Kiromic BioPharma Reports Six-Month Results from First Patient Enrolled in Deltacel-01 Clinical Trial

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Favorable Follow-up Findings Include Stable Disease and a 13% Decrease in Tumor Size

HOUSTON--(BUSINESS WIRE)--Jun. 6, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) (“Kiromic” or the “Company”)** reports favorable six-month follow-up results from the first patient enrolled in the Deltacel-01 Phase 1 clinical trial. 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.

Scans taken six months post-treatment showed the patient’s tumor size had decreased by 13% compared with the pre-treatment size, and no new tumor lesions were detected, which translates into a six-month progression-free survival. In addition, no dose-limiting toxicities were reported, reinforcing the safety profile of Deltacel observed in previous follow-up visits. This patient is being treated at the Beverly Hills Cancer Center (BHCC).

“We are delighted to report that Patient 1 in the Deltacel-01 clinical trial has achieved six-month progress-free survival, and that they continue to do well with no side effects. This is an important clinical milestone that underscores the potential of Deltacel in treating advanced cancers,” said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma. “Notably, we observed a 13% decrease in tumor size. These results are encouraging and support our belief in the potential of Deltacel to provide an effective new treatment for patients with advanced cancers. We are committed to advancing this trial and bringing hope to those with limited treatment options.”

Kiromic continues to expect to report long-term follow-up results for the other two subjects in the first cohort and the first subject in the second cohort by the end of June.

Additionally, the fifth patient in Deltacel-01 began treatment in May, is currently doing well without any signs of toxicity and is expected to have their first efficacy assessment in July. The sixth patient is currently undergoing pre-enrollment screening and is projected to start treatment in mid-June.

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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