dose Relative to Approved Proleukin Dose (0.037 mg/kg)	CUE-101 IL-2* Content (nmol/kg)	CUE-101 IL-2 Content Relative to Approved Proleukin Dose (2.4 nmol/kg)
Cohort 1 ✓	0.06 mg/kg (starting dose)	~ 1.6x	1.1	~ 0.46x
Cohort 2 ✓	0.18 mg/kg	~ 4.9x	3.4	~ 1.4x
Cohort 3 ✓	0.54 mg/kg	~ 14.6x	10.3	~ 4.3x
Cohort 4 ✓	1 mg/kg	~ 27.0x	19.1	~ 8.0x
Cohort 5	2 mg/kg	~ 54.0x	38.2	~ 16.0x
Cohort 6	4 mg/kg	~ 108.0x	76.4	~ 32.0x
Cohort 7	8 mg/kg	~ 216.0x	152.9	~ 64.0x

Modified IL-2 to abrogate binding to IL-2R alpha and reduce binding affinity to IL-2R beta

CUE-101: Safety & Activity Observations from Cohorts 1 – 3

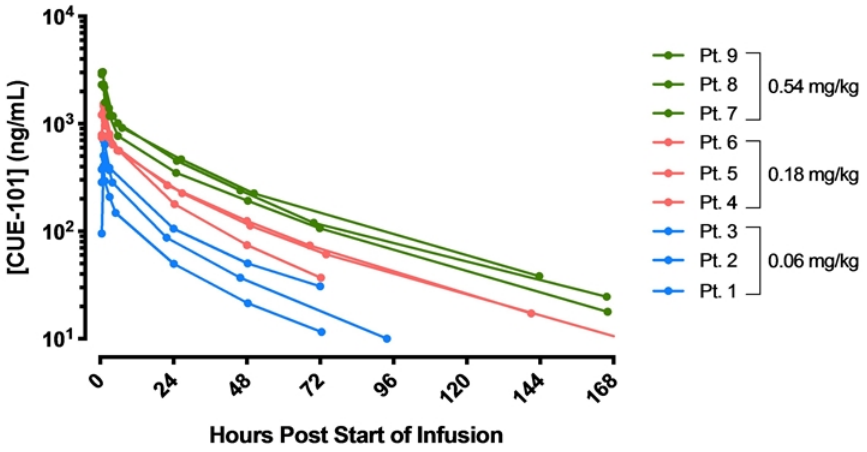
Safety

- Multiple patients receiving multiple injections indicates favorable safety and tolerability profile
- No drug-related DLTs in cohorts 1-3
- Cohort 4 still being analyzed in the safety review period

Activity

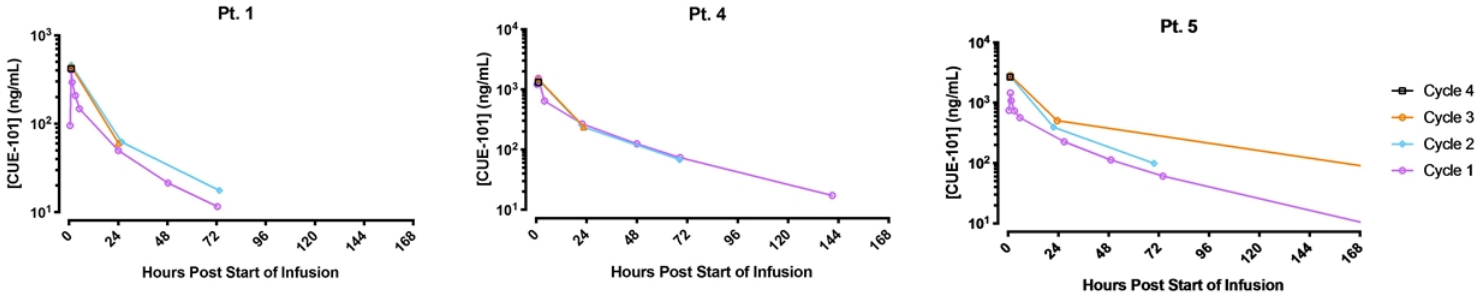
- PK data from the first three cohorts indicates:
  - *Exposure in-line with preclinical projections*
  - *Dose-proportional drug exposure*
  - *Comparable exposures observed upon repeated administration*
- PD data indicates early signals of selective T cell expansion
- Preliminary evidence that CUE-101 is clinically active

