Kiromic BioPharma Announces Company Will Directly Submit Amended IND for Procel™ to the FDA in Second Half of 2022

May 11, 2022

Company Provides Regulatory Update on Progress to Address Previously Outlined Chemistry, Manufacturing, and Control (CMC) Issues Related to Clinical Hold on Investigational New Drug Applications (INDs)

A Type A FDA Meeting Will Not Be Pursued

Company Announces Ongoing Progress Towards the Implementation by the Beginning of the Third Quarter of 2022 of a Current Good Manufacturing Practice (cGMP) Mammalian Master Cell Bank (mMCB), a Key Component to Manufacture a GMP-Grade Retroviral Vector for Gamma Delta T (GDT) Cell Engineering

HOUSTON--(BUSINESS WIRE)--May 11, 2022-- **Kiromic BioPharma, Inc. (NASDAQ: KRBP) ("Kiromic" or the "Company")**, a clinical-stage fully integrated biotherapeutics company using its proprietary DIAMOND® artificial intelligence (AI) and data mining platform to discover and develop cell and gene therapies with a therapeutic focus on immuno-oncology, today announces the Company will submit an amended Investigational New Drug Application (IND) for its first oncology cell therapy candidate Procel™ directly to the FDA in the second half of 2022.

Over the course of the last ten months, the Company has developed a solid plan to address the previously outlined chemistry, manufacturing, and control (CMC) issues cited in the FDA's July 2021 letter regarding the clinical hold on the Company's INDs. Based on the unanimous advice from independent regulatory experts, the Company has determined that it is not necessary to proceed with the previously contemplated Type A meeting with the FDA to further address the CMC issues and instead will move forward with a submission of an amended IND for Procel™ directly to the FDA during the second half of this year.

The Company also announces ongoing progress toward the implementation of a current good manufacturing practice (cGMP) mammalian master cell bank (mMCB), which will provide a GMP-grade retroviral vector for gamma delta T (GDT) cell engineering. A cGMP mammalian master cell bank is a significant step forward in the Company's clinical pathway and would address a key issue identified by the FDA in the clinical hold letter.

"We are very pleased to share these significant regulatory updates, reflecting the progress we have been making as a Company. In addition, progress toward establishing the master cell bank will enable us to create the GMP-grade retroviral vector for gamma delta cell engineering - a cornerstone of our clinical program" stated Pietro Bersani, Kiromic BioPharma's Chief Executive Officer. "These achievements demonstrate our team's execution efforts toward our goal of beginning the activation of the clinical trial for our first oncology cell therapy candidate Procel™ by the end of the fourth quarter of 2022."

About Kiromic BioPharma

Kiromic BioPharma, Inc. is a clinical-stage, fully integrated 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 ALEXIS, a multi-indication allogeneic CAR-T 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 billions of drug development dollars required to develop a cell therapy. The Company maintains offices in Houston, Texas. To learn more, visit www.kiromic.com and connect with us on Twitter and LinkedIn.

Note Regarding 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; the ability of the Kiromic to address any issues related to its clinical trials including the FDAs comments and concerns; Kiromic's fulfillment of regulatory obligations related to our clinical development programs, including implementation of cGMP platforms; Kiromic's regulatory approach, including statements about plans to file any IND amendments or seek a Type A meeting with the FDA; implementation or expansion of Kiromic's manufacturing capabilities, including statements related to the mammalian master cell bank; the benefits from developing a mammalian master cell bank; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220511005431/en/

Linda Phelan Dyson, MPH
Global Head, Corporate Communications
ldyson@kiromic.com
M: 281-468-7683

Source: Kiromic BioPharma, Inc.