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): November 9, 2023

KIROMIC BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39619**	**46-4762913**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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") intends to conduct meetings with third parties in which its corporate slide presentation will be presented. A copy of the presentation materials is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and the document attached as Exhibit 99.1 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), nor otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On November 9, 2023, the Company issued a press release announcing the start of the patient recruitment in the Deltacel™ Phase 1 Clinical Trial at Beverly Hills Cancer Center. A copy of the press release is furnished as Exhibit 99.2 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Corporate Presentation
99.2	Press release dated November 9, 2023

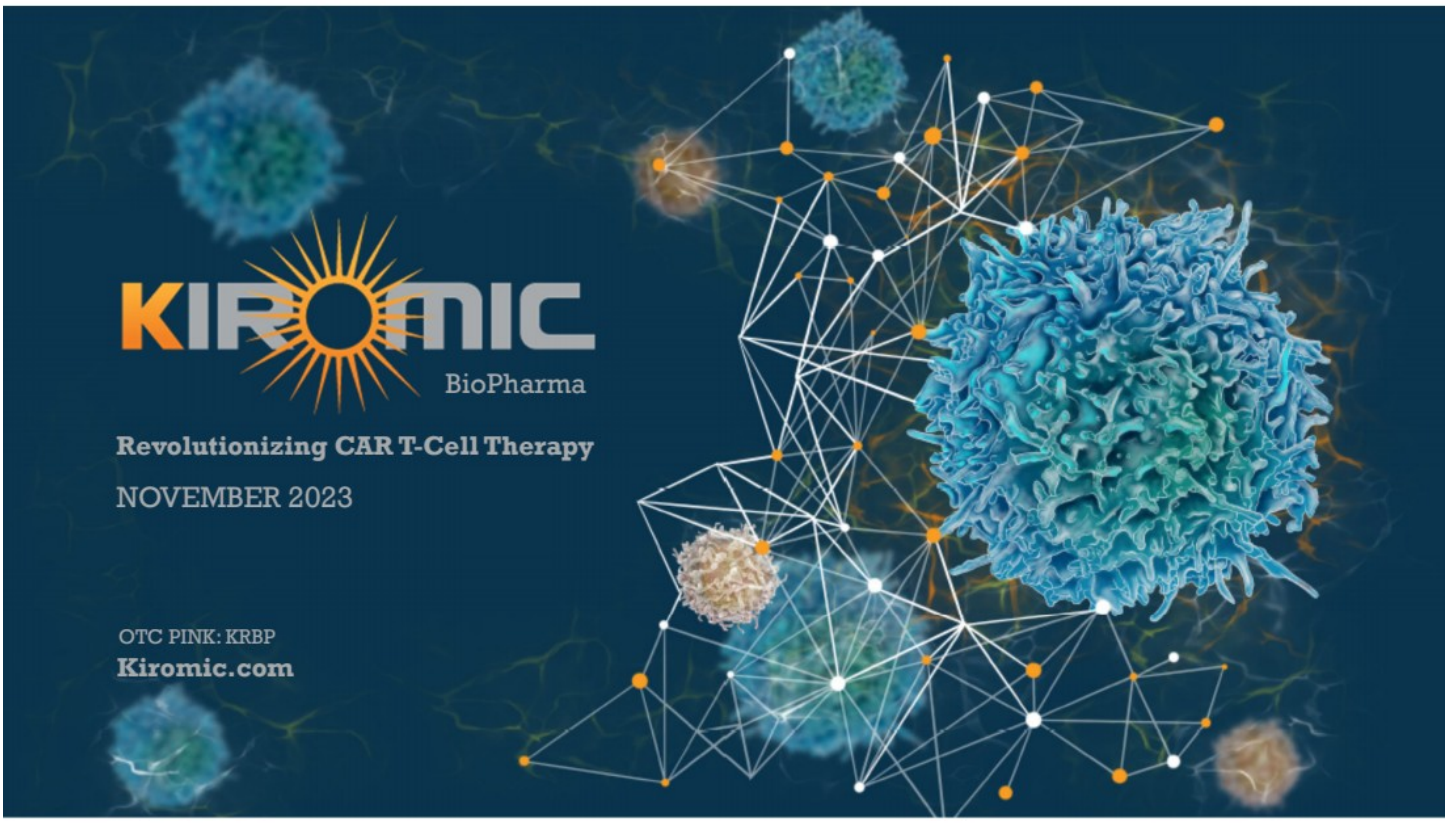
SIGNATURES

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: November 9, 2023

By: */s/ Pietro Bersani*
Pietro Bersani
Chief Executive Officer

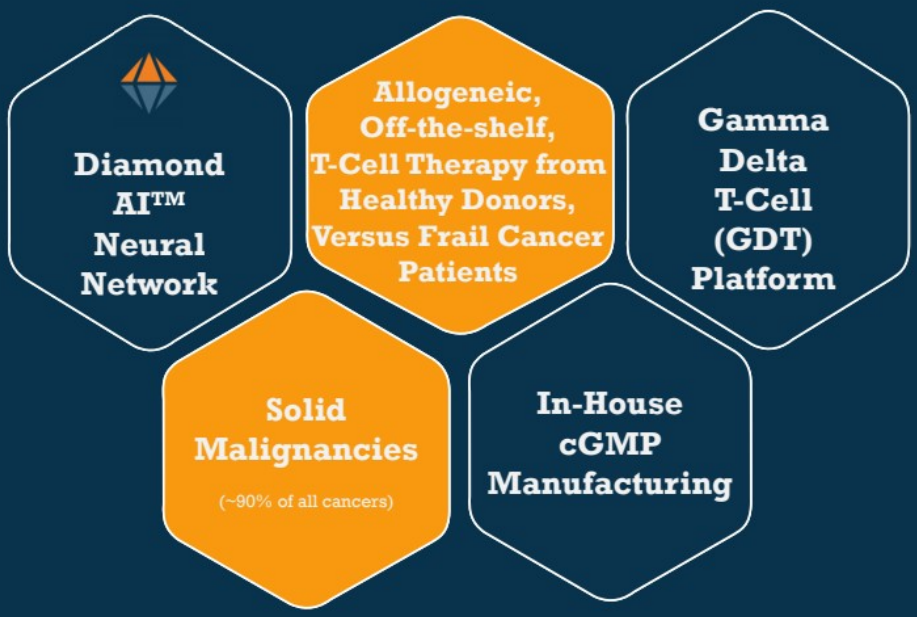

KIROMIC
BioPharma
Revolutionizing CAR T-Cell Therapy
NOVEMBER 2023
OTC PINK: KRBP
Kiromic.com

