
**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 8, 2021

KIROMIC BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

| | | |
|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------------------|
| Delaware (State or other jurisdiction of incorporation) | 001-39619 (Commission File Number) | 46-4762913 (IRS Employer Identification No.) |
| 7707 Fannin, Suite 140 Houston, TX, 77054 (Address of principal executive offices) (Zip Code) | | |
| Registrant's telephone number, including area code (832) 968-4888 | | |

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, \$0.001 par value | KRBP | 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.

Kiromic BioPharma, Inc. (the “Company”) is furnishing presentation materials (the “Investor Presentation”) that management intends to use, possibly with modifications, in one or more meetings from time to time with current and potential investors. The Investor Presentation includes an update on the Company’s current operations and major projects, as well as information relating to the Company’s strategic plans, goals, growth initiatives and outlook, and forecasts for future performance and industry development. A copy of the investor presentation is furnished as Exhibit 99.1 to this report and is also available on the Company’s website at <https://kiromic.com/>.

The foregoing description of the Investor Presentation does not purport to be complete and is qualified in its entirety by reference to the complete text of the Investor Presentation attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 7.01 of this Report, including without limitation the Investor Presentation, is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such a filing.

Item 9.01 Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|------------------------------------------------------------------------------------------|
| 99.1 | Kiromic BioPharma, Inc. October 2021 Investor Presentation. |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101) |

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.

Kiromic BioPharma, Inc.

Date: October 8, 2021

By: /s/ Maurizio Chiriva Internati
Maurizio Chiriva Internati
Chief Executive Officer



Revolutionizing Solid Tumor Allogeneic Cell Therapy

October 2021
NASDAQ: KRBP



Forward Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the U.S. Private Securities Litigation Reform Act, Section 21E of the Securities Exchange Act of 1934, as amended, and other federal securities laws. All statements other than statements of historical facts are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about: our goals and strategies; our future business development, financial condition and results of operations; expected changes in our revenue, costs or expenditures; growth of our company; competition trends in our industry; our expectations regarding demand for, and market acceptance of, our products; future milestones and objectives, including scope and timing of our growth and opportunity for CAR-T therapies including any potential growth related to the approval of solid tumor therapies; the efficacy of our products and approaches relative to other alternatives; the ability of our chPD1 approach to enhance current commercial therapies and overall immune responses; the ability of Isocel to target solid tumors; the ability of our Diamond Donor AI to identify the best targets, improve final products, or reduce development costs in our discovery efforts; our expectations regarding our relationships with investors, institutional funding partners and other parties we collaborate with; fluctuations in general economic and business conditions in the markets in which we operate; including those fluctuations caused by COVID-19; and relevant government policies and regulations relating to our industry.

In some cases, you can identify forward-looking statements by terms such as "may," "in coming years," "could," "by," "if," "will," "should," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "project" or "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those risks described in our filings with the Securities and Exchange Commission (SEC), including those discussed in our annual report on Form 10-K for the year ended December 31, 2020, in our quarterly reports on Form 10-Q for any subsequent quarterly periods, and elsewhere in this press release. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements made in this report relate only to events or information as of the date on which the statements are made in this report. Except as expressly required by the federal securities laws, there is no undertaking to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changing circumstances or any other reason.

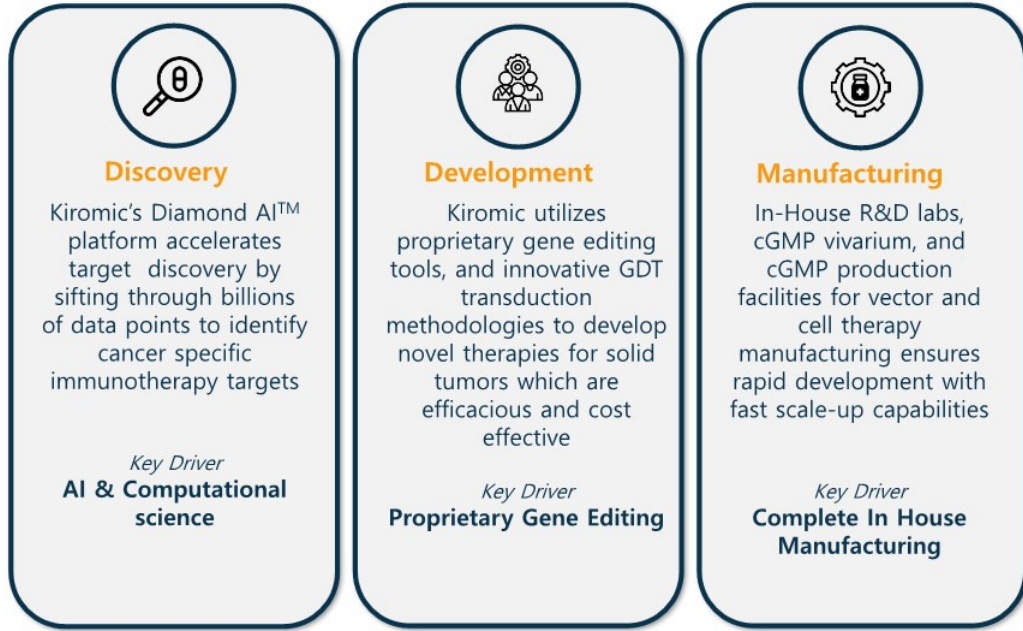
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- Introducing KIROMIC
 - The Opportunity for Gamma Delta T-Cell based therapy
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Kiromic Biopharma is an **AI-driven, end-to-end CAR-T & gene therapy company**, developing the **first multi-indication allogeneic CAR-T cell therapy**, that exploits the natural potency of **Gamma Delta T-cells** to target **solid cancers**

Kiromic's **End to End** Approach to Next Generation Gene Therapy



Kiromic Focus Areas

1. **Allogeneic, off-the-shelf, CAR-T Therapy**
- (Cells from healthy donors not ill patients)
2. **Gamma Delta T-Cell Approach**
3. **Solid Cancers** (~90% of all cancers¹)

¹American Cancer Society 2020 Cancer Facts & Figures; Leading sites of new cancer cases and deaths; epub.

