Kiromic BioPharma's Deltacel Receives FDA Fast Track Designation

August 14, 2024

HOUSTON--(BUSINESS WIRE)--Aug. 14, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) ("Kiromic" or the "Company")** announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Deltacel ™ (KB-GDT-01), the Company's allogeneic, off-the-shelf, Gamma Delta T-cell (GDT) therapy. The designation was awarded for KB-GDT-01 in combination with low-dose radiation therapy for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have progressed on at least two lines of standard of care therapy including platinum-based chemotherapy, immune checkpoint inhibitors and targeted therapy to improve progression-free survival and overall survival. Deltacel is currently being evaluated in the Deltacel-01 Phase 1 study in patients with stage 4 NSCLC who have failed to respond to standard therapies.

Fast Track designation is designed to facilitate the development and expedite the review of drugs intended to treat serious conditions and fill an unmet medical need. The designation allows for more frequent communication with the FDA, potential priority review, and a rolling submission of Biologics License Application or New Drug Application.

"Receipt of Fast Track designation is a significant milestone for Kiromic and underscores the potential of Deltacel to address the urgent needs of patients with advanced solid tumors," said Pietro Bersani, Chief Executive Officer of Kiromic BioPharma. "We are encouraged by the FDA's recognition of our innovative approach and are committed to the clinical development of Deltacel. Fast Track designation will enable us to work more closely with the FDA as we complete Deltacel-01 and advance this promising therapy into later stage studies."

The Fast Track designation follows recent positive data from the ongoing Deltacel-01 clinical trial, in which Deltacel has demonstrated a favorable safety profile and preliminary clinical efficacy in NSCLC patients. Kiromic expects to activate a fifth clinical trial site on August 30th.

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.

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

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