Kiromic BioPharma Provides Update on Part 1 of the Deltacel-01 Trial

August 9, 2024

On track to initiate Part 2 in September

HOUSTON--(BUSINESS WIRE)--Aug. 9, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) ("Kiromic" or the "Company")** reports interim results near the completion of Part 1 of 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.

Based on data from the five patients evaluated for Progression-Free Survival (PFS) in the long-term follow-up, Kiromic has registered a PFS ranging from 2 to 8 months, with an average of 4.8 months.

No dose limiting toxicities (DLTs) have been reported by the clinical site for patients that have completed the full course of therapy. One patient was withdrawn from the study before completing the full course of therapy due to an adverse event related to a pre-existing co-morbidity and unrelated to Deltacel. Consequently, this subject could not be evaluated for PFS.

Additionally, the sixth and last patient in Part 1 of the Deltacel-01 study started treatment on August 6th.

"We are pleased to have completed enrollment in Part 1 of our clinical trial. The favorable results of our GDT therapy, particularly with respect to PFS, in the first two cohorts that comprise Part 1 underscore the potential of Deltacel to treat solid tumors, and we look forward to launching Part 2 of this study," said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma.

Kiromic expects to obtain early safety and tolerability outcomes from the last enrolled patient in September and efficacy results in early October. Kiromic is on track to initiate Part 2 of Deltacel-01 in September.

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 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240809927283/en/

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

Source: Kiromic BioPharma, Inc.