

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, DC 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 3, 2019**

**Oncternal Therapeutics, Inc.**  
(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-50549**  
(Commission File  
Number)

**62-1715807**  
(IRS Employer Identification No.)

**12230 El Camino Real  
Suite 300  
San Diego, California**  
(Address of Principal Executive Offices)

**92130**  
(Zip Code)

Registrant's telephone number, including area code: **(858) 434-1113**

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

- Written communication 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 | ONCT              | 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.

Oncternal Therapeutics, Inc. (“Oncternal” or the “Company”), has posted an updated corporate slide presentation to the Company’s website, [www.oncternal.com](http://www.oncternal.com). A copy of the updated presentation is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01. Oncternal plans to use its website to disseminate future updates to its corporate presentations and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information set forth in this Item 7.01 is being furnished pursuant to Item 7.01 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, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

By filing this Current Report on Form 8-K and furnishing the information in this Item 7.01, Oncternal makes no admission as to the materiality of Item 7.01 in this report or the presentation available Oncternal’s website. The information contained in the presentation is summary information that is intended to be considered in the context of Oncternal’s filings with the Securities and Exchange Commission (the “SEC”) and other public announcements that Oncternal makes, by press release or otherwise, from time to time. Oncternal undertakes no duty or obligation to publicly update or revise the information contained in this Item, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, by updating its website or through other public disclosure.

**Item 8.01.****Other Events.**

On October 3, 2019, the Company announced that it has opened for enrollment a Phase 1b expansion cohort of its Phase 1/2 clinical trial of cirmtuzumab, a Receptor tyrosine kinase-like Orphan Receptor 1 (“ROR1”) targeted monoclonal antibody, combined with ibrutinib, in patients with mantle cell lymphoma (“MCL”). The decision to open an expansion cohort in MCL of the ongoing Phase 1/2 CIRLL (Cirmtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma) clinical trial was based on favorable interim results from the dose-finding cohort of the trial, including that the combination was well-tolerated and that complete responses were observed in two heavily pre-treated patients who had received and failed multiple chemotherapy regimens and an autologous transplant, as well as either an allotransplant or chimeric antigen receptor T cell (“CAR-T”) therapy, prior to participating in this clinical trial.

In June 2019, the Company presented interim data at the American Society of Clinical Oncology (“ASCO”) annual meeting, including the preliminary results from the first six patients with MCL treated in the CIRLL clinical trial. One patient with MCL, who had relapsed following an allogeneic stem cell transplant, experienced a confirmed complete response (“CR”) after 3 months of cirmtuzumab plus ibrutinib treatment, including complete resolution of a large mediastinal mass. This CR appears to be sustained and has been confirmed to be ongoing after completing 12 months of cirmtuzumab plus ibrutinib treatment. Following ASCO, a second confirmed CR occurred in a patient who had progressive disease after failing several different chemotherapy regimens, autologous transplant and CAR-T therapy. Additional data from this clinical trial will be presented at a future medical conference. The CIRLL clinical trial is supported by a grant from the California Institute for Regenerative Medicine (CIRM) and is being conducted in collaboration with the University of California San Diego (UCSD).

**Cautionary Note Regarding Forward-Looking Statements**

The Company cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negatives of these terms or other similar expressions. These statements are based on the Company’s current beliefs and expectations. Forward looking statements include statements regarding: the Company’s plans to present additional data from its ongoing Phase 1/2 clinical trial of cirmtuzumab; the expectation that the Company will be able to enroll patients into the Phase 1b expansion cohort; and the Company’s belief that favorable outcomes from the ongoing Phase 1 portion of the clinical trial support opening the Phase 1b portion. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in the Company’s business, including, without limitation: uncertainties associated with the clinical development and process for obtaining regulatory approval of cirmtuzumab and the Company’s other product candidates, including potential delays in the commencement, enrollment and completion of clinical

trials; the Company's dependence on the success of cirmtuzumab and its other product development programs; the risk that interim results of a clinical trial do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as cirmtuzumab and the Company's other product candidates; the Company's limited operating history and that fact that it has incurred significant losses, and expects to continue to incur significant losses for the foreseeable future; risks related to the inability of the Company to obtain sufficient additional capital to continue to advance the development of cirmtuzumab and its other product candidates; and other risks described in the Company's prior reports as well as in public periodic filings with the U.S. Securities & Exchange Commission. All forward-looking statements in this report are current only as of the date hereof and, except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

**Item 9.01. Financial Statements and Exhibits.**

*(d) Exhibits.*

| <u>Exhibit<br/>No.</u> | <u>Description</u>   |
|------------------------|--|
| 99.1                   | <a href="#">Corporate Slide Presentation as of October 3, 2019</a> |

**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.

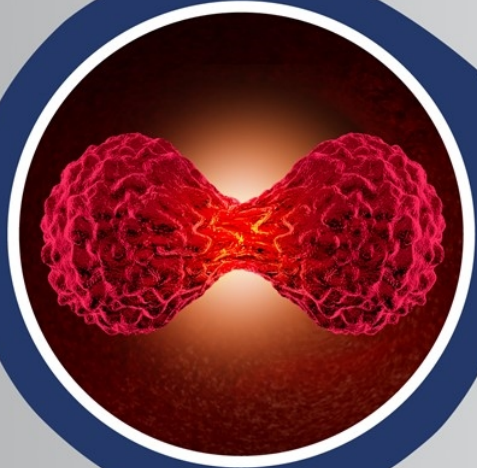
**Oncternal Therapeutics, Inc.**

Date: October 3, 2019

By: /s/ James B. Breitmeyer

Name: James B. Breitmeyer, M.D., Ph.D.