Forward Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. Kiromic makes such forward-looking statements pursuant to the safe harbor provisions of the United States 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. In some cases, you can identify forward-looking statements by terms such as: "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements regarding: Kiromic's current and anticipated IND applications including statements regarding the scope of and timing for submission of an IND application; the Deltacel™ product platform; the sponsored research agreement and the data that will be generated as a result of such collaboration; the timing for submitting and activating Kiromic's IND applications; the benefits of utilizing non-genetically engineered Gamma Delta T cells as our first in-human study; Kiromic's ability to achieve its objectives; and the timing for the initiation and successful completion of Kiromic's clinical trials of its product candidates. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in our Annual Report on Form 10-K for the year ended December 31, 2022, and as detailed from time to time in our SEC filings. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Such forward-looking statements relate only to events as of the date of this press release. We undertake no obligation to update any forward-looking statements except to the extent required by law.

The Kiromic Difference

Kiromic BioPharma is the only cell therapy company combining AI-driven genetically edited Gamma Delta T-cells (GDT) with proprietary targeting technology to address solid malignancies.

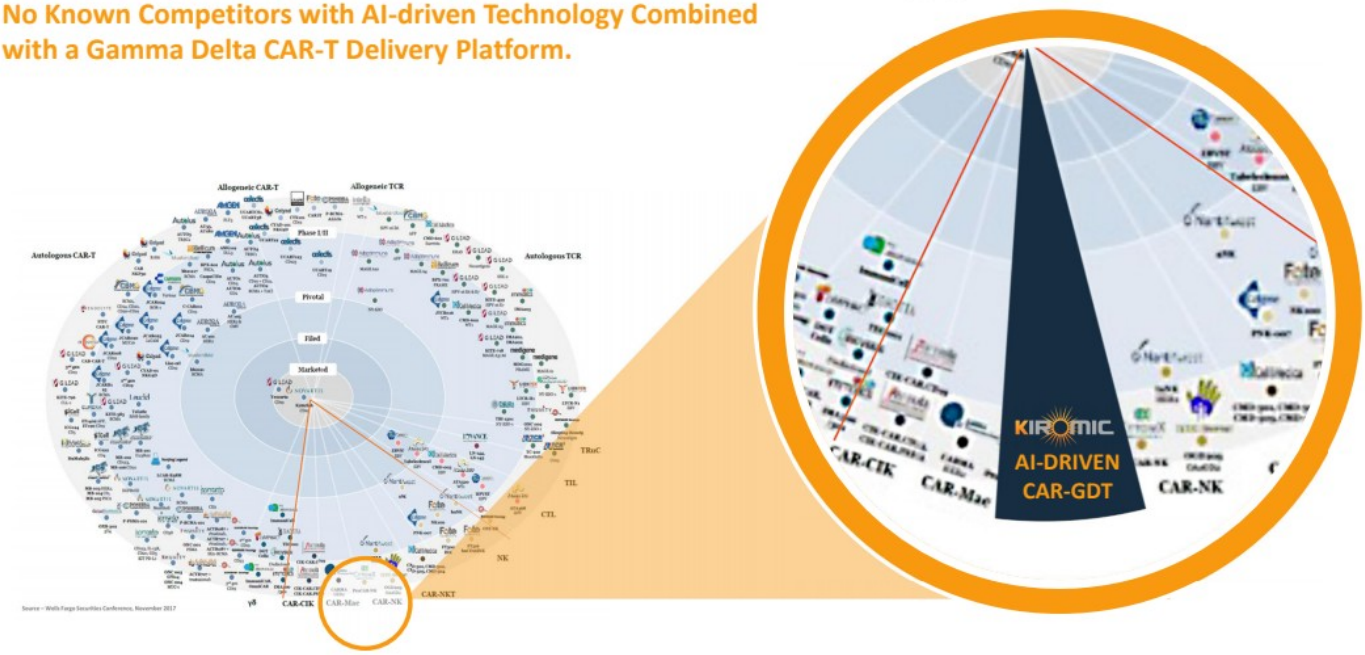


Contents

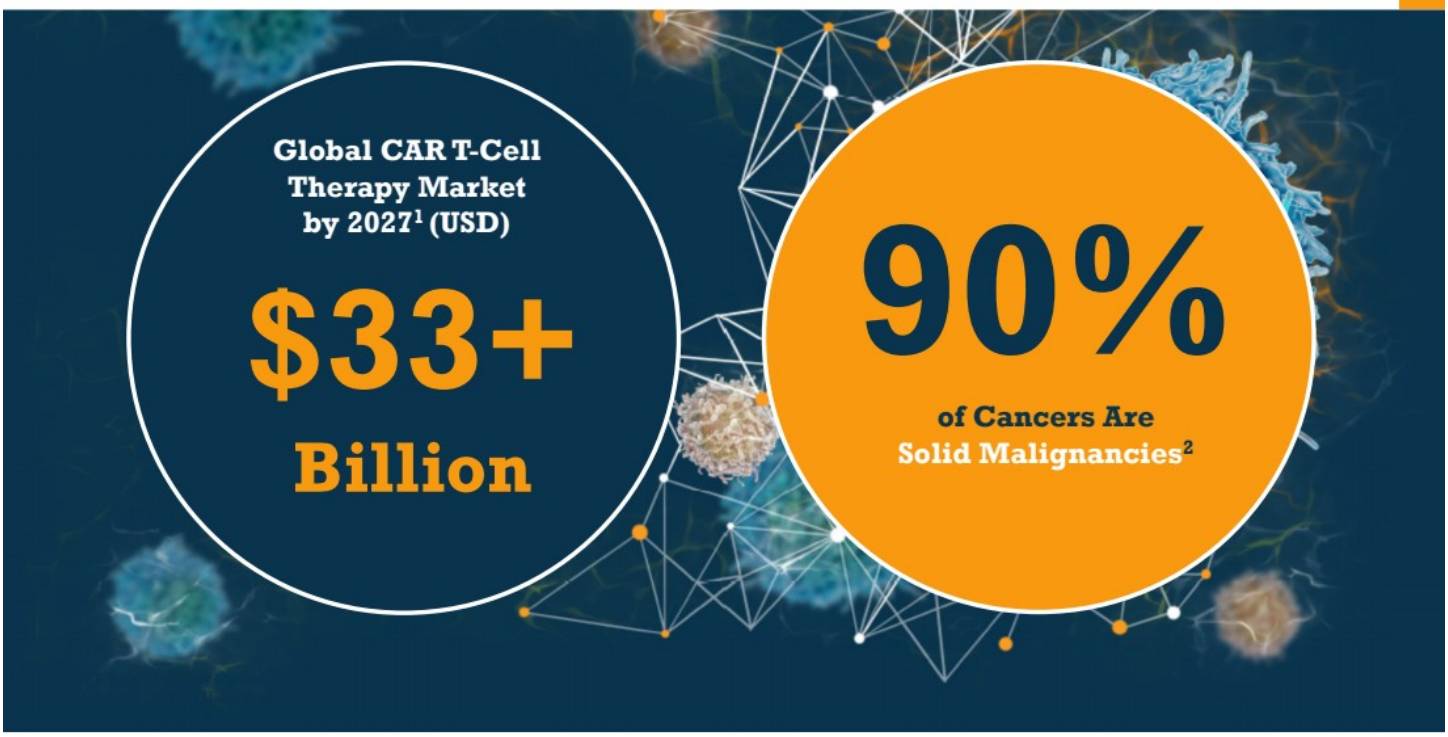
Strategic Competitive Landscape

8 Known Companies (including Kiromic) in the Gamma Delta T Cell Therapy space.

No Known Competitors with AI-driven Technology Combined with a Gamma Delta CAR-T Delivery Platform.