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KIROMIC's Market Opportunity

Significant upside opportunity for CAR-T Therapies in coming years, especially if **solid tumor therapies** are approved

**Global Car-T Cell
Therapy Market
by 2028¹ (USD)**
(Only Including blood
cancer opportunity)



**Potential Market
Opportunity for
Solid Malignancies²**



¹Global CAR T Cell Therapy Market To Reach US\$ 7.7 Billion By 2028, Coherent Market Insights

²T-cell Therapy Market - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2019 – 2027, Transparency Market Research

Comparables

A.I. Target

 Personalis® **\$0.87 BLN**
IPO June 2019

 BLACK DIAMOND THERAPEUTICS **\$0.36 BLN**
IPO Jan 2020

 gritstone **\$0.62 BLN**
IPO Sep 2018

CAR-T and CAR-NK

 Fate THERAPEUTICS **\$6.14 BLN**
IPO Nov 2013

 Kite Pharma **\$11.9 BLN**
GILD acqui. Post approval

 JUNO THERAPEUTICS **\$9.0 BLN**
BMS acqui. End Phase 2

NASDAQ: KRBP Market Data as of 09/27/2021 - Yahoo Finance and SEC.GOV

Major Barriers Currently Restrict Mass Adoption of Traditional CAR-T Therapy for Cancer Treatment

1. Efficacy

Cancer cells can begin to mutate resulting in "antigen escape" which reduces the efficacy of CAR-T. The lack of available predictive biomarkers is also an issue which limits the development of new and effective cancer immunotherapeutics.¹



2. Cost Effectiveness

Hospitals must charge \$2-2.5M per treatment to avoid losing money with current autologous CAR-T cell treatments due to treatment related toxicities (the cost for Kymriah/Novartis alone is \$475K per treatment with the additional costs secondary to inpatient treated toxicities).²



3. Safety & Toxicity

Current FDA approved CAR-T cell therapy products carry a high risk of side effects including the Cytokine Release Syndrome (CRS) and Immune Cell Associated Neurotoxicity Syndrome (ICANS).³



5. Manufacturing Challenges

Traditional CAR-T cell manufacturing can range from 2-5 weeks. This can be an issue for late-stage cancer patients when timing is especially critical. Harvesting viable patient derived T-cells can also be a challenge for very sick patients. As traditional autologous CAR-T cell therapies are also specific to the patient, "mass" production is also not possible as each infusion is only for the patient themselves.



4. Development Lead Time

Traditional development lead time for new immunotherapies usually take years, significant expert resources, and can cost over \$1B in development expenditures.⁴



¹Research and Markets; Immune Checkpoint Inhibitors Market. Feb 6, 2020;epub.

²Maziarz RT. CAR T-cell Therapy total cost can exceed \$1.5M per treatment. Cell Therapy Next; May 29, 2019.

³American Cancer Society. CAR T-cell Therapy and Its Side Effects; epub.

⁴Burke CW. Why does immunotherapy cost so much?; Biospace; October 4, 2018;epub.

The Kiromic Difference

– Engineered Allogeneic Gamma Delta Based Therapies

| | | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1</p> <p>Next Gen Allogeneic Therapy</p> <p>Allogeneic approach results in simplified and efficient supply chain (vein-to-vein lead time) with improved product availability.</p> <p>Previous generation of autologous therapy results in manufacturing challenges that made repeat dosing challenging</p> | <p>2</p> <p>Multi Indication Solid Tumor Therapies</p> <p>Potential broad treatment for solid malignancies that express Kiromic developed biomarkers such as Isomesothelin.</p> <p>Solid tumors represent approx. 90% of new cancer cases¹</p> | <p>3</p> <p>Superior Safety²⁻⁴</p> <p>1. Minimal to no Cytokine Release Syndrome (CRS)</p> <p>2. Minimal to no Immune Cell Associated Neurotoxicity Syndrome (ICANS)</p> <p>3. Minimal Graft versus Host Disease (GvHD) therefore no compatibility issues between donors and patients</p> | <p>4</p> <p>Superior Efficacy⁵</p> <p>100% efficacy in pre-Clinical animal models</p> <p>Addressed issues related to low efficacy :</p> <ol style="list-style-type: none"> 1. Suppressive Tumor micro-environment (TME) 2. T-Cell exhaustion and loss of efficacy | <p>5</p> <p>Inhouse Manufacturing</p> <p>1.No lead time (Off-The-Shelf) vs up to 3-5 weeks for autologous CAR-T such as Kymriah⁶</p> <p>2. In-house cGMP manufacturing (full control and vertical integration of manufacturing process) including:</p> <ol style="list-style-type: none"> a. Unique In-house Vector production b. Cell therapy production | <p>6</p> <p>Lower Costs/ Greater Access⁷</p> <p>1.Outpatient treatment means reduced hospitalization and other treatment related costs – hospitals struggle to break even if given in the inpatient setting</p> <p>2. Lower production cost – competitor costs \$373K and \$475K per treatment for Yescarta and Kymriah respectively</p> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

