Kiromic BioPharma Announces FDA Authorization of IND to Initiate Phase 1 Clinical Trial Evaluating Deltacel in Non-Small Cell Lung Cancer

May 1, 2023

Company Expects Beginning of First in Human Trial Activation in Second Quarter of 2023

Deltacel is Being Developed to Treat Solid Malignancies, Which Comprise 90% of All Cancers

HOUSTON--(BUSINESS WIRE)--May 1, 2023-- **Kiromic BioPharma, Inc. (NASDAQ: KRBP) (“Kiromic” or the “Company”),** a clinical-stage, fully-integrated biotherapeutics company using its proprietary DIAMOND® artificial intelligence and data mining platform to develop cell therapies with a focus on immuno-oncology, today announces that the U.S. Food and Drug Administration (FDA) has authorized the Company’s Investigational New Drug (IND) application to initiate a Phase 1 clinical trial to evaluate Deltacel (KB-GDT-01) for patients with non-small cell lung cancer (NSCLC).

Deltacel is the Company’s allogeneic, non-engineered, off-the-shelf Gamma Delta T-cell (GDT) therapy. Notably, Deltacel does not require the use of any viral vector as many other cell therapies do, which, among other advantages, allows for reduced manufacturing costs. Kiromic is seeking to address a significant unmet need by applying cell therapy to treat solid malignancies, which comprise 90% of all cancers, including NSCLC. Lung cancer is by far the leading cause of cancer death in the US, accounting for about 1 in 5 of all cancer deaths. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined.

“Receiving the authorization from the FDA to administer Deltacel to patients enables us to advance our GDT therapy candidate into the clinic. As a potentially well tolerated and effective treatment, we look forward to the opportunity for Deltacel to have a meaningful impact on the hundreds of thousands of patients with non-small cell lung cancer and with other solid cancers,” stated Pietro Bersani, Chief Executive Officer of Kiromic BioPharma. “We are in the process of activating clinical trial sites, and we look forward to providing updates on our progress.”

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 cancers. 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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