Solid Malignancy Market Opportunity



Competitive Difference

Allogeneic Gamma Delta Based T-Cell Therapies

Superior specificity for multiple solid tumors

Potential broad treatment for solid malignancies that express Kiromic developed biomarkers such as Iso-mesothelin.
Solid tumors represent approx. 90% of new cancer diagnoses but finding specific targets to treat them has been challenging.
Kiromic tackles the issue by identifying new cancer specific targets.

Vertical Integration

In-house **cGMP manufacturing**

In-house **QC/EM lab**

In-house **product and process development** (R&D and MSAT)

Superior Efficacy from γδT cells

Strong efficacy in pre-Clinical animal models.
In solid tumors, the benefit of infiltrating conventional T cells may vary.
In contrast, GDT cells are the infiltrating immune cells most likely to be associated with positive outcomes, as shown in an analysis of 18,000 tumors from 39 indications[1]

Lower Costs/ Greater Access[2]

1.Outpatient treatment means reduced hospitalization and other treatment related costs.

2. Lower projected cost
increases patient and health care professional access to these therapies, and potentially provides important quality-of-life benefits for patients as well.

1. Gentles AJ, Newman AM, Liu CL, *et al*. The prognostic landscape of genes and infiltrating immune cells across human cancers. Nat Med. 2015 Aug;21(8):938-945.
2. Maziarz RT. CAR T-cell therapy total cost can exceed $1.5M per treatment. Cell Therapy Next; May 29, 2019.

Contents

Artificial Intelligence and Bioinformatic Analytic Discovery & Development Platform

Algorithms and Large-Scale Genomics Analysis for Target Prediction

Diamond AI™

Artificial Intelligence Neural Network

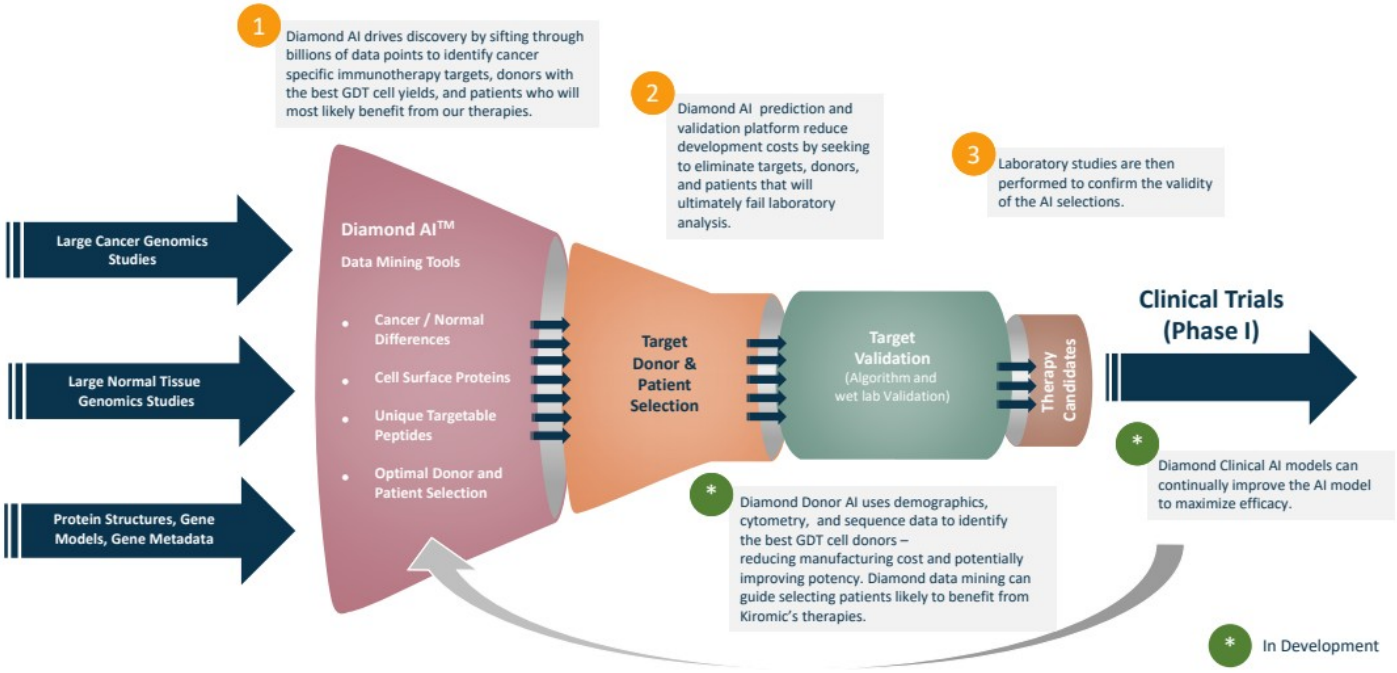
A.I. integrated with each stage of the Kiromic therapy production lifecycle