¹American Cancer Society 2020 Cancer Facts & Figures; Leading sites of new cancer cases and deaths; epub.
²Wang X, et al. Mesothelin isoform 2 is a novel target for allogeneic CAR gamma delta T cell therapy in solid tumors. AACR 2021:Abstract No. 1534
³Barber A, et al. Gamma delta T cells engineered with a chimeric PD-1 receptor effectively controls PD-L1 positive tumors in vitro and in vivo with minimal toxicities. AACR 2021: Abstract No.18148
⁴Xu Y, et al. Allogeneic Vgamma9delta2 T-cell immunotherapy exhibits promising clinical safety and prolongs the survival of patients with late-stage lung or liver cancer. Cell Mol Immunol 18(2):427-439.
⁵Parriott G, et al. T-cells expressing a chimeric-PD1-Dap10-CD3zeta receptor reduce tumour burden in multiple murine syngeneic models of solid cancer. Immunology 160(3):280-294
⁶NPS Medicine Consumer Medicine Information; epub
⁷Maziarz RT. CAR T-cell therapy total cost can exceed \$1.5M per treatment. Cell Therapy Next; May 29, 2019.

The Kiromic Difference - Engineered Gamma Delta T Cells

Engineered Gamma Delta delivers on critical factors compared to other CAR T/Chimeric approaches

Kiromic's engineered Gamma Delta (chPD1) approach has the potential to significantly enhance current commercial therapies by **minimizing side effects**, **expanding indications**, and reducing **manufacturing costs** compared to current CAR-T therapies

| | Autologous & Allogeneic CAR-T technology challenges | Autologous CAR-T | Allogeneic CAR-T | Allogeneic AI engineered GD CAR-T |
|----------------------|-------------------------------------------------------|---------------------------------------------|------------------|---------------------------------------------|
| SAFETY | Graft Versus Host Disease Risk(GvHD) | NA | - | + |
| | Cytokine Release Syndrome (CRS) | - | + | + |
| | Immune Cell Associated Neurotoxicity Syndrome (ICANS) | - | + | + |
| EFFICACY | Efficacy | + | + | ++ ¹ |
| | Indication | Blood cancers (<8% of cancers) ² | Solid Tumors | Solid tumors (~90% of cancers) ² |
| | T-Cell exhaustion | - | + | ++ |
| | Tumor immunosuppressive microenvironment | - | + | ++ |
| | Tumor specific antigens (Shedding) | - | - | ++ |
| MANUFACTURING | Off-the-Shelf Product | N/A | + | + |
| | Cost of Manufacturing (per patient) | \$\$\$ | \$\$ | \$ |
| | Lead time (Auto vs off-the-shelf) | - | + | + |
| | Manufacturing success | - | + | + |
| APPLICATION | Market opportunity | \$ | \$\$ | \$\$\$ |
| | Cost of ancillary toxicity related treatments | \$\$\$ | \$\$ | \$ |
| | Treatment setting | Inpatient | Inpatient | Outpatient |

¹Based upon Kiromic's pre-clinical animal models

²American Cancer Society 2020 Cancer Facts & Figures; Leading sites of new cancer cases and deaths; epub.

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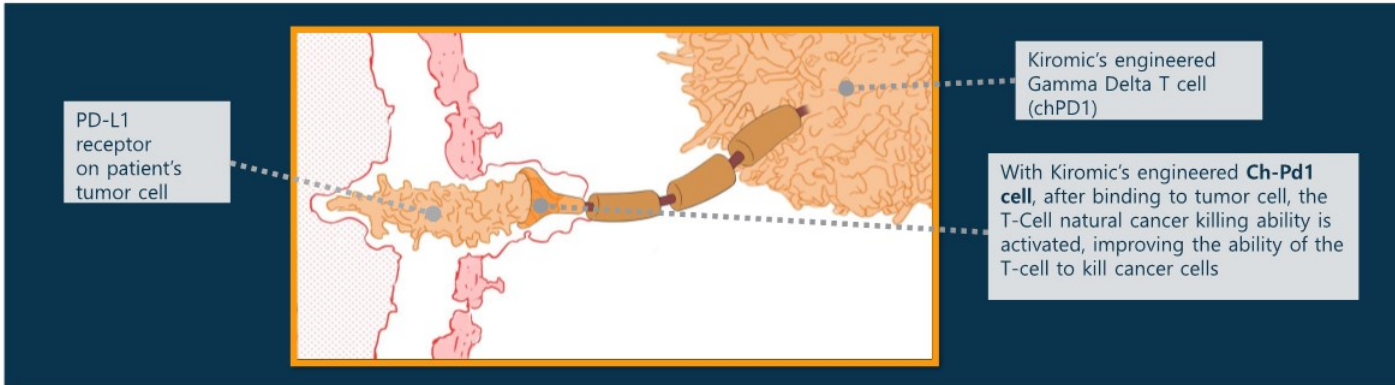
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The Kiromic Difference - ALEXIS™ Immunotherapy Platform (1/2)

Kiromic's engineered Gamma Delta T-Cell allogeneic approach

1. Kiromic ALEXIS™-PRO-1 (Procel™) - Targeting PDL-1 Expression In Tumor Tissues

- Human T-cells are very effective natural cancer killers. Many cancer cells however can **evade T-cell detection** by developing **PD-L1** receptors that **"put the brakes"** on the T-cell's cancer killing abilities. That is why traditional T-Cell based therapies can be ineffective.
- Kiromic's **engineered Gamma Delta T-Cell (chPD1)** approach seeks to introduce 2 key elements that have the potential to **significantly enhance** immune response
 - Blocks the ability of checkpoints like PD-L1 from inactivating a T-cell (similar to checkpoint inhibitors)**
 - Engineered gamma delta T-cells are now able to kill cancer cells with enhanced potency upon binding with the PD-L1 receptor.**
- Since many solid tumors have a **wide expression of PD-L1¹**, this means that most solid cancers such as **lung, melanoma, gastric, esophagus, colorectal, breast, prostate, liver, urothelial, renal, cervical, and head and neck** can potentially now be effectively treated.