CUE-101: Exposures from Cohorts 1 - 3



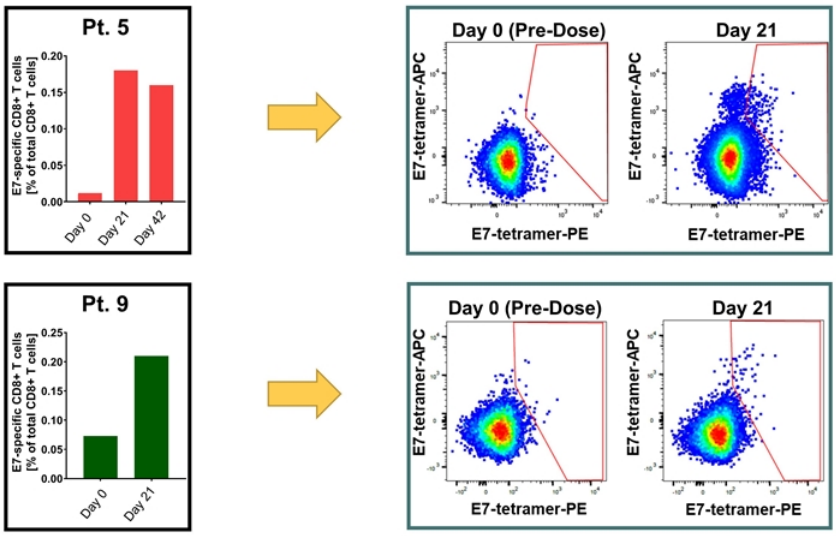
CUE-101 exhibits dose-proportional increases in exposure in line with projections from non-clinical studies

CUE-101: Exposure is Consistent Upon Repeated Administration



Patients exhibit comparable exposures upon repeated administration of CUE-101

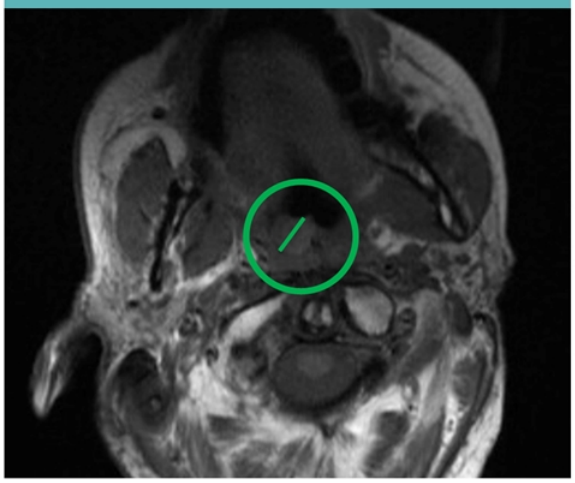
CUE-101: Expansion of E7-specific T Cells



Preliminary evidence of expansion of E7-specific T cells observed in several patients

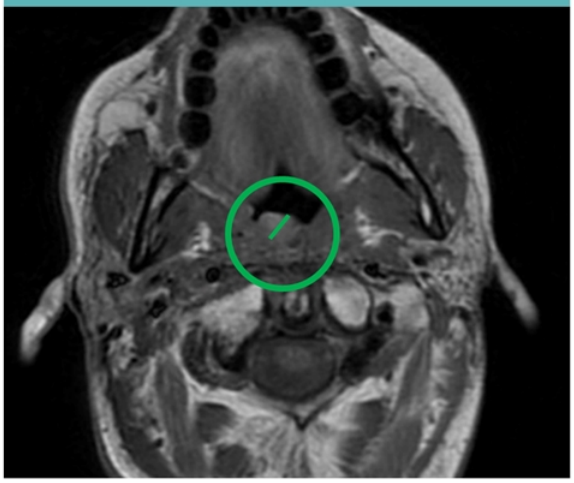
CUE-101: Cohort 2 Patient Case Study

Day 0: Baseline Tumor



Scan at day 42 (after 2 cycles of CUE-101) indicates reduction of >1cm target lesion