Discovering New Multi-tumor Targets

Identifying Optimal Donors and Patients to Maximize the Therapy Success

The Kiromic Difference - Diamond AI™ Target Discovery Platform

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



Contents

Kiromic GDT Cell Therapy Pipeline

Multiple Indications

Deltacel™

Unmodified, off-the-shelf product candidate targeting stress ligands on cancer cells
Initial indication: NSCLC in combination with targeted, low-dose radiation

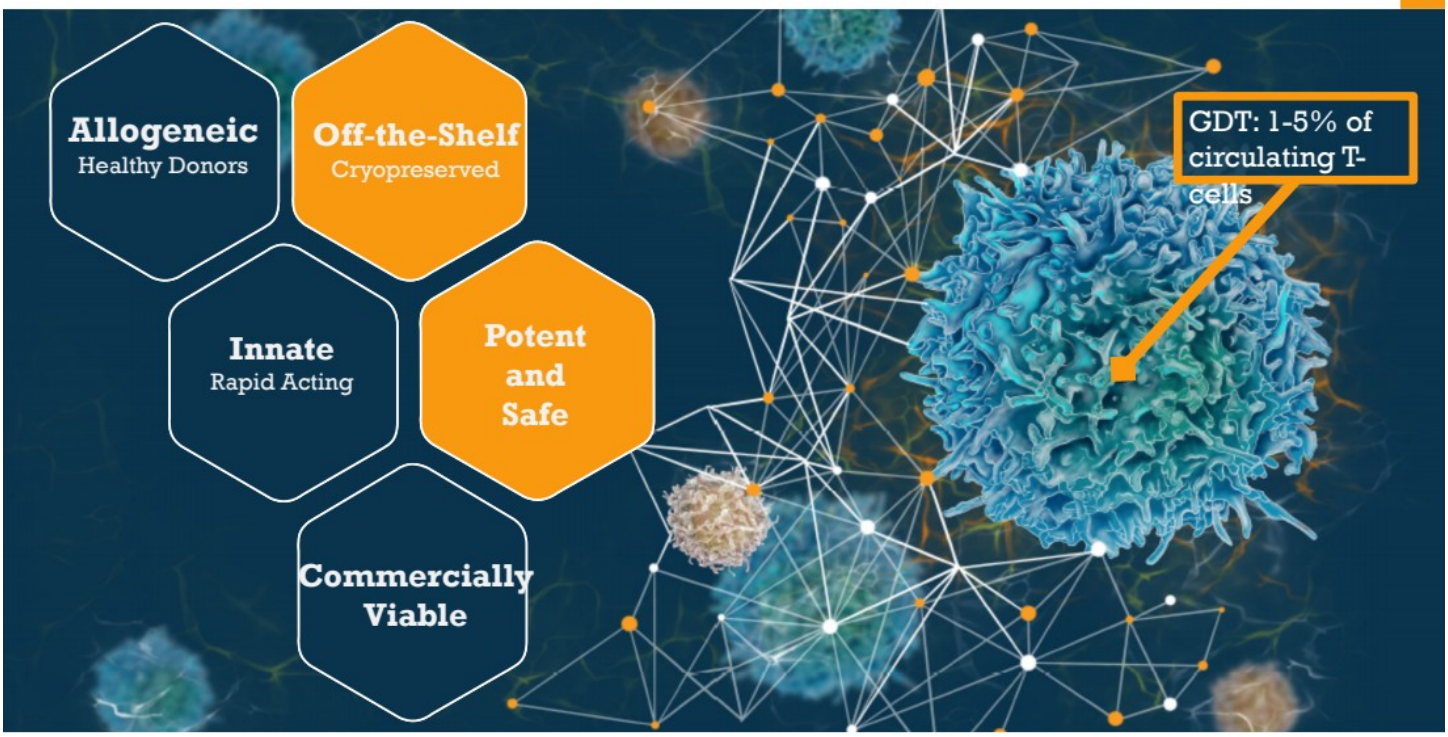
Isocel™

Engineered off-the-shelf product candidate targeting a tumor-specific variant of Mesothelin in Ovarian Cancer, Mesothelioma, and Pancreatic Cancer

