



Kiromic BioPharma Pipeline to Prioritize a New Gamma Delta T-cell Product Candidate

June 21, 2022

IND for Non-Engineered Deltacel/KB-GDT™ to be Submitted in the Second Half of 2022 with Beginning of Clinical Trial Activation Expected by Year-End

Three Additional IND Filings Will Expand the Company's Pipeline to Five Allogeneic Gamma Delta T-cell Clinical Trials and Three Product Candidates

HOUSTON--(BUSINESS WIRE)--Jun. 21, 2022-- **Kiromic BioPharma, Inc. (NASDAQ: KRBP)**, a clinical-stage biotherapeutics company using its proprietary DIAMOND AI® (artificial intelligence) and data mining platform to discover and develop cell therapies with a focus on immuno-oncology, announces a strategic pipeline shift to prioritize its allogeneic, non-engineered off-the-shelf product candidate, Deltacel/KB-GDT™.

Kiromic expects to submit its first new investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) in the second half of 2022. The IND will seek to evaluate Deltacel in combination with a standard antitumor modality, with the expected beginning of trial activation by year-end. Deltacel consists of Gamma Delta T-cells (GDT) that are expanded, enriched, and activated through a proprietary method. Kiromic will also pursue INDs for its Procel™ and Isocel™ product candidates in combination with a standard antitumor modality in 2023.

These three additional IND filings will expand the Company's pipeline to five allogeneic GDT clinical trials and three product candidates.

This reprioritization and expansion of Kiromic's pipeline follows a recently announced sponsored research agreement to generate *in vivo* preclinical data. The Company believes that, through this agreement, we will be able to efficiently generate data for our GDT allogeneic therapies and other pre-clinical assets to support our anticipated IND filings.

"We are well positioned to prioritize Deltacel/KB-GDT™ in combination with a standard antitumor modality as our first IND, which we intend to submit to the FDA during the second half of this year with the expected beginning of trial activation by year-end. We believe that this shift both de-risks and accelerates our immediate path forward, enabling us to advance our non-viral, non-engineered product candidate while also reducing costs and mitigating current supply chain headwinds associated with a virus-based approach," stated Pietro Bersani, Chief Executive Officer of Kiromic BioPharma.

"Against the backdrop of a global cancer cell therapy market that's expected to exceed \$33 billion by 2027, Kiromic's product pipeline now encompasses three additional Gamma Delta T-cell therapeutic candidates, Deltacel™, Procel™, and Isocel™. Each is being developed to target solid tumors – which represent 90% of all cancers – and each is ideally positioned to address unmet medical needs. We look forward to advancing these candidates into the clinic with the goal of providing new treatment options to patients with cancer," added Mr. Bersani.

These three IND applications will expand Kiromic's therapeutic pipeline to five allogeneic GDT clinical trials (see accompanying graphic), including:

1. **New IND #1: Deltacel™** in combination with a standard antitumor modality, with clinical activation expected to begin by the end of the fourth quarter of 2022
2. **New IND #2: Procel™** in combination with a standard antitumor modality, with clinical activation expected to begin by the end of the second quarter of 2023
3. **ALEXIS – PRO-1 Procel™** as a monotherapy, with clinical activation expected to begin by the end of second quarter 2023
4. **New IND #3: Isocel™** in combination with a standard antitumor modality, targeting clinical activation to begin by the end of the fourth quarter of 2023
5. **ALEXIS – ISO-1 Isocel™** as a monotherapy, targeting clinical activation to begin by the end of the fourth quarter of 2023

Clinical Trial Candidate	Target	Phase I
New IND #1 Deltacel™ In combination with standard antitumor modality Allogeneic, Non-Viral, Non-engineered off-the-shelf GDT therapy	Universal Non-Engineered	Q4 2022 Expected Beginning of Activation Process for New IND #1 Clinical Trial
New IND #2 Procel™ in combination with standard antitumor modality Allogeneic, off-the-shelf, GDT CAR-T	PD-L1	Q2 2023 Expected Beginning of Activation Process for New IND #2 Clinical Trial

therapy

ALEXIS – PRO-1

Procel™

Allogeneic, off-the-shelf, GDT CAR-T therapy

PD-L1

Q2 2023

Expected Beginning of Activation Process for ALEXIS-PRO-1 Clinical Trial

New IND #3

Isocel™ in combination with standard antitumor modality

Allogeneic, off-the-shelf, GDT CAR-T therapy

Isoform of Mesothelin

Q4 2023

Expected Beginning of Activation Process for New IND #3 Clinical Trial

ALEXIS – ISO-1

Isocel™

Allogeneic, off-the-shelf, GDT CAR-T therapy

Isoform of Mesothelin

Q4 2023

Expected Beginning of Activation Process for ALEXIS-ISO-1 Clinical Trial

About Kiromic BioPharma

Kiromic BioPharma is a clinical stage biotherapeutics company using its proprietary DIAMOND® artificial intelligence (AI) platform to discover and develop cell and gene therapies with a therapeutic focus on immuno-oncology and other diseases. Kiromic is in the process of developing a multi-indication gamma delta allogeneic T cell therapy treatment platform that exploits the natural potency of gamma delta T cells to target solid cancers. Kiromic is focused on discovering, developing, and commercializing novel immuno-oncology therapies through its robust product pipeline, leveraged by DIAMOND® AI, a proprietary target discovery engine where data science meets target identification to dramatically compress the timeline and cost of drug development. The Company maintains offices in Houston, Texas. To learn more, visit www.kiromic.com and connect with us on [Twitter](https://twitter.com) and [LinkedIn](https://www.linkedin.com).

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 sponsored research agreement and the data that will be generated as a result of such collaboration; the timing for submitting and activating Kiromic’s IND applications; the benefits of utilizing non-genetically engineered Gamma Delta T cells as our first in-human study; Kiromic’s ability to achieve its objectives; and the timing for the initiation and successful completion of Kiromic’s clinical trials of its 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 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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Source: Kiromic BioPharma, Inc.