¹Vaddepally RK, et al. Review of Indications of FDA Approved checkpoint inhibitors per NCCN guidelines with the level of evidence. Cancers; Mar 2020;12(3):738.

The Kiromic Difference - ALEXIS™ Immunotherapy Platform (2/2)

First A.I. engineered Allogeneic Gamma Delta CAR-T cell therapy developed with Diamond AI™

2. Kiromic's ALEXIS™-ISO-1 (Isocel™) - Targeting Isomesothelin Expression In Tumor Tissues

- First A.I. engineered gamma delta CAR-T cell therapy¹ developed with Diamond AI™
- Multiple solid tumors express the Isoform of mesothelin - Isomesothelin.²
- Kiromic's ALEXIS™-ISO-1 cells target and destroy Isomesothelin expressing cancer cells.³
- This suggests ALEXIS™-ISO-1 has the potential to be an immunotherapy that targets solid cancers including Ovarian, Cervical, Mesothelioma, Ovarian, Endometrial, and Pancreatic cancers.

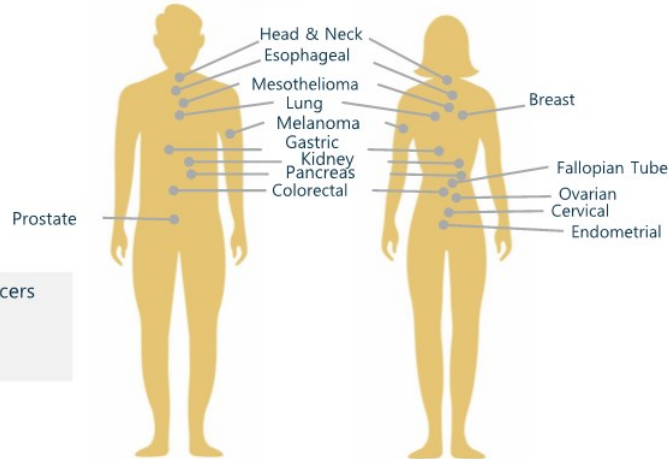


Fig.1 – Potential solid tumor cancers that the Alexis™ platform can potentially target with Kiromic's Procel™ and Isocel™

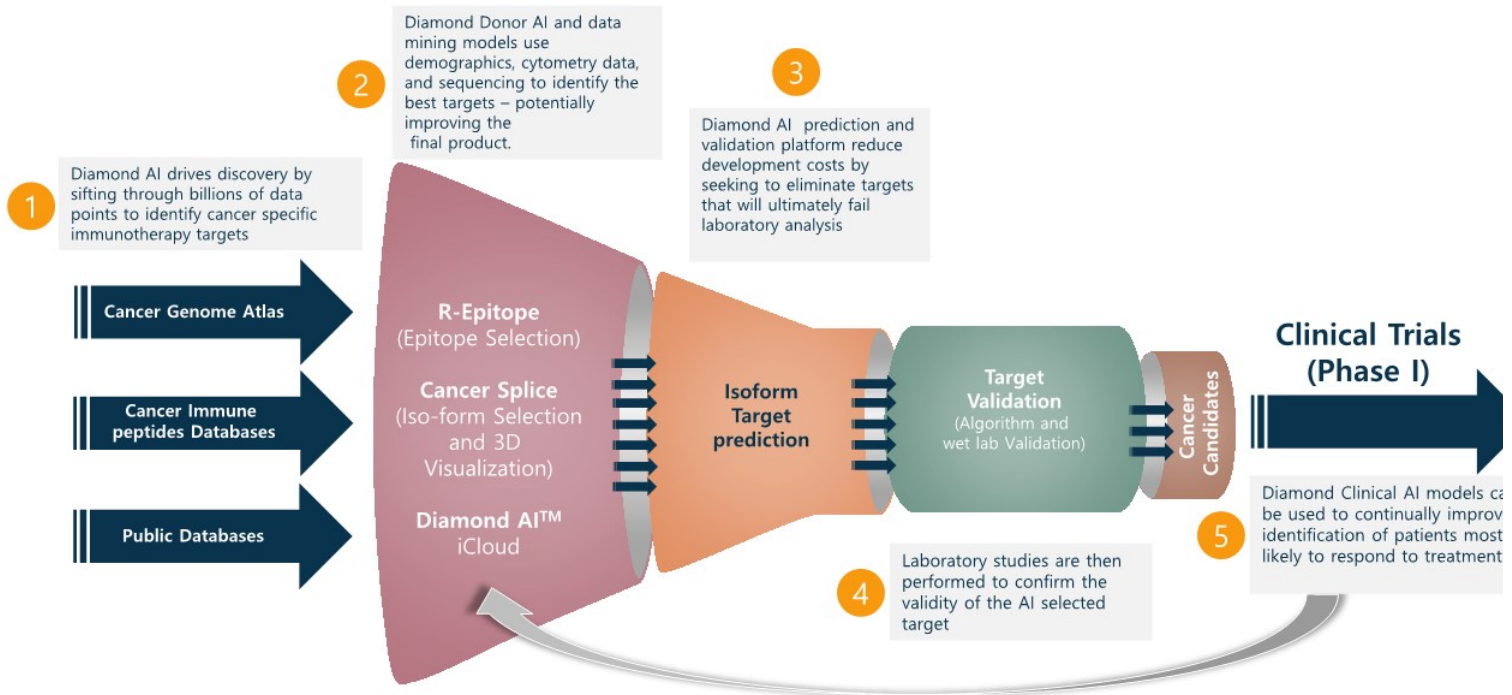
¹Kiromic AACR 2021 presentation

²Unpublished Kiromic Biopharma data

³Wang X, et al. Mesothelin isoform 2 is a novel target for allogeneic CAR gamma delta T cell therapy in solid tumors. AACR 2021;Abstract No. 1534.