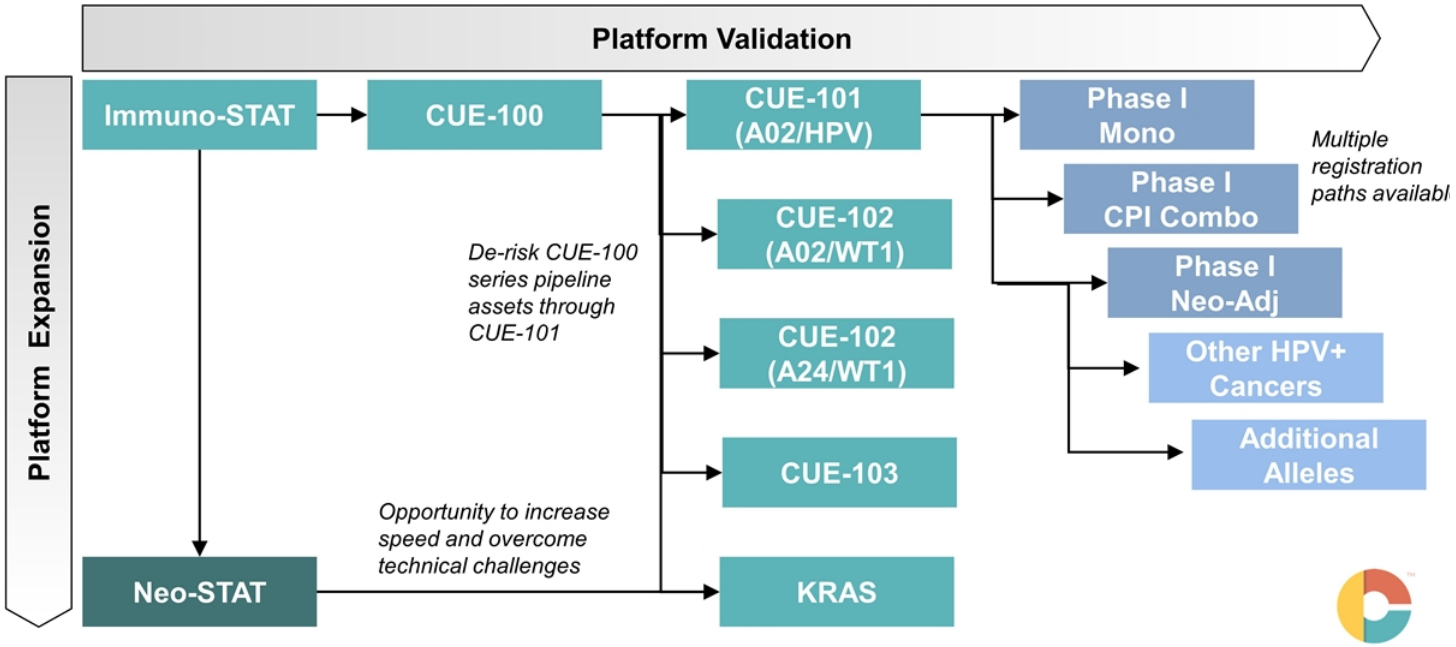
Day 42: 2 Cycles of CUE-101 Monotherapy



At day 84 the repeat scan showed sustained regression of the target lesion, and at that point the patient was confirmed as stable disease

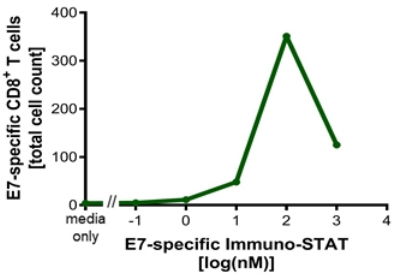
Patient had received multiple lines of therapy, including checkpoint inhibition

IO Growth Strategy

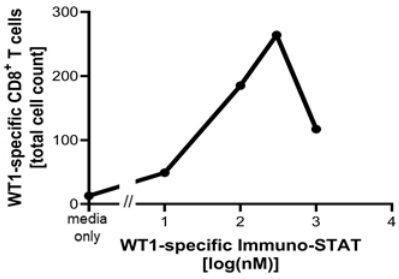


Immuno-STATs Demonstrate Selective T Cell Expansion

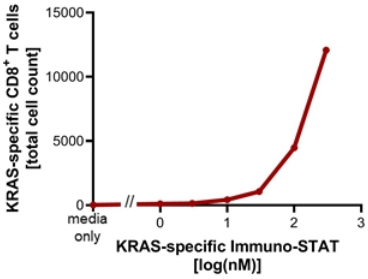
HPV (CUE-101)



WT1 (CUE-102)



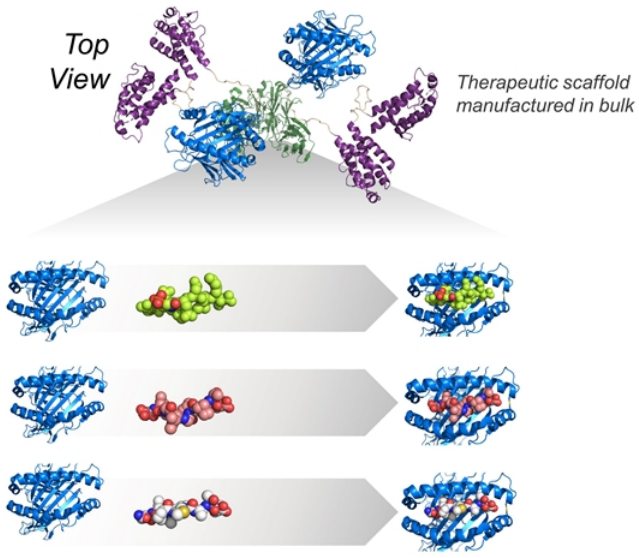
KRAS IST



Emerging data from CUE-102 (WT1) recently presented at NYAS Frontiers in Cancer Immunotherapy