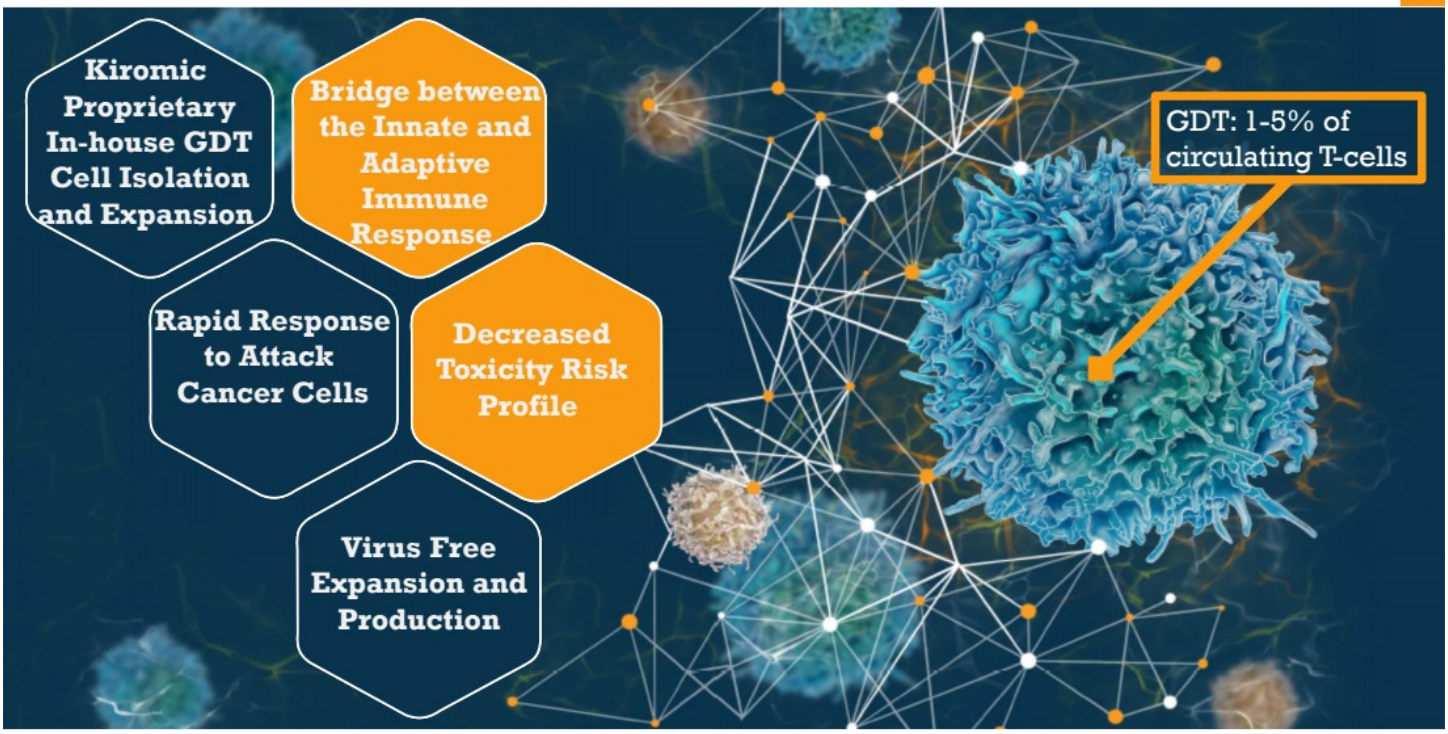
Procel™

Engineered off-the-shelf product candidate targeting PDL-1+ tumors

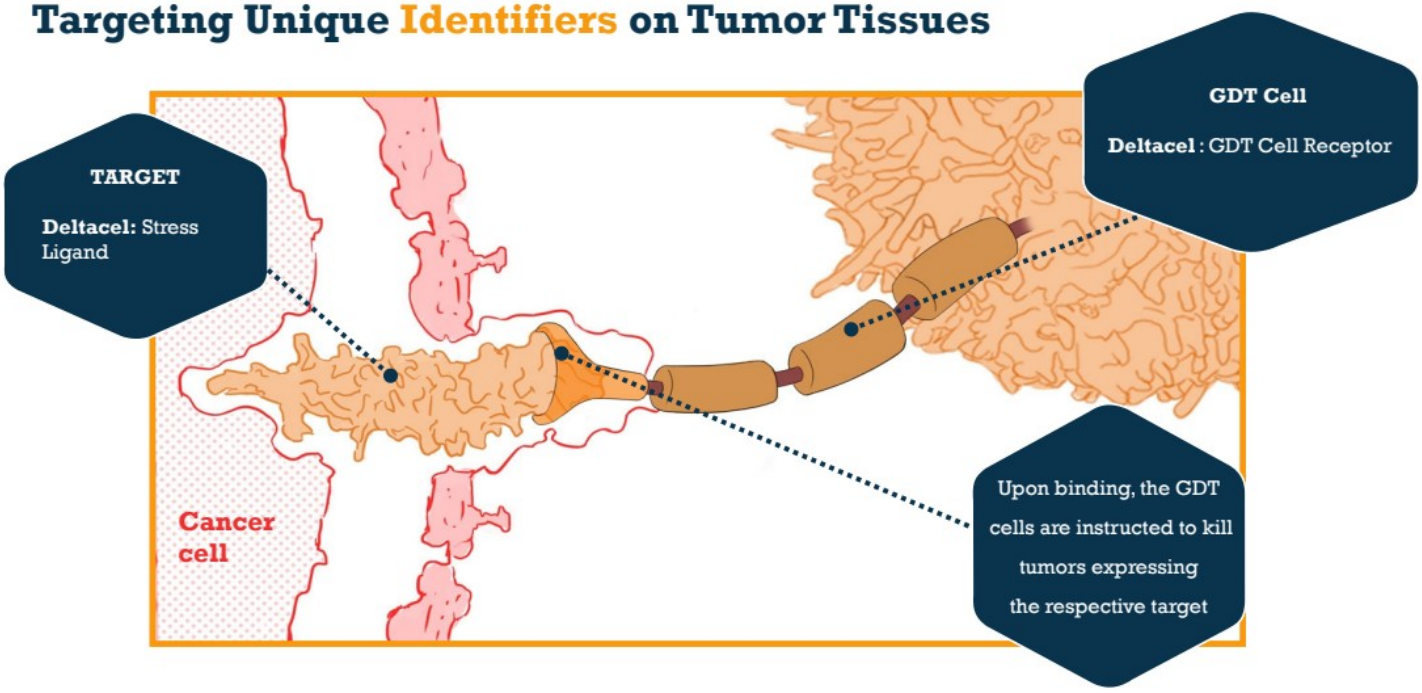
Gamma Delta T-Cells (GDT): Guardians of the Immune System