The Kiromic Difference - Diamond AI™ Target Discovery Platform

Diamond AI™ target discovery platform powers innovation and significantly reduces development time and cost.



Kiromic's Engineered Gamma Delta Approach – Superior Efficacy

Kiromic's **engineered Gamma Delta** approach (**chPD1-GDT™**) is potentially **more efficacious** than non-engineered Gamma Delta Allogeneic approach.

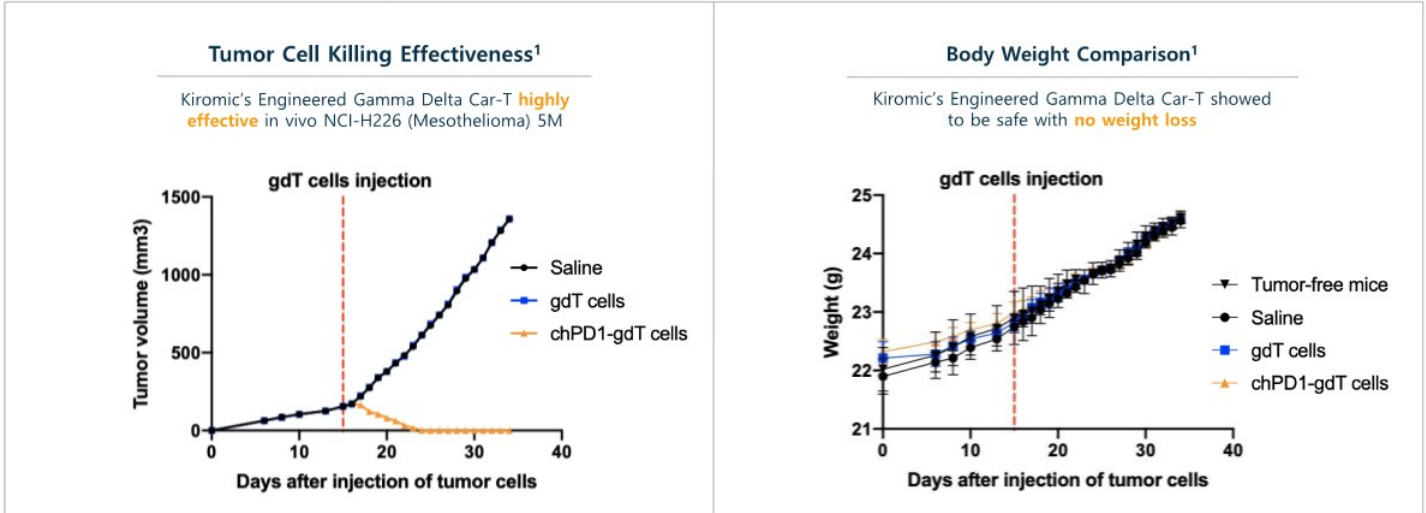
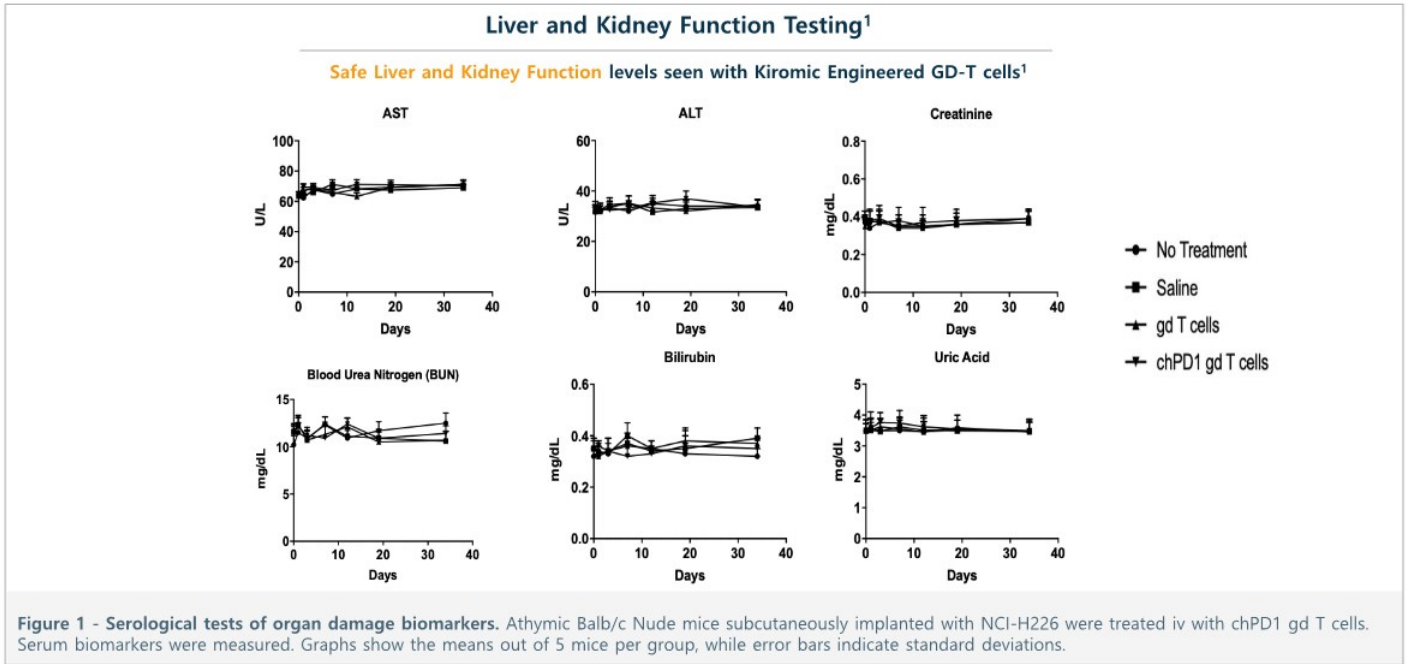