Title: President and Chief Executive Officer



**TARGETING  
CANCER**

**New Science. New Cancer Therapies. New Hope.**

Corporate Presentation, October 2019

## FORWARD LOOKING STATEMENTS

This presentation includes forward-looking statements (including within the meaning of §21E of the U.S. Securities Exchange Act of 1934, as amended, and § 27A of the U.S. Securities Act of 1933, as amended). Forward looking statements, which generally include statements regarding goals, plans, intentions and expectations, are based upon current beliefs and assumptions of Oncternal Therapeutics, Inc. (“Oncternal,” or the “Company”) and are not guarantees of future performance. Statements that are not historical facts are forward-looking statements, and include statements regarding the expected timing for achieving key milestones, including completing and announcing results of clinical trials of the Company’s product candidates, and the anticipated market potential, duration of patent coverage, and ability to obtain and maintain favorable regulatory designations for the Company’s product candidates and preclinical programs.

All forward looking statements are subject to risks and uncertainties, which include, but are not limited to: risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; uncertainties associated with the clinical development and process for obtaining regulatory approval of Oncternal’s product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that results seen in a case study of one patient may not predict the results seen in other patients in the clinical trial, including the possibility that there may not be additional complete or sustained responses from any other patients in the study; the risk that interim results of a clinical trial do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing Oncternal’s product candidates; potential changes in the regulatory environment for developing and obtaining approval of product candidates and preclinical programs, which may result in delays or termination of development of such product candidates or preclinical programs, or unexpected costs in obtaining regulatory approvals; and the risk that Oncternal may be unable to obtain sufficient additional capital to continue to advance the development of its product candidates and preclinical programs.

Except as required by applicable law, Oncternal undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements in this presentation are current only as of the date on which the statements were made. Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the SEC by Oncternal, including its most recent Annual Report on Form 10-K, Form 10-K/A, Quarterly Report on Form 10-Q, and Current Reports on Form 8-K filed with the SEC. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Cirmtuzumab, TK216 and Oncternal’s CAR-T targeting ROR-1 are investigational product candidates or preclinical programs that have not been approved by the U.S. Food and Drug Administration for any indication.

## CIRMTUZUMAB - ROR1 mAb IN RANDOMIZED PHASE 2

- Encouraging early efficacy and safety with ibrutinib in CLL
- Phase 1b in HER2 negative, metastatic breast cancer
- Potential in multiple ROR1 expressing tumors (TNBC, NSCLC)

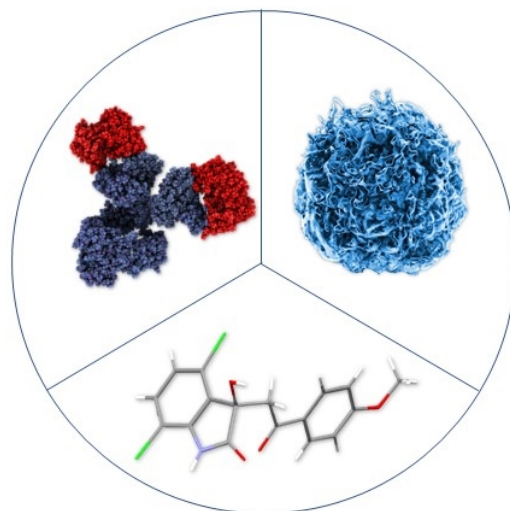
## TK216 - TARGETED ETS INHIBITOR IN PHASE 1

- Objective response in patient with metastatic Ewing sarcoma
- Potential for targeting multiple ETS-driven tumors (AML, prostate)

## MULTIPLE CLINICAL DATA CATALYSTS

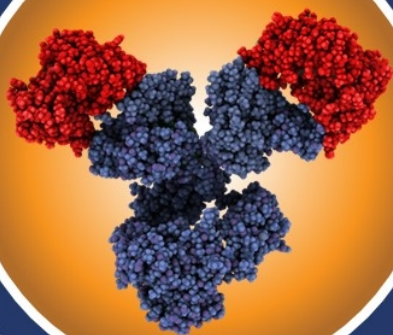
- Clinical data updates expected over next three quarters
- CAR-T targeting ROR1 expected to reach clinic in 2020

## EXPERIENCED MANAGEMENT AND FOUNDERS



| Product Candidate  | Indication                         | Preclinical | Phase 1 | Phase 2 | Phase 3   | Approach   |
|--------------------|------------------------------------|-------------|---------|---------|---|--|
| <b>Cirmtuzumab</b> | Chronic Lymphocytic Leukemia (CLL) | ▶           |         |         |   | <br><i>ROR1 mAb</i> |
|                    | Mantle Cell Lymphoma (MCL)         | ▶           |         |         |   |  |
|                    | Breast Cancer                      | ▶           |         |         |   |  |
| <b>TK216</b>       | Ewing Sarcoma                      | ▶           |         |         | <br><i>ETS oncoprotein inhibitor</i> |  |
|                    | Acute Myeloid Lymphoma (AML)       | ▶           |         |         |   |  |
|                    | Prostate Cancer                    | ▶           |         |         |   |  |
| <b>ROR1 CAR-T</b>  | Heme Cancers                       | ▶           |         |         | <br><i>CAR-T targeting ROR1</i>      |  |
|                    | Solid Tumors                       | ▶           |         |         |   |  |





