



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

November 9, 2023

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

HOUSTON--(BUSINESS WIRE)--Nov. 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](http://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](http://www.kiromic.com) and connect with us on [Twitter](#) and [LinkedIn](#).

### **Forward-Looking Statements**

This press release 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 ability to achieve its objectives and Kiromic’s financing strategy and availability of funds. 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 other 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.

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