Figure 1,2 In vivo efficacy of chPD1 gdT cells. The in vivo efficacy and tolerability of gd T cells (5×10^6 cells) in athymic Balb/c Nude mice subcutaneously implanted with the PDL1+ cell line, NCI-H226 (10^6 cells). The dotted vertical line indicates the day when the gdT cells were administered (shday +15). Graphs show the average A) tumor volumes and B) weights of 10 mice (Saline, gdT cells, chPD1 gdT cells), or 5 mice (tumor-free), +/- 95% C.I.

¹Barber A, et al. Gamma delta T cells engineered with a chimeric PD-1 receptor effectively controls PD-L1 positive tumors in vitro and in vivo with minimal toxicities. AACR 2021; Abstract No.LB148.

Kiromic's Engineered Gamma Delta Approach– Superior Safety

Kiromic's engineered Gamma Delta approach (chPD1-GDT™) shown to be safe in animal testing



¹Barber A, et al. Gamma delta T cells engineered with a chimeric PD-1 receptor effectively controls PD-L1 positive tumors in vitro and in vivo with minimal toxicities. AACR 2021; Abstract No.LB148.

Kiromic's Engineered Gamma Delta Approach – Superior Efficacy

Kiromic's **engineered Gamma Delta** approach is shown to be potentially more **efficacious** than non-engineered Gamma Delta Allogeneic approach.

Tumor Cell Killing Effectiveness¹

Kiromic's Engineered Gamma Delta Car-T **highly effective** in vivo NCI-H226 (Mesothelioma) 5M

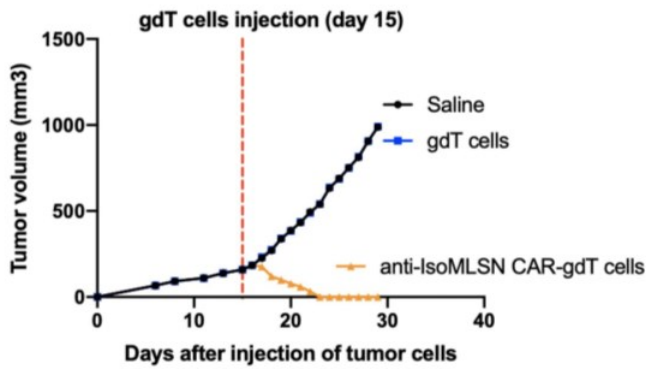


Figure 1 In vivo efficacy of CAR gdT cells. We tested the *in vivo* efficacy and tolerability of a high dose of gdT cell in Balb/c nude mice sub-cutaneously implanted with the IsoMSLN+ cell line, NCI-H226. 15 days after tumor cell implantation, mice with comparable tumor volumes were then divided into 3 groups (n=10 mice/group): i) injected with gdT cells, ii) injected with CAR gdT cells, iii) injected with saline solution. Tumor volumes and mice weight were measured daily for an additional 30 days. The dotted vertical line indicates the day when the gdT cells were administered. Graphs show the average values out of 10 mice (Saline, gdT cells, CAR gdT cells), or 5 mice (tumor-free), +/- 95% C.I.

Body Weight Comparison¹

Kiromic's Engineered Gamma Delta Car-T shown to be **safe with no weight loss**

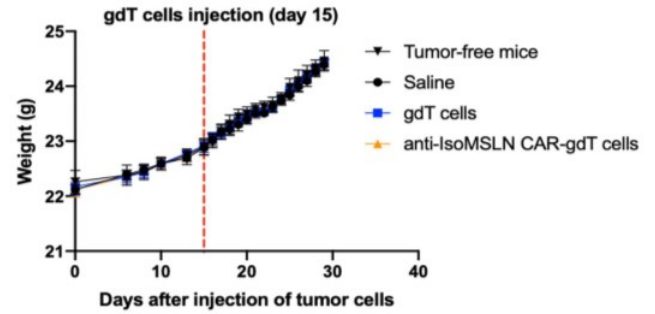
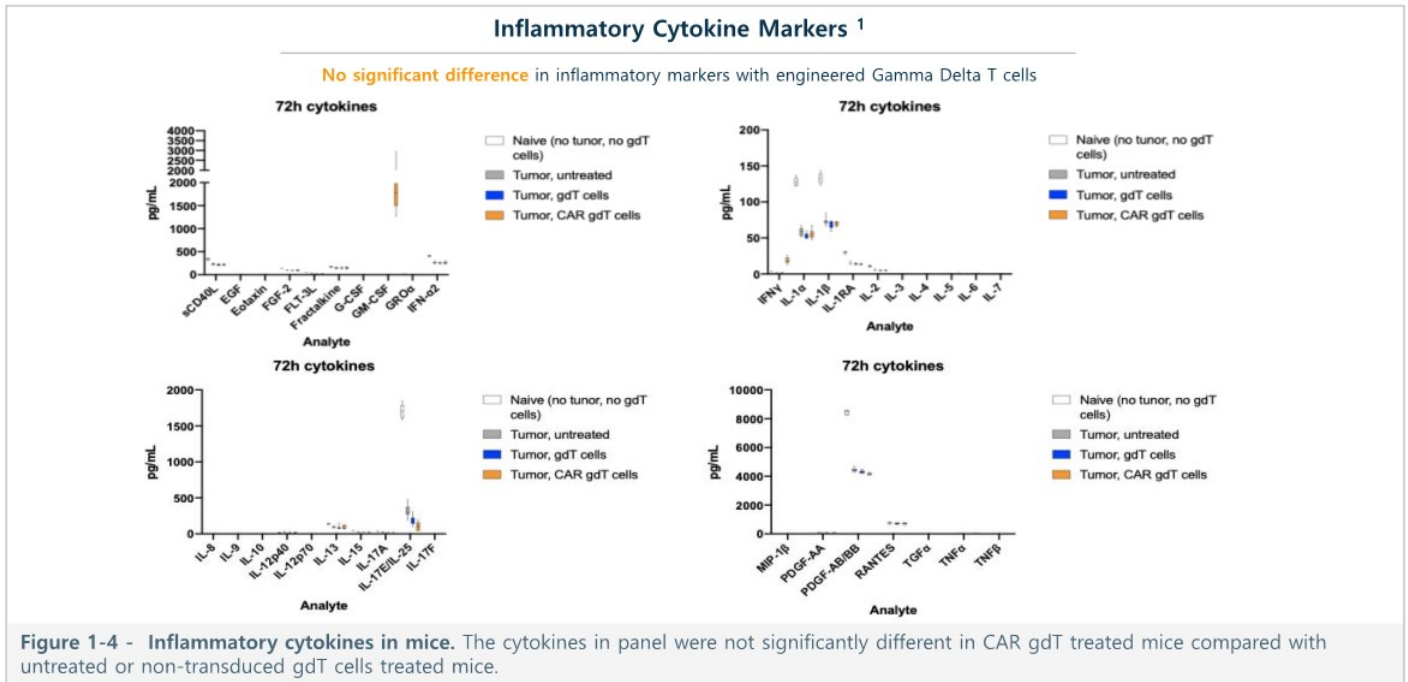