Neo-STAT: Next-gen Evolution of the Immuno-STAT Framework

CUE-100 Neo-STAT

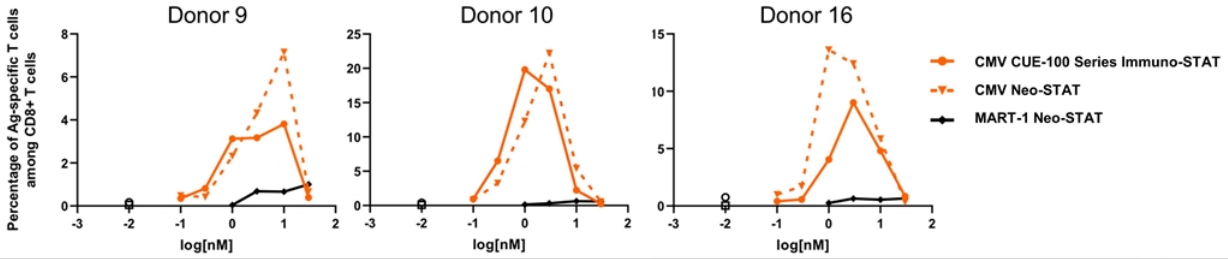


Therapeutic scaffold receptive for chemical conjugation of peptides, that potentially:

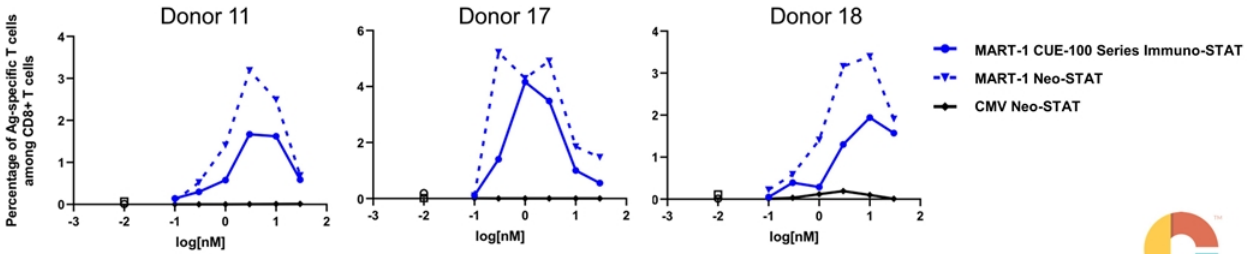
- **Increases R&D efficiency** and reduces cost of the generation of clinical grade material on the CUE-100 framework
- **Enables targeting of multiple tumor antigens** including post-translationally modified peptides and neo-antigens for personalized therapy

Primary Human T Cell Expansion: Neo-STAT = Immuno-STAT

CMV Responsive Donors



MART-1 Responsive Donors



Corporate Development Strategy

Validate

- Continue to generate clinical metrics for CUE-101 demonstrating safety, tolerability and clinical activity to de-risk CUE-101, CUE-100 series, as well as Immuno-STAT framework
- Establish therapeutic synergy with checkpoint inhibition through clinical collaboration with Merck to assess CUE-101 in combination with Keytruda in the front-line setting for HPV+ H&N Cancer

Expand

- Pursue additional targets (i.e., WT1, KRAS) and alleles (i.e., A11, A24) with CUE-100 series and establish preclinical datasets demonstrating selective T cell expansion and activation
- Expand Immuno-STAT applications in autoimmune diseases via Merck collaboration focused on two indications

Accelerate

- Provide proof of concept data supporting the biological activity of molecules generated via the Neo-STAT platform, and comparability to Immuno-STAT format
- Deploy Neo-STAT to enhance productivities, efficiencies, and provide greater flexibility with the IL-2-based CUE-100 series

Key 2020 Milestones

1. PK/PD results from the Phase 1 CUE-101 clinical trial in **2Q20**
2. Clinical responses from the Phase 1 CUE-101 clinical trial via RECIST criteria in **2H20**
3. Initiate CUE-101 combination trial with Keytruda in 1L SCCHN in **2H20**
4. Initiate and extend IND-enabling activities for CUE-102 in **2H20**
5. Select target for CUE-103 in **3Q20**
6. Demonstrate Neo-STAT manufacturability and efficiencies in **2H20**
7. Identify potential clinical candidates in collaboration with Merck in **2H20**

Key objectives met in 2019 and early 2020 have set the stage for data flow from multiple programs in the remainder of 2020