



Kiromic BioPharma Adds Virginia Oncology Associates, PC as the Second Clinical Trial Site in the Ongoing Phase 1 Deltacel-01 Trial

March 1, 2024

Third Patient Enrolled in Deltacel-01 Completes Treatment

HOUSTON--(BUSINESS WIRE)--Mar. 1, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP)** (“**Kiromic**” or the “**Company**”) announces that Virginia Oncology Associates, PC (Norfolk, Virginia) has been activated as the second clinical trial site in the Phase 1 Deltacel-01 trial evaluating Deltacel™ (KB-GDT-01), Kiromic’s allogeneic, off-the-shelf, Gamma Delta T-cell (GDT) therapy, in patients with non-small cell lung cancer (NSCLC).

“Virginia Oncology Associates is known for its excellence in oncology-focused research and patient care, and we are delighted to add them as the second Deltacel-01 clinical trial site. With encouraging preliminary results from the first patient in Deltacel-01, we are proud to expand trial access to more sites with the goal of enhancing enrollment efficiency and data quality,” said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma.

The site initiation process at Virginia Oncology Associates has been completed and patient enrollment is expected to begin in April, following receipt of preliminary results from the first three-patient cohort in Deltacel-01. Dr. Gary Simmons, D.O., MSHA, will serve as the principal investigator at this site, and brings to Deltacel-01 extensive experience in clinical studies focused on oncology and on CAR T-cell therapies.

Kiromic also announces that the third patient in Deltacel-01 completed treatment at the Beverly Hills Cancer Center on February 21. Kiromic expects to announce initial safety and tolerability data, as well as preliminary efficacy results, from this patient and from the trial’s second patient by the end of March.

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 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 Virginia Oncology Associates

Virginia Oncology Associates is an oncology and hematology practice of physicians specializing in diagnosing and treating cancer and blood disorders. With locations spanning the southeast region of Virginia and Northeastern North Carolina, it extends multiple services and treatments to patients, including medical oncology, radiation oncology, gynecologic oncology, hematology, diagnostics, clinical research, stem cell transplantation, genetic counseling, and psychosocial oncology.

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, 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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Kiromic BioPharma

Linda Phelan Dyson, MPH
Global Head, Corporate Communications
ldyson@kiromic.com
281-468-7683

LHA Investor Relations

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

Source: Kiromic BioPharma, Inc.