



Early Efficacy Results Show Primary Lung Tumor Stabilization and Complete Disappearance of Brain Metastases in Second Patient in Kiromic BioPharma's Deltacel-01 Clinical Trial

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Favorable Safety and Tolerability also Observed

HOUSTON--(BUSINESS WIRE)--Mar. 19, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) ("Kiromic" or the "Company")** reports early efficacy results showing primary lung tumor stabilization and the complete disappearance of brain metastases in the second patient 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).

Preliminary results obtained six weeks from the beginning of treatment show Deltacel's efficacy in controlling tumor growth, as well as favorable safety and tolerability. Stable disease status was confirmed by CT scan. An MRI scan of the patient's brain performed before treatment began noted new onset metastatic disease, which completely resolved on repeat MRI imaging performed six weeks from the beginning of treatment. This patient is being treated at the Beverly Hills Cancer Center (BHCC).

"These six-week results in the second patient enrolled in Deltacel-01 are extremely promising. Along with preliminary results from the first patient [we previously reported](#), they strengthen the candidacy of Deltacel as a potential treatment for patients with advanced disease. The complete eradication of this patient's preexisting brain metastases supports a growing body of evidence for the benefit of our therapy and could also support Deltacel-01 crossing the blood-brain barrier," said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma.

"These preliminary results, especially the CT and MRI scan findings and the absence of dose-limiting toxicities, underscore the promise of Deltacel as a potentially efficacious therapy. We are cautiously optimistic given we have achieved a stable disease status for this patient. This aligns with our center's commitment to bringing pioneering care for patients with few or no available treatment options," commented Afshin Eli Gabayan, M.D., Medical Oncologist, Medical Director, and Principal Investigator at BHCC.

Kiromic expects to announce initial safety, tolerability, and preliminary efficacy results from the third patient enrolled in Deltacel-01 by the end of March.

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 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.

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

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.

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Kiromic BioPharma

Linda Phelan Dyson, MPH
Global Head, Corporate Communications
ldyson@kiromic.com
281-468-7683

LHA Investor Relations

Tirth T. Patel
tpatel@lhai.com
212-201-6614

Beverly Hills Cancer Center

Sharon Neman
Chief Strategy Officer
SN@BHCancerCenter.com
310-432-8925

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