Deltacel: Non-Viral Gamma Delta T-Cell Development

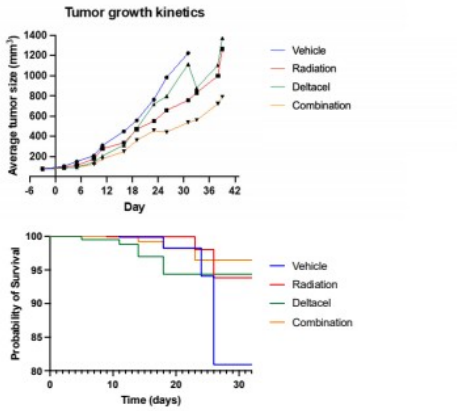


GDT Cell Therapy Mechanism of Action: Targeting Unique Identifiers on Tumor Tissues



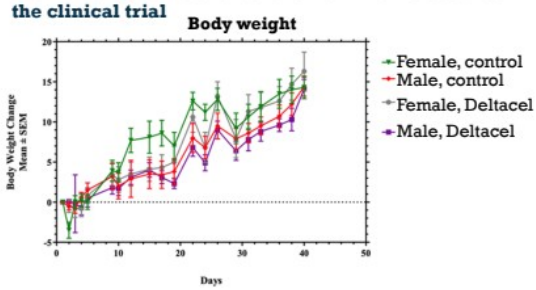
KB-GDT-01 T-Cell Therapy (Deltacel) Strong Efficacy

Deltacel™ effectively controls established A549 NSCLC tumors in immunocompromised mice when combined with a low-dose radiation



KB-GDT-01 T-Cell Therapy (Deltacel) Strong Safety

Deltacel™ does not cause any macroscopic or microscopic toxicity, even when given at over 8x the maximum dose that will be tested in the clinical trial

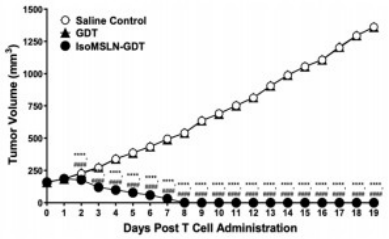


- ✓ There were no treatment-associated impacts on body weights, food consumption, or cage-side/clinical observations. Macroscopic evaluations at necropsy did not identify any evidence of test article-related toxicity. Microscopic histopathological evaluations showed no evidence of Deltacel-related toxicity
- ✓ Clinical pathology evaluations determined that all fluctuations among individual and mean values of tested analytes were considered sporadic, and not related to the administration of Deltacel.
- ✓ Plasma cytokine analysis showed that Deltacel administration did not result in the overproduction of inflammatory cytokines which may pose a safety concern.

GDT CAR T-Cell Therapy (Isocel™)* Strong Efficacy

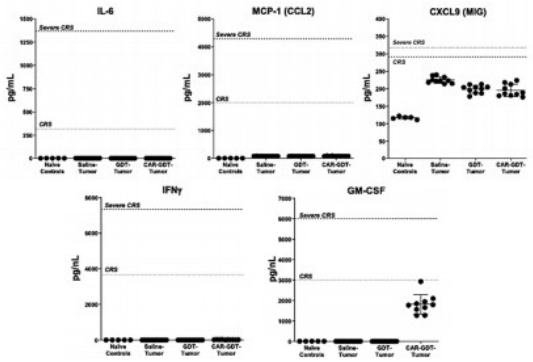
Isocel™ eradicates established NCI-H226 pleural epithelioid mesothelioma and prevents tumor growth in a model of recurrence.

Tumor eradication



GDT CAR T-Cell Therapy (Isocel™)* Strong Safety

Isocel™ does not lead to cytokine level increases modeled to cause severe CRS or CRS, with circulating cell numbers regulated by objective response.

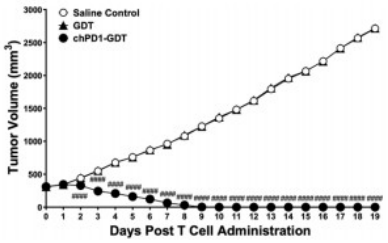


*Preclinical models: nude mice with subcutaneous NCI-H226 cells injections

GDT chPD1 T-Cell Therapy (Procel™)* Strong Efficacy

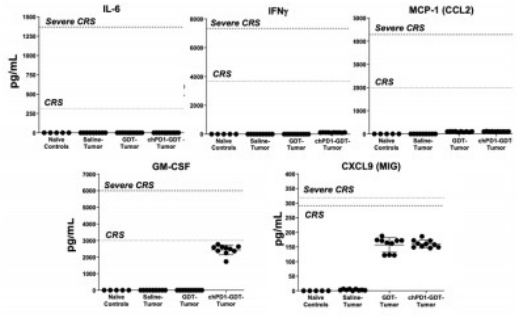
Procel™ eradicates established NCI-H226 pleural epithelioid mesothelioma and extends survival.

Tumor eradication



GDT chPD1 T-Cell Therapy (Procel™)* Strong Safety

Procel™ does not lead to cytokine level increases modeled to cause severe CRS or CRS, with circulating cell numbers regulated by objective response.