## CIRMTUZUMAB

ROR1 monoclonal antibody

## DEVELOPMENT STATUS

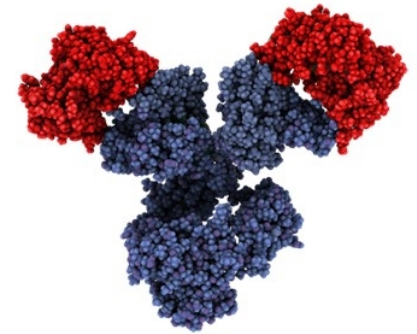
- Enrolling randomized Phase 2 in CLL in combination with ibrutinib
  - Phase 1 interim ORR 91.7% with CRs and encouraging safety profile
- Phase 1b trial ongoing in HER2<sup>neg</sup> breast cancer
- CRs in ongoing Phase 1 in mantle cell lymphoma with ibrutinib

## MECHANISM OF ACTION

- High-affinity humanized ROR1 monoclonal antibody
- Inhibits Wnt5a signaling
  - Decreased proliferation, invasion, metastasis, stemness

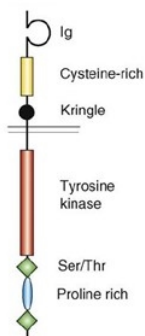
## OPPORTUNITY

- Potential in multiple hematologic and solid cancers
- Supported by ~\$16M non-dilutive CIRM grant
- Patent coverage through 2033



**ROR1 = Receptor tyrosine kinase-like Orphan Receptor 1**  
**CIRM = California Institute for Regenerative Medicine**

**Receptor  
Tyrosine  
Kinase-like  
Orphan  
Receptor 1**

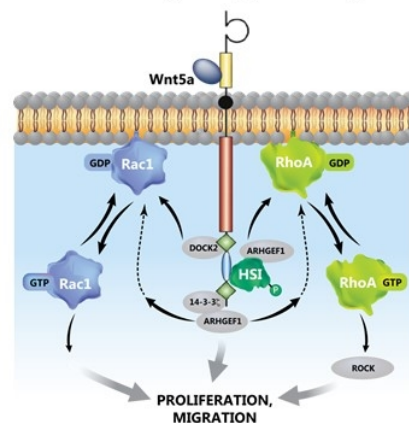


- ROR1, essential for fetal CNS development, is suppressed in adult life until reactivated as a survival factor by many different cancers
- Blocking ROR1 can overcome tumor resistance to therapy (e.g., EGFR inhibitors in lung adenocarcinoma models)

## ROR1 Expression on Tumors

|            |      |
|------------|------|
| MCL        | >95% |
| CLL        | 95%  |
| Uterus     | 96%  |
| Lymphoma   | 90%  |
| Prostate   | 90%  |
| Skin       | 89%  |
| Pancreatic | 83%  |
| Adrenal    | 83%  |
| Lung       | 77%  |
| Breast     | 75%  |
| Testicular | 73%  |
| Colon      | 57%  |
| Ovarian    | 54%  |
| Bladder    | 43%  |

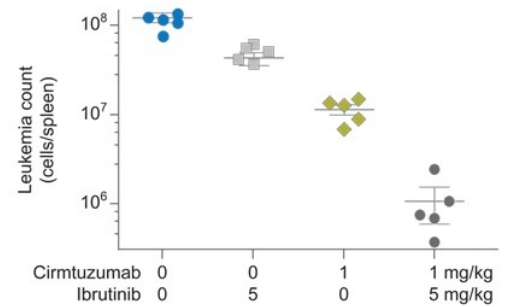
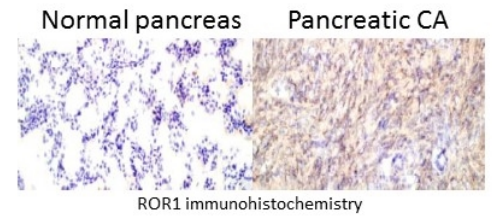
## ROR1 Signaling Pathway



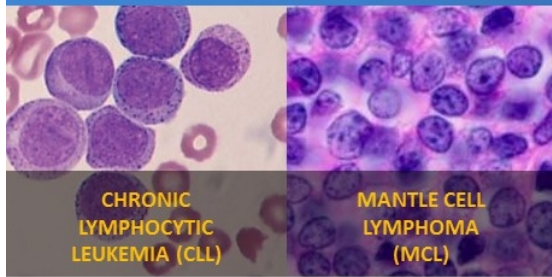
In hematological cancers ROR1 is activated by Wnt5a, leading to increased proliferation, invasion and is associated with shorter patient survival

Zhang & Kipps 2012, *AJP* 181:1903  
 Yu, J. et al *J Clin Invest.* 2015  
 Wang *OncLett* 2019

- High affinity humanized monoclonal antibody
  - Biophysical properties support monthly dosing
- Binds important inhibitory epitope
  - Issued patent claim covering epitope
- No binding to normal adult tissues in GLP tissue cross-reactivity studies
- Biologically active and well tolerated in completed single agent Phase 1 study
- Synergistic with ibrutinib in preclinical studies
  - ROR1-Wnt5a pathway not inhibited by ibrutinib
  - Rationale for lead indication and ongoing clinical trial
- Synergistic with paclitaxel in breast cancer preclinical studies



Choi 2015 *ClinLyLeuk*  
Choi 2018 *Cell Stem Cell*  
Yu 2017 *Leukemia*  
Zhang 2019 *PNAS*



**CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)**

**MANTLE CELL LYMPHOMA (MCL)**

**UNMET MEDICAL NEED:**

While ibrutinib alone is active, there is a low Complete Response rate in previously treated patients with CLL & MCL:

