



Kiromic BioPharma Reports Favorable Early Efficacy Results from First Patient in Deltacel-01 Phase 1 Clinical Trial in Non-Small Cell Lung Cancer

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Stabilization of Disease Observed at Six Weeks, Therapy Continues to Be Well Tolerated

HOUSTON--(BUSINESS WIRE)--Jan. 29, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) (“Kiromic” or the “Company”)** reports favorable early efficacy results from the first patient enrolled in the Phase 1 Deltacel-01 clinical trial with Deltacel™ for treating stage 4 metastatic non-small cell lung cancer (NSCLC).

Favorable preliminary evidence demonstrates Deltacel's efficacy in controlling the growth of NSCLC. Deltacel continues to be well-tolerated, further confirming the early safety assessment reported on January 5th. The first patient was enrolled at the Beverly Hills Cancer Center (BHCC) and was confirmed to suffer from an actively progressing disease three days prior to beginning treatment. The CT scan performed six weeks later confirmed stabilization of the disease, indicating a preliminary progression-free survival of one and one-half months. Kiromic plans to provide updates as more data becomes available from follow-up monitoring activities and as additional subjects are enrolled in the study.

“We are delighted to share these best-case scenario, preliminary efficacy results following recently announced favorable safety and tolerability data in this patient. It is a significant clinical milestone in a deadly cancer that counts more than 2 million new diagnoses globally each year and is almost three times as deadly as breast and ovarian cancers,” said Pietro Bersani, Chief Executive Officer of Kiromic. “Our initial results with Deltacel offer a glimpse of hope and are a testament to our dedication to improving patient outcomes with this challenging disease. We look forward to sharing more detailed data as our trial progresses and remain committed to the rigorous investigation of Deltacel's potential in treating NSCLC.”

“The first patient treated in the Deltacel-01 study continues to do well. We remain hopeful regarding the treatment outcome with subsequent patients and look forward to working with Kiromic to advance enrollment in this study,” said Afshin Eli Gabayan, M.D., Medical Oncologist, Medical Director, and Principal Investigator at Beverly Hills Cancer Center.

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 study 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 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 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](#).

About Beverly Hills Cancer Center

As a private, academic, community-based cancer center, 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 composed 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 on: www.BHCancerCenter.com.

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, 2022, 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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