Figure 2 Animal body weight and general health. No adverse reactions were observed over the course of the study in the tumor-bearing mice treated with CAR- expressing human gamma delta T cells. Adverse reactions that were monitored included presence of labored breathing, ruffled fur, reduced appetite, lethargy, or hunched posture. Furthermore, the mice treated with CAR- expressing human gamma delta T cells did not experience any weight loss over the course of the study. Non tumor bearing mice were also included as a healthy animal control. The dotted vertical line indicates the day when the gdT cells were administered. Graphs show the average values out of 10 mice (Saline, gdT cells, CAR gdT cells), or 5 mice (tumor-free), +/- 95% C.I.

¹Xiao W., et al. Mesothelin isoform 2 is a novel target for allogeneic CAR $\gamma\delta$ T cell therapy in solid tumors. AACR 2021; Abstract No. 1534

Kiromic's Engineered Gamma Delta Approach – Superior safety

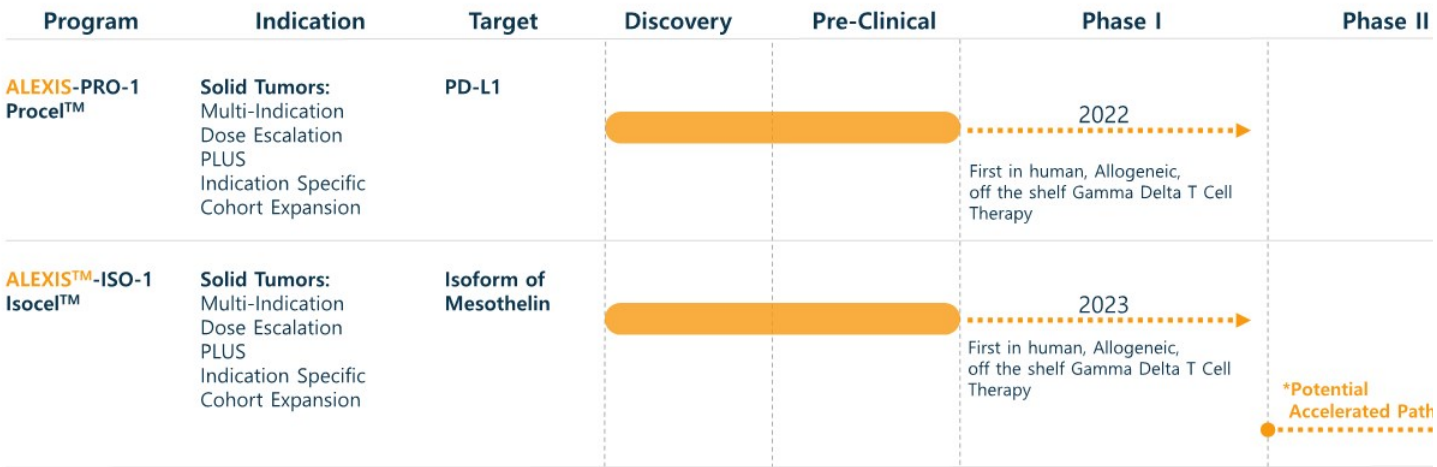
Kiromic's engineered Gamma Delta approach (AICAR-Iso-GDT™) is shown to be safe with no CRS



¹Xiao W., et al. Mesothelin isoform 2 is a novel target for allogenic CAR $\gamma\delta$ T cell therapy in solid tumors. AACR 2021; Abstract No. 1534

Kiromic's T-Cell Immunotherapy Pipeline

Kiromic has developed a robust pipeline of product candidates addressing **solid cancers** utilizing **engineered Gamma Delta** based therapy for potential **multi-indications** for cancer therapy. An **accelerated pathway** for a potential BLA submission by 2026 is also planned



*Apart from the current path to market, Kiromic has developed a potential **accelerated clinical development plan** focussed on a one product one Indication approach, with the most promising and **rare indications** from upcoming basket trial. This will enable a potential **BLA submission by 2026**

Kiromic's Upcoming Milestones*

- 1 Finalize Chemistry, Manufacturing and Control (CMC) Specifications Requested by FDA**
 - H1 2022

- 2 Submit Formal Request for FDA Type A Meeting**
 - H1 2022 - Addresses the clinical hold and will allow us to discuss path toward our first-in-human dosing.