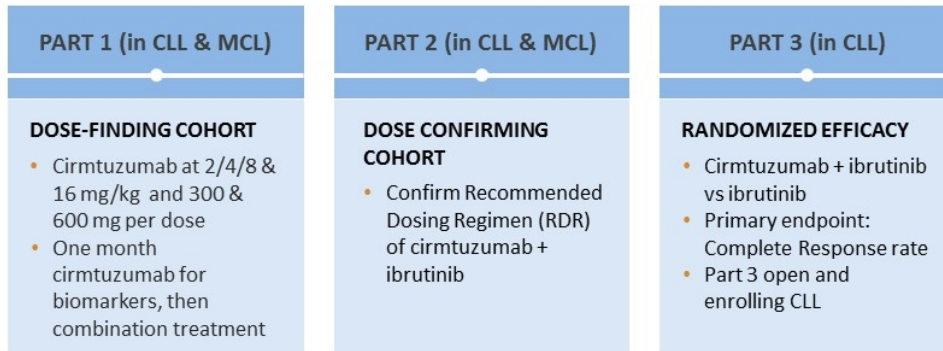
- CLL CR <10%<sup>1</sup>
- MCL CR ~25%<sup>2</sup>

1 Byrd JC (2014) NEJM, Byrd JC (2013) NEJM, Farooqui MZ (2015) Lancet Oncology, O'Brien S (2016) Lancet Oncol  
2 O'Brien (2018) JAMA Oncol

**VALUE PROPOSITION:**

**Improve complete response rate and durability with minimal added toxicity**

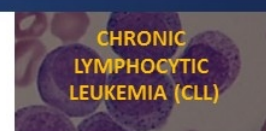
**STUDY DESIGN**



**CIRLL Study:**

- Cirtuzumab and Ibrutinib targeting ROR1 for Leukemia and Lymphoma
- Data will determine whether to seek regulatory approval through accelerated approval pathway

- Adverse events typical for ibrutinib alone
  - No dose limiting toxicities and no discontinuations due to cirmtuzumab
- Objective response rate of 91.7% for first 12 CLL patients treated in dose finding cohort<sup>1</sup>
  - 1 confirmed complete response
  - 2 clinical complete responses
  - Recommended dosing regimen (RDR) selected
    - 600 mg cirmtuzumab monthly + 420 mg ibrutinib daily
- Objective response rate of 100% at 12 weeks for first 9 CLL patients with evaluable disease treated with the RDR in dose confirming cohort<sup>2</sup>
- No progressive disease observed

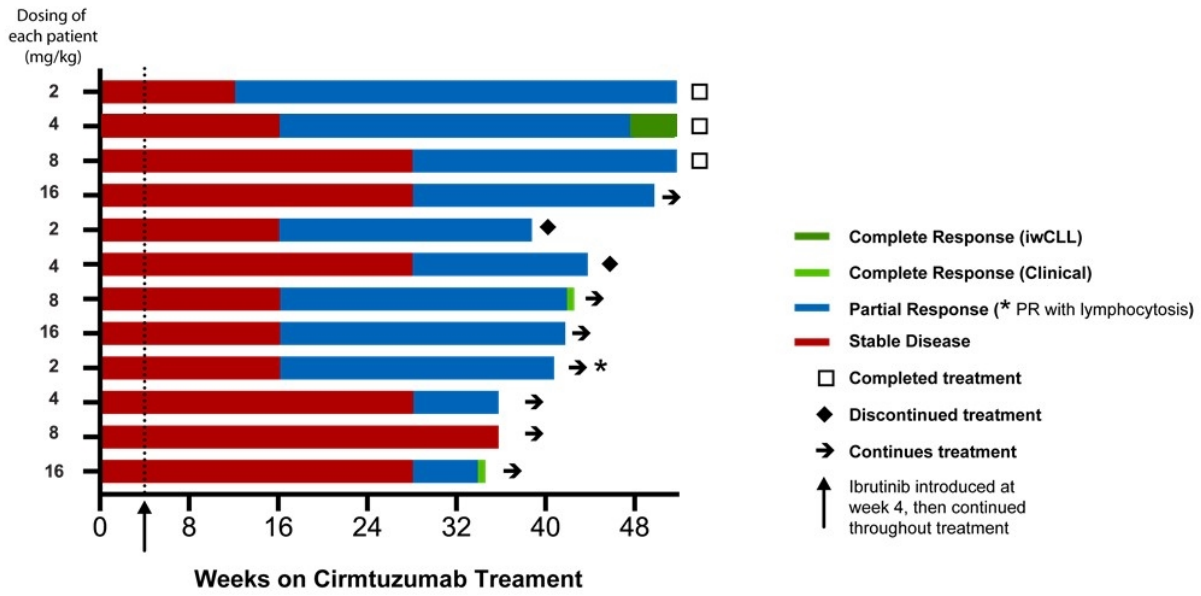


#### ASCO 2019 presentation of interim data

- CIRLL study
- 12 patients with CLL evaluable for efficacy
  - ages 57-86
  - median 2 prior therapies
- Cirmtuzumab dosing 2-16 mg/kg for 32-52 weeks
- Fixed dosing regimens of 300 mg & 600 mg per dose mAb tested
- RDR selected based on PK, PD and clinical data

