

Kiromic BioPharma Provides Update on IND Filings on its Off-the-Shelf, Allogeneic CAR-T for Solid Tumors

July 16, 2021

HOUSTON--(BUSINESS WIRE)--Jul. 16, 2021-- Kiromic BioPharma, Inc. (Nasdag: KRBP)

Two INDs were submitted to the FDA in May 2021 for the first-in-human off-the-shelf allogeneic CAR-T for Solid Tumors.

FDA returned with comments on the Company's allogeneic CAR-T products with respect to:

- -- Tracing of all reagents used in manufacturing
- -- Flow chart of manufacturing processes
- -- Certificate of Analysis (COA) for the Company's CAR-T products (allogeneic CAR-T)

The company has an FDA response taskforce, staffed with 30 yr industry veterans, working on answering the FDA comments above.

Our CMC processes are rigorous.

Our product is allogeneic gamma delta T cell manufacturing which few companies have mastered.

The company's timeline for commencement of the dosing of its first in human clinical trial is expected to be tighter but we still plan on delivering in 3Q 2021.

Previous Press Release

June 2, 2021, Kiromic announces the closing of public offering

About Kiromic

Kiromic BioPharma, Inc. (Nasdaq: KRBP) is a target discovery and gene-editing company utilizing a state-of-the-art artificial intelligence (AI) platform focused on unleashing the power of the patient's own immune system to fight cancer.

Kiromic's pipeline development is leveraged through the Company's proprietary target discovery Artificial Intelligence engine called "DIAMOND." Kiromic's DIAMOND is big data science meeting target identification, dramatically compressing the man-years and the millions of drug development dollars needed to develop a live drug.

Forward-Looking Statements

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on our company's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the Company's annual report on Form 10-K for the most recently completed fiscal year and subsequent reports filed after the date of the annual report with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and our company undertakes no duty to update such information except as required under applicable law.

Source: Kiromic BioPharma, Inc. (www.kiromic.com)

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