- 3 Submit IND Amendment after Type A Meeting Feedback**
 - H2 2022

- 4 GMP 2 Manufacturing Construction Completed**
 - Start construction in Q4 2021 on second GMP Manufacturing Center
 - Construction expected to be completed by H2 2022

- 5 FDA Authorization to proceed and First In Human Dosing**
 - H2 2022

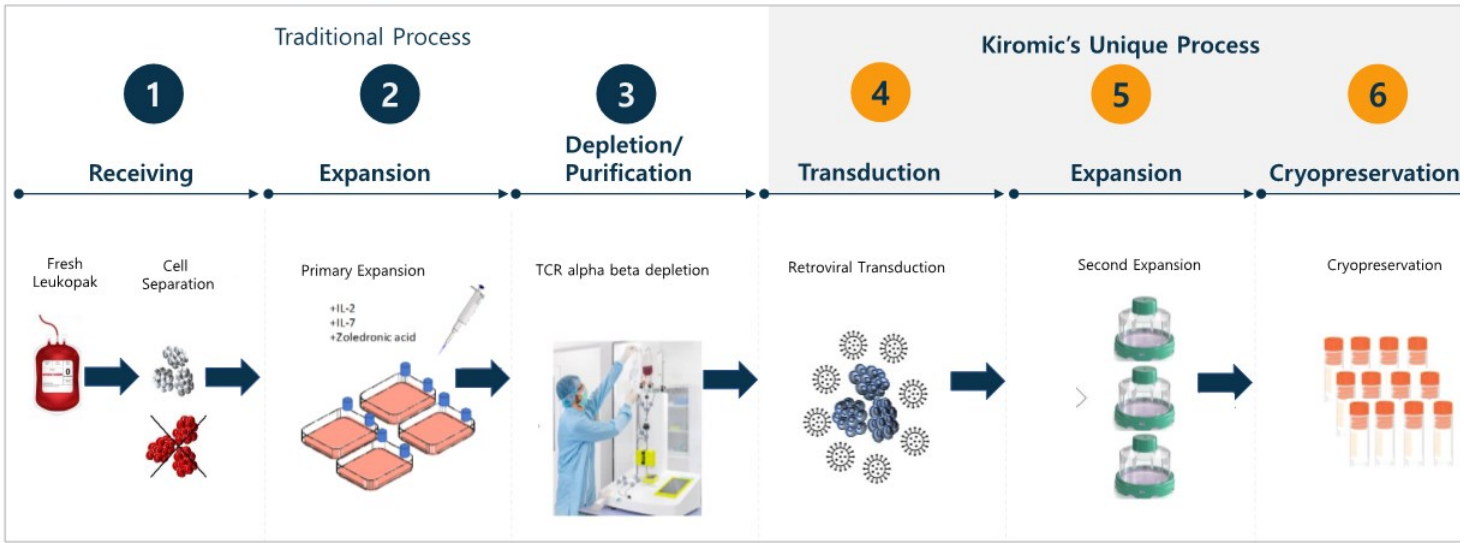
*The milestones and timing of completion are based upon the company's current expectations in consultation with its partners and vendors

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Kiromic's Manufacturing **Process Differentiator**

Kiromic's proprietary manufacturing approach utilizes unique in-house processes that **maximizes yield** and delivers engineered T-Cells that are **significantly more potent** compared to competition. This results in a much lower quantity of engineered T-Cells needed per therapeutic dose further improving **cost effectiveness**.



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Kiromic Summary

Leading the Next Generation of A.I. Engineered Gamma Delta T-Cell Gene Therapy

- 1** **ALEXIS™-PRO-1 (Procel™): Chimeric PD1 gamma delta T cell therapy (chPD1-GDT™)**
 - Phase I clinical trial 2022: PD-L1 positive metastatic solid malignancies
- 2** **ALEXIS™-ISO-1 (Isocel™): Artificial Intelligence (AI) guided target discovery CAR gamma delta T cell therapy (i.e., Isoform of Mesothelin)**
 - Phase I clinical trial 2023: CAR-T therapy for Isomesothelin positive metastatic solid malignancies
- 3** **Healthy donor derived allogeneic off-the-shelf product.**
- 4** **In-House R&D labs, vivarium and cGMP production facilities for vector and cell therapy manufacturing.**
- 5** **Value drivers:**
 - Large market opportunity with projected ~\$7.7B Car-T cell therapy market (liquid tumors) and potential 1 increased opportunity with solid tumors. ^{1,2}
 - Lower expected production, treatment and administration costs (outpatient versus inpatient)
 - Lower expected toxicity profile
 - Higher expected efficacy profile

¹Global CAR T Cell Therapy Market To Reach US\$ 7.7 Billion By 2028, Coherent Market Insights

²T-cell Therapy Market - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2019 – 2027, Transparency Market Research

Kiromic Management Team



Maurizio Chiriva-Internati
DBSc, PhDs



Gianluca Rotino



Scott Dahlbeck
MD, PharmD



Dan Clark
CPA, MBA



Ignacio Nunez
MSCHE, MBB



Michael Ryan
PhD

CEO & Chairman

CSIO, Director

CMO

CFO (interim)

COO

CBCRO





Revolutionizing Solid Tumor Allogeneic Cell Therapy

For more information contact

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