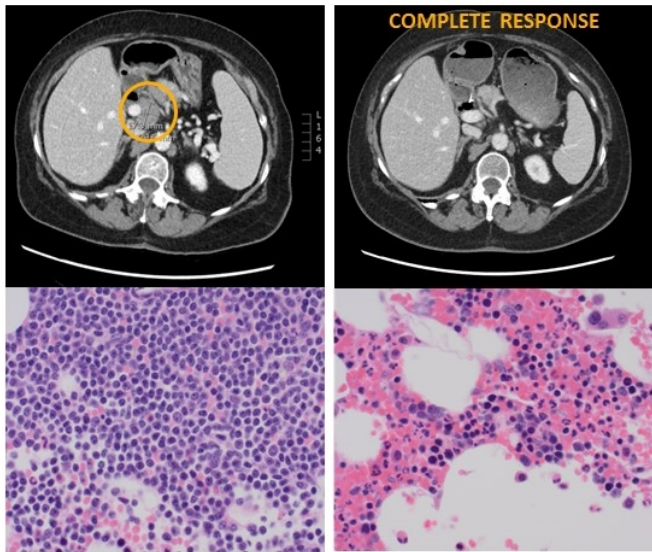
1 - Choi, 2019 ASCO  
2 - Company data

**Responses in the CLL cohort of 12 evaluable patients based on investigator assessments**



BASELINE

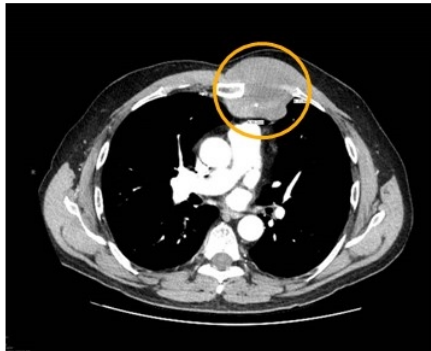
CIRMTUZUMAB + IBRUTINIB



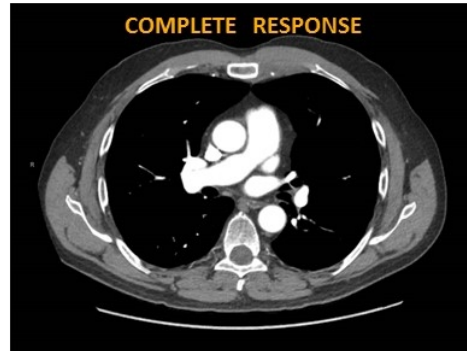
- CIRLL Study (Part 1)
- Patient characteristics
  - Negative prognostic feature: Del 11q
  - Prior treatment chlorambucil, obinutuzumab
- Complete Response details
  - Steady decrease in lymph node size to within normal limits by 9 months cirmtuzumab + ibrutinib
  - Steady decrease in absolute lymphocyte count to within normal limits by 10 months cirmtuzumab + ibrutinib
  - Bone marrow biopsy with no visible CLL by 10 months cirmtuzumab + ibrutinib



**BASELINE**



**CIRMTUZUMAB + IBRUTINIB**



- CIRLL Study (Part 1)
- Patient characteristics
  - Mantle cell lymphoma relapsed after high dose chemotherapy and stem cell transplant
  - 9x7 cm mediastinal/ chest wall lesion
- Complete Response details
  - Rapid clinical response with confirmed CR after 3 months cirmtuzumab + ibrutinib
  - CR confirmed and durable at 6, 9 and 12+ months cirmtuzumab + ibrutinib

**High Unmet Medical Need**

- 270,000 new breast cancer cases per year in the US
- 42,000 deaths per year
- Her2<sup>neg</sup> and triple negative variants harder to treat

**Scientific Rationale**

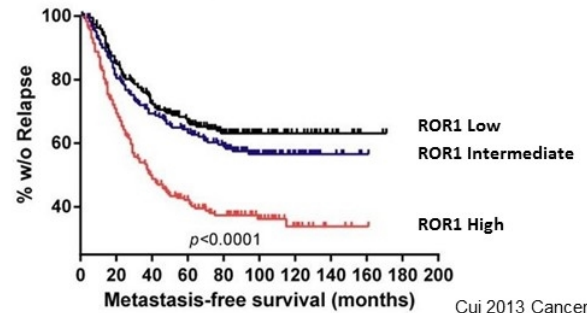
- Patients with ROR1+ breast cancer have a worse prognosis

**Strong Preclinical Data**

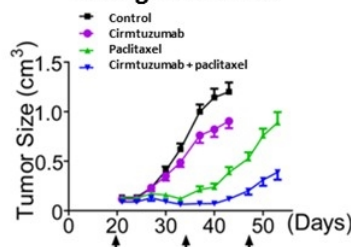
- Cirtuzumab + paclitaxel synergistic in preclinical models

ONCT Corporate Presentation 20191003

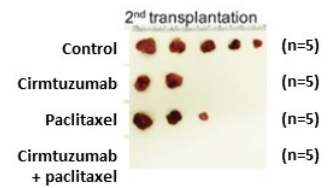
**ROR1 Expression is Associated with Higher Risk of Breast Cancer Relapse**

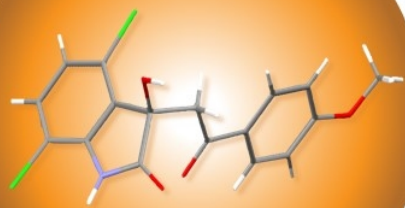


**Cirtuzumab Synergistic with Paclitaxel in TNBC PDX Xenograft Model**



**No Tumor Take After Cirtuzumab + Paclitaxel Treatment**





**TK216**  
Targeted ETS  
Oncoprotein Inhibitor

## DEVELOPMENT STATUS

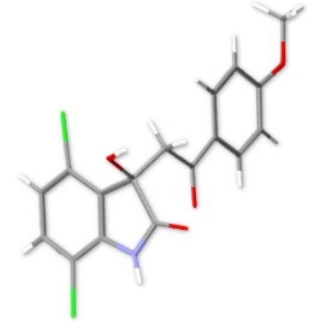
- Moving toward expansion cohort, Phase 1 clinical trial in Ewing sarcoma, rare pediatric bone tumor
- Fast Track Status and Orphan Drug designation with FDA

## MECHANISM OF ACTION

- Novel small molecule inhibitor of ETS family oncoproteins
- Epigenetic/transcriptome effect

## OPPORTUNITY

- Fast to market potential in Ewing sarcoma
  - Potentially Pediatric Voucher eligible
- Significant market potential in AML and prostate cancer
- Patent coverage through 2037



