Kiromic BioPharma Reports Favorable 10-Month Follow-Up Results for the First Patient Treated in its Deltacel-01 Clinical Trial

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HOUSTON--(BUSINESS WIRE)--Oct. 1, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) (“Kiromic” or the “Company”)** reports good safety and favorable ongoing efficacy results from the 10-month follow-up visit of the first patient treated in its 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.

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 progression-free survival (PFS) has reached 10 months with no reported adverse events. These results follow an approximate 20% reduction in tumor size detected at eight months post-treatment and an approximate 13% reduction at six months post-treatment. This patient is being treated at the Beverly Hills Cancer Center (BHCC).

“As this patient is the most advanced in our ongoing Deltacel-01 clinical trial, we are particularly encouraged by these latest follow-up results that continue to validate the potential of Deltacel as a safe and effective treatment for patients with later-stage cancers,” said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma. “We believe these findings underscore the promise of our allogeneic GDT therapy in providing durable clinical benefit.”

“The latest results from this patient are highly promising, particularly given the durable progression-free survival and tumor reduction we observed,” said Afshin Eli Gabayan, M.D., Medical Oncologist, Medical Director and Deltacel-01 Principal Investigator at BHCC. “This patient’s response to Gama Delta T-Cell Treatment continues to provide optimism as we evaluate Deltacel’s therapeutic potential. Continued meaningful results could represent a significant breakthrough for these late-stage cancer patients with limited treatment options.”

Kiromic expects to report additional follow-up results from the fourth patient enrolled in this study in October.

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

Beverly Hills Cancer Center
Sharon Neman, MBA
Chief Strategy Officer
SN@bhcancercenter.com
310-432-8925

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