



Kiromic BioPharma Reports 32% Decrease in Tumor Volume Eight Months Post-Treatment in Fourth Patient Enrolled in Deltacel-01

December 12, 2024

HOUSTON--(BUSINESS WIRE)--Dec. 12, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) ("Kiromic" or the "Company")** reports favorable ongoing efficacy results from the eight-month follow-up visit for the fourth patient enrolled in its Deltacel-01 Phase 1 clinical trial, and provides additional updates on the first and seventh patients. This trial is evaluating Deltacel™ (KB-GDT-01), the Company'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.

8-Month Follow-Up for Patient #4: Partial Response with Tumor Reduction of 32%

Preliminary results from the eight-month follow-up visit for the fourth patient enrolled in Deltacel-01 revealed an approximately 32% decrease in tumor volume compared with the pre-treatment size. This patient continues to experience clinical benefit without adverse events.

11-Month Follow-Up for Patient #1: Stable Disease Maintained

The first patient enrolled in the Deltacel-01 trial has maintained stable disease with no evidence of disease progression or new sites of malignancy. Kiromic last reported that in this patient, the tumor size was reduced by approximately 27% compared with the pre-treatment size, and no new sites of disease were identified. As a result, the PFS has reached 11 months with no reported adverse events. This patient's final follow-up visit is scheduled for the end of December.

Patient #7 Completes Treatment

The seventh patient successfully completed the Deltacel-01 treatment regimen and is tolerating therapy well. Initial efficacy results for this patient are expected in early January 2025.

Patient #8 Enrolled

The eighth patient in the Deltacel-01 clinical study was enrolled this week at the Clinical Research Advisors Koreatown, a satellite location of the Beverly Hills Cancer Center (BHCC).

"The magnitude of the tumor reduction observed in Patient #4 is significant and highly encouraging. We look forward to reporting results from the first and seventh patients in January, and expect to enroll additional patients through the beginning of 2025," said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma.

"The remarkable 32% tumor reduction seen in the fourth patient treated with Deltacel is truly exciting and holds great promise for improving outcomes for patients with advanced lung cancer. As a leading cancer center focused on delivering the most innovative and effective therapies, we are proud to partner with Kiromic on this important clinical trial. The early safety and tolerability data, coupled with these signs of robust antitumor activity, suggest Deltacel's promise as a transformative new treatment option. We look forward to continued enrollment and results that could change the standard of care for these patients who have exhausted other options," said Dr. Afshin Eli Gabayan, Medical Oncologist, Medical Director, and Principal Investigator at Beverly Hills Cancer Center. "At the Beverly Hills Cancer Center, our mission is to provide our patients with access to the most advanced and cutting-edge cancer treatments available. By working with visionary companies like Kiromic, we are able to offer our patients the opportunity to participate in groundbreaking clinical trials that have the potential to transform cancer care. We look forward to continuing to support the Deltacel-01 trial and reporting on the progress of the additional patients enrolled at our center. Together, we are making important strides in the fight against this devastating disease."

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 Deltacel-01 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 the 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 Clinical Research Advisors LLC

Founded in 2022 by current researchers and technology entrepreneurs at Beverly Hills Cancer Center, Clinical Research Advisors is a first-of-its-kind clinical trial optimization company harnessing the power of AI and real-world data capitalizing on the decade success of the high-quality clinical trial program developed at its main site, Beverly Hills Cancer Center, established over 15 years ago. Having a central site makes us different than other site networks. We strive to accelerate the development of new treatments and cures by addressing major roadblocks in patient recruitment and site activation. By leveraging our central site, Beverly Hills Cancer Center, integrated network of growing satellite sites and advanced technologies, we aim to make clinical research participation more accessible and efficient. More information is available at www.ClinicalResearchAdvisors.com

About Kiromic BioPharma

Kiromic BioPharma, Inc. is a clinical-stage, fully integrated biotherapeutics company developing a multi-indication allogeneic cell therapy platform that exploits the natural potency of Gamma Delta T-cells to target solid tumors. Kiromic is using its proprietary DIAMOND[®] artificial intelligence (AI) 2.0 platform to discover novel targets for immuno-oncology. The Company maintains offices in Houston, Texas. To learn more, visit www.kiromic.com and connect with us on [Twitter](https://twitter.com) and [LinkedIn](https://www.linkedin.com).

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. 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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Source: Kiromic BioPharma, Inc.