ETS = E26 Transformation-Specific  
oncogene family

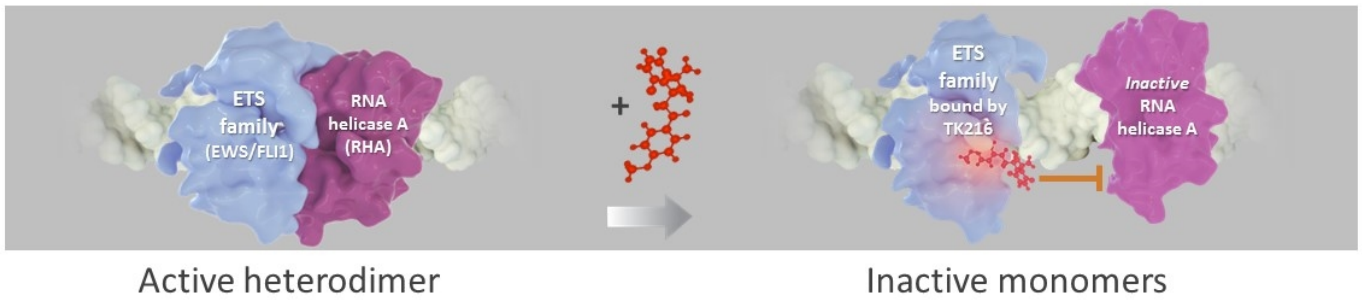
## ETS (E26 Transformation-Specific Oncogene) family proteins

- Critical transcription factors for embryonic development
- ETS oncogenes regulate many target genes implicated in cancer development and progression
- Dysregulation can occur through overexpression, gene fusion and modulation
- Abnormal, dysregulated ETS function can lead to increased proliferation, angiogenesis, invasion and metastasis

## ETS Overexpression or Fusion Proteins Incorporating ETS Family Member in Multiple Tumors:

|                               |     |
|-------------------------------|-----|
| Ewing sarcoma*                | 98% |
| Prostate cancer*              | 55% |
| Diffuse Large B Cell Lymphoma | 52% |
| Head & Neck cancer            | 33% |
| Acute Myeloid Leukemia*       | 30% |
| Breast cancer*                | 25% |
| Melanoma                      | 25% |
| Ovarian cancer                | 23% |
| Lung cancer                   | 21% |
| Glioblastoma multiforme       | 15% |

*Overexpression of FLI1, ERG, SPIB, ETV1, ETV4, ETV5, ETV6, ETS1, or ETS2  
cBioportal for Cancer Genomics, The Cancer Genome Atlas (TCGA), RNA seq data  
\* Fusion protein identified*

**TK216 Inhibits Interaction of ETS Fusion Protein EWS/FLI1 with RNA Helicase A**

In Ewing sarcoma, a key heterodimer forms the core of a transcriptome complex causing

- Activated oncogenes
- Inhibited tumor suppressors
- Abnormal RNA transcription
- Abnormal RNA splicing

TK216 was designed to disrupt the core heterodimer, resulting in

- Decreased oncogene expression
- Increased tumor suppressor function
- Improved transcription and splicing
- Apoptotic cell death

*Erkizan 2009 Nature Medicine  
Hong 2013 Oncotarget*



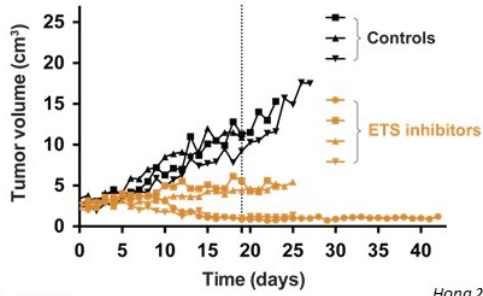
**HIGH UNMET NEED:**

- Second most common pediatric bone tumor
- No standard second line treatment
- 10-15% 5-year survival in recurrent disease
- 30% 5-year survival metastatic disease
- Top ten NCI Moonshot Program target

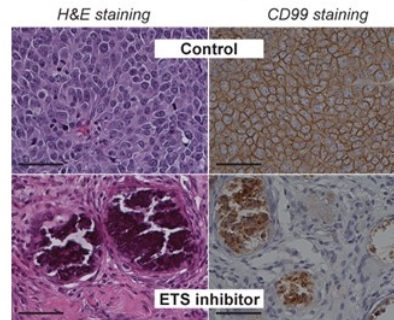
**VALUE PROPOSITION:**

- Demonstrate antitumor activity in relapsed, refractory Ewing sarcoma with acceptable toxicity profile
- Fast Track and Orphan designations
- Potentially Pediatric Voucher eligible

**Complete and partial responses of human Ewing sarcoma tumors in rat xenograft model**



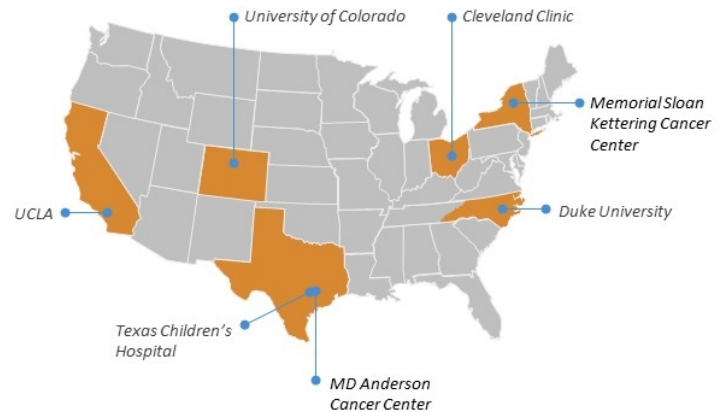
**Responding CD99+ human Ewing sarcoma tumors undergo apoptotic cell death in rat xenograft model**



