Kiromic BioPharma Reports Consistent Favorable Safety, Tolerability, and Efficacy in Deltacel-01 Clinical Trial First Three Patients

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Follow-up Scans Show Continued Stable Disease in First Patient Cohort

Company to Apply for FDA Fast Track Designation

HOUSTON--(BUSINESS WIRE)--Apr. 24, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) (“Kiromic” or the “Company”)** announces consistent favorable safety, tolerability, and efficacy from follow-up visits of the first cohort of three patients 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). All three patients in the first cohort are being treated at the Beverly Hills Cancer Center (BHCC).

Two months after completing treatment, Patients 2 and 3 continued to show stable disease. Imaging scans from Patient 2 also showed no brain metastases, confirming findings from that patient’s six-week follow-up visit.

Four months after completing treatment, the first patient continues to show stable disease compared with the two-month post-treatment scans, which showed a primary tumor size reduction of 6.6%. The four-month follow-up for the second and third patients on trial is scheduled for June.

A summary of all findings reported to date for the first cohort can be found in the table below.

In addition, the fourth patient in Deltacel-01 completed treatment on April 18 at BHCC. Kiromic expects to report preliminary safety, tolerability, and early efficacy results from this patient in May.

Based on encouraging preliminary results from the first patient cohort, Kiromic intends to apply for Fast Track Designation (FTD) from the U.S. Food and Drug Administration (FDA) by the end of the second quarter. FTD offers several benefits and expedited review of drugs targeting a serious condition and fulfilling an unmet medical need, including NSCLC. FTD also facilitates more frequent communication with the FDA, enabling sponsors to receive timely feedback and guidance throughout the drug-development process. Additionally, FTD may qualify Deltacel for Accelerated Approval and Priority Review, potentially reducing the time required to bring the drug to market.

"We are highly encouraged by the initial outcomes from the first three patients in our Deltacel-01 Phase 1 clinical trial. Consistency in safety, tolerability, and disease stability is of paramount importance at this stage of testing, and the data thus far bolster our confidence in Deltacel's potential as a transformative treatment," stated Pietro Bersani, Chief Executive Officer of Kiromic BioPharma. "The findings are especially promising considering the robustness of response in the absence of brain metastasis, and the notable reduction in tumor size for the second and the first patient, respectively.

"These early results establish the foundation of our planned FDA application for Fast Track Designation. Achieving this designation could significantly accelerate the process to bring Deltacel to patients versus traditional timelines. We also have the potential to apply for Breakthrough Therapy Designation, enabling more guidance due to demonstrating a substantial improvement over current standard of care. We look forward to sharing more updates, including the results from additional patients, as Deltacel-01 progresses."

Patient	Safety	Six Weeks Post-treatment	Two Months Post-treatment	Four Months Post-treatment
1	No dose-limiting toxicities	Stable disease	Tumor size reduction of 6.6%	Stable disease compared with two-month follow-up
2	No dose-limiting toxicities	Stable disease Complete resolution of brain lesions	Stable disease Confirmed clean brain scan No new brain lesions	Expected in June 2024
3	No dose-limiting toxicities	Stable disease	Stable disease	Expected in June 2024

"We are very pleased with the initial safety and efficacy results seen in the first cohort of patients treated with Deltacel as part of the Phase 1 clinical trial at our cancer center. The consistency we have observed so far in disease control and lack of dose limiting toxicities is encouraging," said Dr. Afshin Eli Gabayan, Medical Oncologist, Medical Director and Principal Investigator at BHCC. "As one of the pioneers of immuno-oncology clinical research, we strive to help advance promising treatments like Deltacel, through our expertise and partnerships with leaders in cellular therapy innovation. Seeing signs of early response and tolerability gives hope for patients facing late-stage cancer. We will continue supporting efforts to better understand and potentially transform outcomes for lung cancer patients."

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 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 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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