*Preclinical models: nude mice with subcutaneous NCI-H226 cells injections

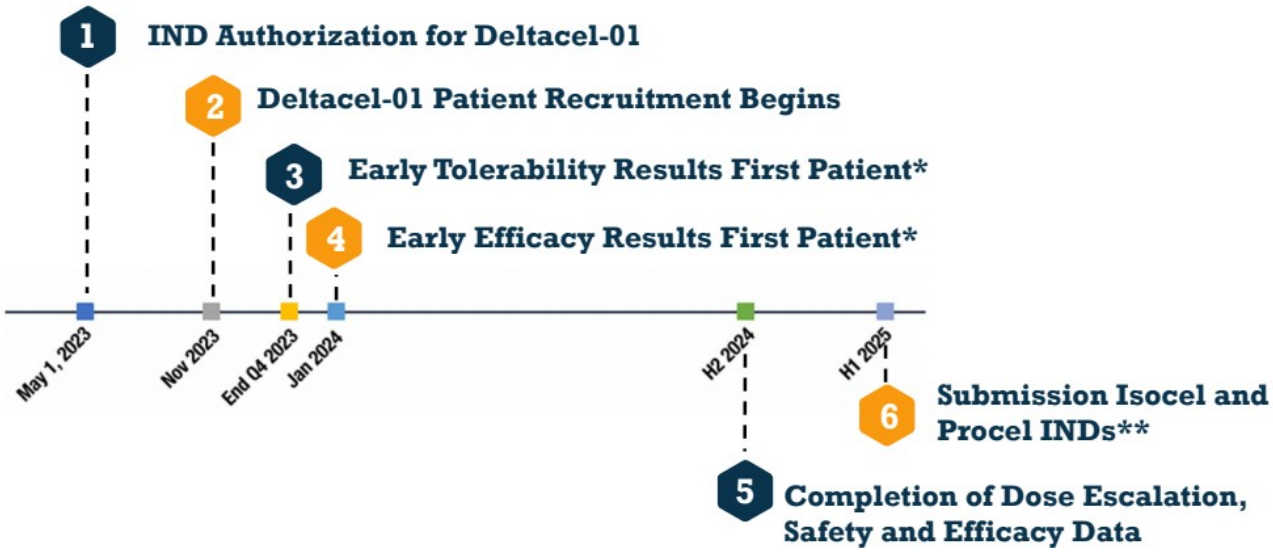
Pipeline

* Subject to obtaining sufficient financing to support the progression of the development of those additional clinical trial candidates.

In-House Manufacturing Creates De-Risked Value

Contents

Recent and Upcoming Milestones*



*The milestones and timing of completion are based upon the company's current expectations in consultation with its partners and vendors.
** Subject to obtaining sufficient financing to support the progression of the development of those additional clinical trial candidates.

Leadership Team

Pietro Bersani
CPA, CGMA

CEO

A&M
B2B CFO SINCE 1987
Fuel Systems Solutions
Deloitte.
ARTHUR ANDERSEN

Leonardo Mirandola
Ph.D.

CSO/INTERIM COO

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER
UNIVERSITÀ DEGLI STUDI DI MILANO
SEMM European School of Molecular Medicine

Scott Dahlbeck
MD, PharmD

COSO

Texas Tech Univ Health Science Center
aurora
ASA
UMC HEALTH SYSTEM
University of TX Health Science Center Houston
KAISER PERMANENTE
Hennepin Healthcare
University of Nebraska Medical Center College of Pharmacy

Brian Hungerford
CPA,CGMA

CFO

Deloitte.
MERRILL A BANK OF AMERICA COMPANY
accenture
Constellation.
DYNEGY

Board of Directors

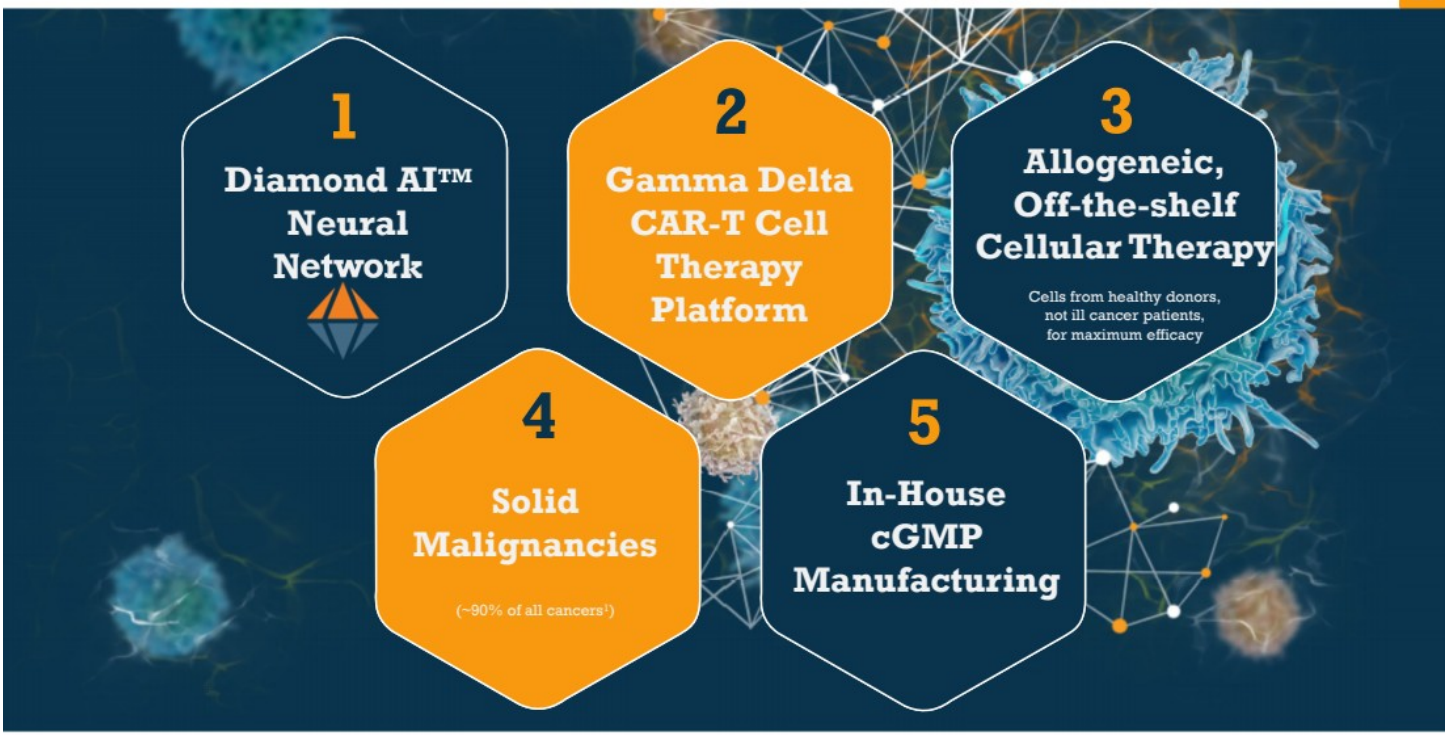
Michael Nagel	Pietro Bersani	Pam Misajon	Michael Catlin
Chairperson	CPA, CGMA Director	Independent Director	Independent Director