### 3+3 Phase 1 clinical trial for patients with relapsed/refractory Ewing sarcoma

- Encouraging safety profile with no off-target toxicities observed (primarily manageable myelosuppression)
- Deep clinical response in heavily pretreated patient reported
- Additional results to be presented at 2019 CTOS conference

### Top Ewing sarcoma centers





Baseline: Lung Nodule Feb 2019



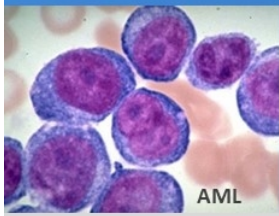
After 2 cycles TK216: Resolved



### Clinical Case Study:

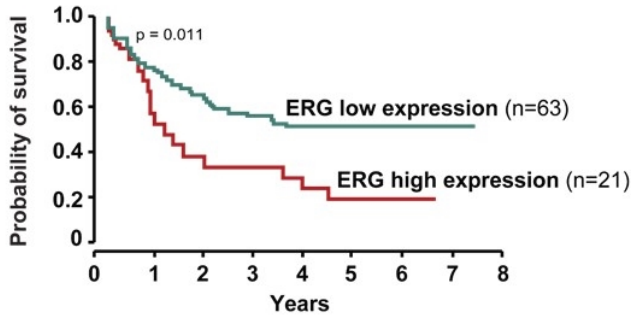
- 19 year with progressive metastatic lung disease despite prior treatment with surgery, radiation, multiple chemotherapies, bevacizumab and pazopanib
- Multiple lung nodules resolved after 2 cycles TK216 alone, which was sustained at 6 months of treatment with the patient receiving planned TK216 plus vincristine after the 2<sup>nd</sup> cycle
- Final remaining residual tumor (<1cm, non-target lesion) was later surgically removed, leading to a surgical CR
- Treatment has been well-tolerated in this patient

Meyers, 2019 COG

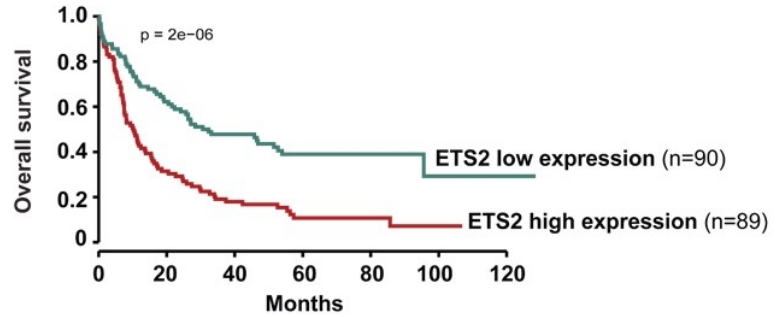


## SCIENTIFIC RATIONALE:

- ETS family overexpressed or fusion proteins in ~30% of AML cases<sup>1</sup>
- Multiple AML cell lines sensitive to killing by TK216, sensitivity proportional to ETS expression
- 21,000 new cases of AML per year with 25% 5-year survival



ERG overexpression is correlated with poor AML survival<sup>2</sup>



ETS2 overexpression is correlated with poor AML survival<sup>3</sup>

1 De Braekeleer 2012 LeukRes 36:945-61  
 2 Marcucci 2005 JCOncol 23:9234  
 3 Fu 2017 JTranslMed 15:159

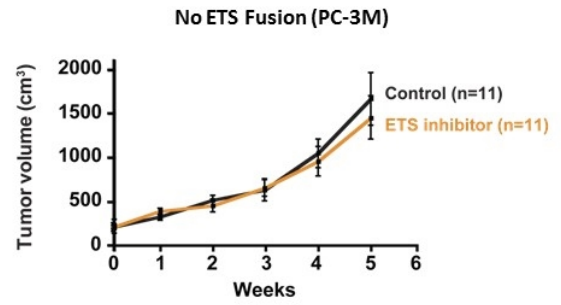
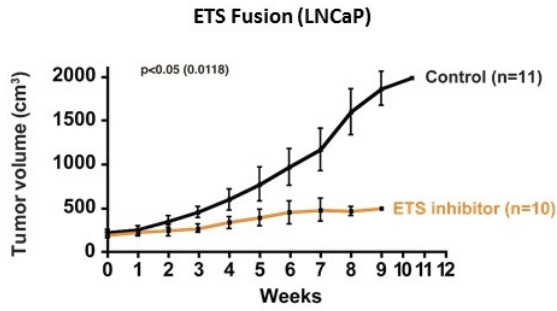


### SCIENTIFIC RATIONALE:

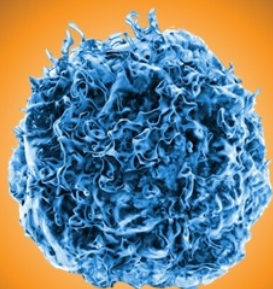
- 55% of men with advanced prostate cancer carry the ETS family fusion protein TMPRSS2-ERG, related to androgen resistance

### HIGH UNMET NEED:

- Incidence of metastatic prostate cancer increasing
- 32,000 deaths per year
- New treatments needed after failure of androgen antagonism and prior to chemotherapy



Prostate cancer sensitivity associated with an ETS-family fusion protein in human prostate cancer xenograft models



