



## **Kiromic BioPharma Reports Favorable Safety, Tolerability, and Early Efficacy from Third Patient in Deltacel-01 Clinical Trial**

April 2, 2024

*Trial's Safety Monitoring Committee Recommends Maintaining Initial Cell Dose Level for Next Cohort of Patients*

HOUSTON--(BUSINESS WIRE)--Apr. 2, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) ("Kiromic" or the "Company")** reports early efficacy results showing tumor stabilization in the third patient enrolled in the Company's Deltacel-01 Phase 1 clinical trial. Deltacel-01 is evaluating Deltacel™ (KB-GDT-01), Kiromic's allogeneic, off-the-shelf, Gamma Delta T-cell (GDT) therapy, in patients with stage 4 metastatic non-small cell lung cancer (NSCLC) who have failed to respond to standard therapies.

Preliminary imaging results for this last patient in the first cohort, obtained six weeks after beginning treatment, show a favorable safety and tolerability profile, and promising early efficacy for the Deltacel™ treatment. While this patient presented with active disease at the time of enrollment, PET/CT, diagnostic CT and MRI scans showed disease stabilization at all tumor sites with no new sites of metastatic disease. This patient is being treated at the Beverly Hills Cancer Center (BHCC).

Additionally, the Deltacel-01 Safety Monitoring Committee (SMC) convened to analyze all preliminary patient data received to date and to determine the next phase of the trial. After reviewing safety and efficacy findings from the first cohort of three patients, the SMC recommended not to escalate the cell dose level and instead to treat the next cohort of patients at the initial dose level. This unanimous recommendation was based on encouraging preliminary data supporting Deltacel™ safety and tolerability, and evidence of anti-tumor activity.

"Early findings from the first three patients enrolled in Deltacel-01 – especially the consistent favorable safety profile and signs of efficacy – reinforce our commitment to advancing Deltacel™ as a potential off-the-shelf, Gamma Delta T-cell therapy. We are particularly pleased to observe a growing body of evidence that Deltacel™ could be a significant step forward in treating cancer. Our team is inspired by these results and remains dedicated to further testing the therapeutic potential of Deltacel™, as confirmed by SMC's recommendation not to increase the Deltacel™ dose level. Achieving a therapeutic effect with the initial dose level will benefit patients, while not having to test additional dose levels will shorten the overall length of the Phase 1 clinical trial," said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma.

### **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](https://clinicaltrials.gov/ct2/show/study/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 Deltacel-01 trial 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 all 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, the 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 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. More information is available at [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, 2023, 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/20240402903280/en/): <https://www.businesswire.com/news/home/20240402903280/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.