Summary Balance Sheet & Cap Table

Balance Sheet Data (As of June 30, 2023)	As Reported
Cash and Cash Equivalents	$2,707,136
Working Capital	($12,851,255)
Total Assets	$14,005,661
Total Stockholders' Deficit	($5,159,281)

Cap Table (As of June 30, 2023)	Common Stock Equivalents
Common Stock	1,176,290
Restricted Stock Units ($258.88 Weighted average grant date fair value)	632
Options ($287.58 Weighted average exercise price)	-
Warrants	-
Convertible Preferred Share Shares ($8MM principal & $6.50 share conversion)	1,230,769
Convertible Notes ($6MM principal a& $6.50 share conversion)	1,292,308
Fully Diluted Common Shares	3,699,999

Value Proposition Summary

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Kiromic BioPharma Announces Deltacel™ Phase 1 Clinical Trial Enters Patient Recruitment Phase at Beverly Hills Cancer Center

Company is Activating Additional Clinical Trial Sites Across the U.S.

HOUSTON (November 9, 2023) – Kiromic BioPharma, Inc. (OTC PINK: KRBP) ("Kiromic" or the "Company"), a clinical-stage, fully-integrated biotherapeutics company using its proprietary DIAMOND® artificial intelligence and data mining platform to develop cell therapies with a focus on immuno-oncology, announces the Deltacel™ Phase 1 Clinical Trial is now recruiting patients at the Beverly Hills Cancer Center (BHCC). The study will evaluate Deltacel™ (KB-GDT-01), Kiromic's allogeneic, off-the-shelf, Gamma Delta T-cell (GDT) therapy, in patients with metastatic non-small cell lung cancer (NSCLC).

The Company continues to engage additional clinical trial sites across the U.S, and will provide updates as additional sites are activated, and as patient recruitment starts at those locations.

The Phase 1 trial, titled "Safety Study for a Gamma Delta T Cell Product Used With Low Dose Radiotherapy in Patients With Stage 4 Metastatic NSCLC" (ID# NCT06069570), expects to enroll up to 48 patients. In this open-label, two-part trial, patients with stage 4 NSCLC will receive two intravenous infusions of Deltacel along with four courses of low-dose, localized radiation, over a 10-day period. The primary objective of the study is to evaluate the safety of Deltacel in combination with low-dose radiation; the secondary outcome measures are objective response, progression-free survival, overall survival, time to progression, time to treatment response, and disease control rates.

"We are delighted to announce the start of patient recruitment in our first clinical trial, and we look forward to working with BHCC and the other prestigious trial sites we will be activating across the U.S. Importantly, we are on target to dose our first patient, and we expect to have early tolerability and safety data from this patient available by the end of 2023," stated Pietro Bersani, Chief Executive Officer of Kiromic BioPharma. "We plan to assess preliminary efficacy by end of January 2024, and complete the dose-escalation portion of the study by the second half of 2024, at which point we expect to have sufficient evidence supporting the tolerability and the efficacy of Deltacel™. These are crucial steps forward as we advance our goal to bring a transformative new treatment to patients with advanced NSCLC."

About Deltacel™ (KB-GDT-01)

Deltacel (KB-GDT-01) is an investigational gamma delta T-cell (GDT) therapy currently in the Deltacel-01 Phase 1 trial for the treatment of non–small cell lung cancer. An allogeneic product consisting of unmodified, donor-derived gamma delta T cells, Deltacel is Kiromic BioPharma's lead candidate in its GDT platform. Deltacel is designed to exploit the natural potency of GDT cells to target solid cancers, with an initial focus on NSCLC, the most prevalent type of lung cancer and representing about 80% to 85% of lung cancer cases. Data from two preclinical studies demonstrated Deltacel's favorable safety and efficacy profile when it was combined with low-dose radiation.

About Beverly Hills Cancer Center

As a private, academic, community-based cancer center, Beverly Hills Cancer Center not only provides state-of-the-art cancer treatment modalities all under one roof, but also leading clinical trials and research for cancer that are offered at very few centers in the world, attracting patients globally and saving lives. By providing access to groundbreaking clinical trials, the Beverly Hills Cancer Center offers patients the opportunity to participate in the most advanced cancer treatments in development in the world. Beverly Hills Cancer Center is comprised of an internationally recognized multidisciplinary medical team consisting of medical oncologists, radiation oncologists, radiologists, hematologists, and internists who provide exceptional patient care and support services including a robust and highly efficient team of clinical research professionals. For more information, visit: www.bhcancercenter.com.

About Kiromic BioPharma

Kiromic BioPharma, Inc. is a clinical-stage, fully integrated biotherapeutics company using its proprietary DIAMOND® artificial intelligence (AI) 2.0 target discovery engine to develop and commercialize cell therapies focusing on immuno-oncology. Kiromic is developing a multi-indication allogeneic cell therapy platform that exploits the natural potency of Gamma Delta T-cells to target solid tumors. Kiromic's DIAMOND® AI is where data science meets target identification to dramatically compress the years and hundreds of millions of dollars required to develop a live drug. The Company maintains offices in Houston, Texas. To learn more, visit www.kiromic.com and connect with us on Twitter and LinkedIn.

Forward-Looking Statements

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