## CAR-T Program

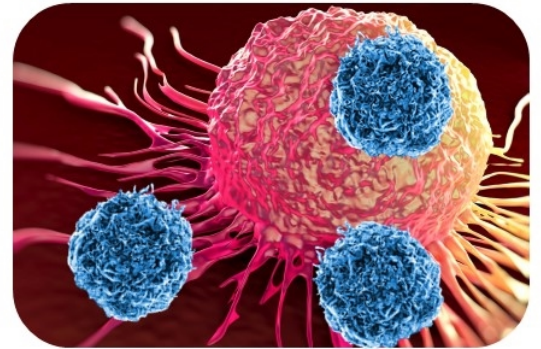
Targeting ROR1

## DEVELOPMENT STATUS

- Preclinical data in hematologic and solid tumor models
- Utilizing cirmtuzumab scFv as targeting component
- Ready for process development and scale-up
- UCSD collaboration with non-dilutive financing from California Institute for Regenerative Medicine (CIRM)
- Planned Shanghai Pharma collaboration for manufacturing and clinical development

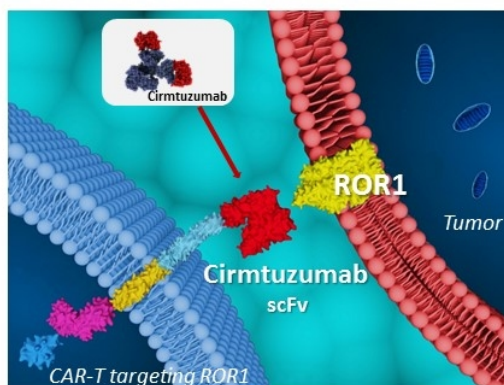
## OPPORTUNITY

- Selective targeting strategy applicable to multiple tumors with ROR1 expression
- Target initial human proof-of-concept in hematological cancers, then expansion into solid tumors



## Emerging CAR-T Issues

- Increasing number of patient relapses following CAR-T therapy, frequently due to mutations or loss of the target antigen tumor (e.g. CD19), evading CAR-T efficacy
- Persistent CAR-T safety issues including deaths potentially related to activation by normal cells expressing the target antigen



## Advantages to Targeting ROR1

### Potential for fewer antigen negative relapses

- ROR1 expression associated with aggressive tumor phenotype
- If a ROR1 mutation or antigen loss should occur, surviving cancer cells may be weakened or less aggressive

### Potential safety advantages

- Cirmtuzumab does not bind to normal human tissues in GLP tissue cross-reactivity studies



**BUSINESS  
& FINANCIALS**

# Robust Pipeline: Upcoming Milestones

| Product Candidate  | Indication                         | Preclinical | Phase 1 | Phase 2 | Next Anticipated Milestone                   |
|--------------------|------------------------------------|-------------|---------|---------|--|
| <b>Cirmtuzumab</b> | Chronic Lymphocytic Leukemia (CLL) |             |         |         | <b>Report Phase 1 data 4Q 2019</b>           |
|                    | Mantle Cell Lymphoma (MCL)         |             |         |         | <b>Report Phase 1 data 4Q 2019</b>           |
|                    | Breast Cancer                      |             |         |         | <b>Report Phase 1 data 4Q 2019</b>           |
| <b>TK216</b>       | Ewing Sarcoma                      |             |         |         | <b>Report Phase 1 data 4Q 2019</b>           |
|                    | Acute Myeloid Lymphoma (AML)       |             |         |         | <b>Initiate study 2H 2020</b>                |
|                    | Prostate Cancer                    |             |         |         | <b>Initiate IND enabling studies 2H 2020</b> |
| <b>ROR1 CAR-T</b>  | Heme Cancers                       |             |         |         | <b>Select candidate 1H 2020</b>              |
|                    | Solid Tumors                       |             |         |         | <b>Select candidate 2H 2020</b>              |



| Ticker  | ONCT (Nasdaq)                       |
|---|-------------------------------------|
| Cash & Cash Equivalents @ 6-30-19<br>Cash Runway through 2Q 2020  | \$28.5M                             |
| Debt  | \$0                                 |
| <b>Capitalization:</b>  |                                     |
| Common Shares Outstanding   | 15.4M                               |
| Options   | 2.5M                                |
| Warrants  | 0.8M                                |
| Fully Diluted   | 18.7M                               |
| <b>Non-Dilutive Support</b>   |                                     |
| <ul style="list-style-type: none"> <li>• CIRM Grant for CIRLL Study</li> <li>• Ibrutinib CTM for CIRLL Study</li> </ul> | ~\$16M<br>Expanded Supply Agreement |

# Highly Experienced Oncternal Team



**James Breitmeyer, MD, PhD**  
CEO, Founder, Director



**Richard Vincent**  
CFO



**Igor Bilinsky**  
CBO



**Frank Hsu, MD, PhD**  
CMO



**Gunnar Kaufmann, PhD**  
CSO



**Raj Krishnan, PhD**  
SVP, Manufacturing



**David Hale**  
Co-founder, Board Chairman



**Michael Carter, MD, Ch.B., F.R.C.P.**  
Director



**Daniel Kisner, MD**  
Director



**Robert Wills, PhD**  
Director



**Bill LaRue**  
Director



**Charles Theuer**  
Director



## CIRMTUZUMAB - ROR1 mAb IN RANDOMIZED PHASE 2

- Encouraging early efficacy and safety with ibrutinib in CLL
- Phase 1b in HER2 negative, metastatic breast cancer
- Potential in multiple ROR1 expressing tumors (TNBC, NSCLC)

## TK216 - TARGETED ETS INHIBITOR IN PHASE 1

- Objective response in patient with metastatic Ewing sarcoma
- Potential for targeting multiple ETS-driven tumors (AML, prostate)

## MULTIPLE CLINICAL DATA CATALYSTS

- Clinical data updates expected over next three quarters
- CAR-T targeting ROR1 expected to reach clinic in 2020

## EXPERIENCED MANAGEMENT AND FOUNDERS

