



Kiromic BioPharma Announces FDA Feedback from Type B Pre-IND Meeting Confirms Deltacel Development Strategy

October 6, 2022

Company Reiterates Deltacel is Next Clinical Trial Candidate, with Projected Clinical Trial Launch Expected in Q1 2023

Company is Streamlining Operations to Execute Deltacel-Aligned Development Strategy

HOUSTON--(BUSINESS WIRE)--Oct. 6, 2022--

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 and gene therapies with a focus on immuno-oncology, announces it received validating written feedback on October 4, 2022 from the FDA pursuant to its Type B Pre-IND meeting request regarding its Deltacel™ development strategy.

The purpose of the Pre-IND meeting request was to seek alignment with and to obtain FDA guidance on Kiromic's proposed development strategy about the chemistry, manufacturing, and controls (CMC), nonclinical studies, and clinical study plan for Deltacel™/KB-GDT for treating subjects with Non-Small Cell Lung Cancer (NSCLC). Kiromic will leverage this FDA Pre-IND written confirmatory feedback and recommendations into a robust IND submission package for a projected clinical trial launch in Q1 2023.

"We are delighted to receive this very productive feedback about Deltacel™/KB-GDT from the FDA, confirming our development strategy for this therapeutic candidate," stated Pietro Bersani, Chief Executive Officer of Kiromic. "It was a strategic decision to focus on metastatic stage 4 lung cancer as our first indication in addressing solid malignancies, and we are very heartened to be continuing to fulfill our mission to address solid malignancies, which represent more than 90% of all cancers."

Further reiterating Management's focus on executing the Deltacel-aligned development strategy, the Company has streamlined its operations and aligned key resources to advance its Deltacel™ product candidate while maintaining its other product candidates Procel™ and Isoce™. As part of the aligned strategy and following a thorough evaluation to maximize operational efficiencies, Kiromic's management made the difficult yet necessary decision to eliminate 20 positions or approximately 29% of its workforce. The Company believes these key actions and overall strategy align with financing options it is actively pursuing.

"Deltacel™ is our most advanced therapeutic candidate, and its use of allogeneic, non-viral, non-engineered off-the-shelf Gamma Delta T-cells (GDT) is a next-generation solution for patients. As such, this prioritization also mitigates supply-chain challenges associated with a virus-based approach. We believe these advantages will allow us to efficiently establish the platform's safety and tolerability and build upon Deltacel™'s previously demonstrated preclinical efficacy across multiple indications. With the FDA guidance in hand, we believe we've further strengthened our case to align operations with Deltacel™ and deliver value sooner to our shareholders," commented Bersani.

About Kiromic BioPharma

Kiromic BioPharma, Inc. is a clinical-stage, fully integrated biotherapeutics company using its proprietary DIAMOND® artificial intelligence (AI) 2.0 platform to discover and develop cell and gene therapies with a therapeutic focus on immuno-oncology and other diseases. Kiromic is developing a multi-indication allogeneic cell therapy platform that exploits the natural potency of Gamma Delta T-cells to target solid cancers. From its heritage as a cancer vaccine development company, Kiromic is focused on discovering, developing, and commercializing novel immuno-oncology applications through its robust product pipeline. The pipeline development is leveraged through the Company's proprietary target discovery engine called "DIAMOND." Kiromic's DIAMOND 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 current and anticipated IND applications including statements regarding the scope of and timing for submission of an IND application; the Deltacel™ product platform; the timing for submitting and activating Kiromic's IND applications and clinical trials; Kiromic's ability to achieve its objectives; the timing for the initiation and successful completion of Kiromic's clinical trials of its product candidates; the potential of Kiromic's product candidates. 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, 2021, 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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