



## Results from First Patient in Kiromic BioPharma's Deltacel-01 Clinical Trial Indicate Tumor Reduction at Two Months

February 14, 2024

### ***Second Patient Completed Treatment and Third Patient Dosed in Phase 1 Study Evaluating Deltacel™ for the Treatment of Non-Small Cell Lung Cancer***

HOUSTON--(BUSINESS WIRE)--Feb. 14, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP)** ("Kiromic" or the "Company") announces continued encouraging clinical findings from the most recent follow-up visit of the first patient enrolled in Deltacel-01, the Company's Phase 1 clinical trial evaluating Deltacel™ for the treatment of stage 4 metastatic non-small cell lung cancer (NSCLC). After stable disease and preliminary progression-free survival of one and a half months were reported six weeks post-treatment, the two-month follow-up PET/CT scan revealed that the patient's tumor size was reduced by 6.6%, and no new disease sites (metastasis) were detected. In addition, a 20% decrease in the tumor lesion's metabolism was noted.

This patient, who was treated at the Beverly Hills Cancer Center (BHCC), continues to do well two months following treatment.

"We are proud and excited to report these highly promising early results showing tumor reduction in a patient population that has few treatment options available. When considering that the first patient enrolled in Deltacel-01 suffered from an actively progressing disease immediately prior to therapy, this is a remarkable finding. We look forward to advancing our trial and to treating additional patients," said Pietro Bersani, Chief Executive Officer of Kiromic.

Kiromic also reports that the second patient in the Deltacel-01 clinical trial has received the second and final infusion of Deltacel. Kiromic expects to report initial tolerability and safety data from this patient in early March, and preliminary efficacy results by the end of the first quarter.

Additionally, Kiromic reports that the third patient has been enrolled and is expected to complete treatment on February 21. Both the second and third patients are being treated at BHCC. The Deltacel-01 clinical trial is expected to start enrolling patients at two additional clinical trial sites in the first half of the year.

"The preliminary data from our first patient offers promising insights into the effectiveness of Gamma Delta T-cell therapy when used alongside low-dose radiation for this condition. We are encouraged by the preliminary data on the first patient and are optimistic about the outcomes of the subsequent patients in the study. We continue to evaluate safety and efficacy outcomes as this study progresses, and are pleased to have enrolled two additional patients in the Deltacel-01 study," said Afshin Eli Gabayan, M.D., Medical Oncologist, Medical Director and Principal Investigator at Beverly Hills Cancer Center.

#### **About Deltacel-01**

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 measurements 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 stage 4 metastatic NSCLC. An allogeneic product consisting of unmodified, donor-derived gamma delta T cells, Deltacel is the leading candidate in Kiromic's GDT platform. Deltacel is designed to exploit the natural potency of GDT cells to target solid cancers, with an initial clinical focus on NSCLC, which represents 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20240214056810/en/): <https://www.businesswire.com/news/home/20240214056810/en/>

### **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 Neman  
Chief Strategy Officer  
[SN@BHCancerCenter.com](mailto:SN@BHCancerCenter.com)  
310-432-8925

Source: Kiromic BioPharma, Inc.