



## **Kiromic BioPharma Announces First Patient Dosed in Phase 1 Study Evaluating Deltacel™ for the Treatment of Non-Small Cell Lung Cancer**

December 14, 2023

### ***Initial Tolerability and Safety Data from First Patient Expected by Year-End, with Preliminary Efficacy Results by End of January 2024***

HOUSTON--(BUSINESS WIRE)--Dec. 14, 2023-- **Kiromic BioPharma, Inc. (OTCQB: 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 that the first patient has initiated treatment at the Beverly Hills Cancer Center (BHCC) in the Company's Deltacel-01 clinical trial. This Phase 1 study is evaluating Deltacel™ for the treatment of stage 4 metastatic non-small cell lung cancer (NSCLC).

Initial tolerability and safety data from this first patient is expected to be available by year-end. Additionally, Kiromic expects to report preliminary efficacy results from the first patient by the end of January 2024.

The Company expects that the Deltacel-01 clinical trial will start enrolling patients at two additional clinical sites in early 2024.

"We are extremely proud to initiate this first-in-human trial of Deltacel when we stated we would," said Pietro Bersani, Chief Executive Officer of Kiromic. "Non-small cell lung cancer represents a significant unmet medical need, and a leading cause of death in the U.S. We look forward to enrolling additional patients to advance the clinical development of Deltacel for the treatment of solid tumors, starting with NSCLC."

"Beverly Hills Cancer Center is pleased to announce the dosing of the first patient in our Deltacel-01 study," said Dr. Afshin Eli Gabayan, Medical Oncologist, Medical Director, and Principal Investigator at Beverly Hills Cancer Center. "We are excited about the potential of this novel Gamma Delta T-cell therapy combined with low dose radiation for our patients with lung cancer who have few treatment options left. We look forward to evaluating long term safety and efficacy outcomes as the study progresses."

Dr. Arash Gabayan, Radiation Oncologist at Beverly Hills Cancer Center and the sub-investigator who administered the low dose radiation treatments, commented: "The first course of combination of Deltacel and low dose radiation was successfully delivered to this first patient. Our clinical research team will continue monitoring this patient closely as we seek to understand how this innovative and exciting dual approach may impact the immune response against the cancer cells. We are hopeful that this investigational treatment approach can make a meaningful difference for lung cancer patients."

In Kiromic's open-label Phase 1 clinical trial, titled "Phase 1 Trial Evaluating the Safety and Tolerability of Gamma Delta T Cell Infusions in Combination With Low Dose Radiotherapy in Subjects With Stage 4 Metastatic Non-Small Cell Lung Cancer" ([NCT06069570](#)), patients with stage 4 NSCLC will receive two intravenous infusions of Deltacel with four courses of low-dose, localized radiation over a 10-day period. The primary objective of the study is to evaluate safety, while secondary ones include objective response, progression-free survival, overall survival, time to progression, time to treatment response, and disease control rates.

### **About Deltacel™**

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 leading 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 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](#).

### **About Beverly Hills Cancer Center**

As a private, academic, community-based cancer center, Beverly Hills Cancer Center not only provides the latest state-of-the-art cancer treatments all under one roof, but also provides leading clinical trials and research, attracting patients globally. By providing access to groundbreaking clinical trials, the Beverly Hills Cancer Center offers patients the opportunity to participate in the most advanced cancer treatments currently in development in the world. Beverly Hills Cancer Center is composed 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. More information is available on: [www.BHCancerCenter.com](http://www.BHCancerCenter.com).

## 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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### **Kiromic BioPharma**

Linda Phelan Dyson, MPH  
Global Head, Corporate Communications  
[ldyson@kiromic.com](mailto:ldyson@kiromic.com)  
281-468-7683

### **LHA Investor Relations**

Tirth T. Patel  
[tpatel@lhai.com](mailto:tpatel@lhai.com)  
212-201-6614

### **Beverly Hills Cancer Center**

Sharon Gabayan, MBA  
Chief Strategy Officer  
[SN@bhcancercenter.com](mailto:SN@bhcancercenter.com)  
310-432-8925

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