Kiromic BioPharma Provides Updates on its Deltacel-01 Clinical Trial

June 20, 2024

Follow-up Findings Show Stable Disease

FDA and IRB Approve IND for a Single-Use, Single-Patient Treatment with Deltacel

Fast Track Designation Request Submitted to FDA

Complete Enrollment in Trial's Second Cohort Expected in July

HOUSTON--(BUSINESS WIRE)--Jun. 20, 2024-- **Kiromic BioPharma, Inc. (OTCQB: KRBP) ("Kiromic" or the "Company")** reports follow-up results from the second, third and fourth patients enrolled in its Deltacel-01 Phase 1 clinical trial. This trial is evaluating Deltacel ™ (KB-GDT-01), the Company's allogeneic, off-the-shelf, Gamma Delta T-cell (GDT) therapy, in patients with stage 4 metastatic non-small cell lung cancer (NSCLC) who have failed to respond to standard therapies.

The third and fourth patients showed stable disease at their four- and two-month follow-up visits, respectively. Both patients are doing well, and neither showed any dose-limiting toxicities. Patients three and four are being treated at the Beverly Hills Cancer Center (BHCC).

The second patient, also being treated at the BHCC, previously had stable disease and showed a complete response in their brain metastasis. At the four-month follow-up visit, while stable disease of previously treated sites and a clean brain MRI were confirmed, a new site of disease, a sub-cutaneous metastasis, was detected by CT and PET scans. This patient is in generally good condition and tolerated their initial treatment well. As such, the Institutional Review Board (IRB) and the U.S. Food and Drug Administration (FDA) approved a single-use, single-patient protocol, and on June 19, the patient started a new course of treatment with low-dose radiation and gamma-delta T cells under a single patient IND.

"We are optimistic the latest targeted treatment with Deltacel will control the second patient's new lesion, which is suspected to have originated from a micro-metastasis not detected and therefore not targeted with radiation during the first course of treatment. This new protocol might be applied to all patients who received or will receive the Deltacel treatment and could be instrumental in controlling any new tumor lesions or progressing lesions," said Pietro Bersani, CEO of Kiromic BioPharma.

Kiromic BioPharma also reports submitting a request for Fast Track designation for Deltacel to the FDA. Fast Track designation facilitates and expedites the development and review of drugs that treat serious conditions and address unmet medical needs. For further information on Fast Track designation, please visit the FDA's website.

"We continue to be encouraged by the favorable results of the Deltacel-01 trial, which reinforce our confidence in the potential of Deltacel to provide meaningful clinical benefits to patients in need. This confidence underscores the recent open-market purchases of common stock by several Kiromic directors and executive officers, as reported on Form 4 filings," noted Mr. Bersani.

"Proceeding with a single-use, single-patient protocol of Deltacel supports our commitment to advancing innovative therapies that address unmet clinical needs in unique ways, which include the possibility for retreatment," he added. "We are also excited about the potential of expediting Deltacel clinical development through Fast Track designation."

The fifth patient in the trial completed their 30-day safety visit at the BHCC with no toxicities reported, and the sixth patient is expected to be enrolled in July.

About Deltacel-01

In Kiromic's open-label Phase 1 clinical trial, titled "Phase 1 Trial Evaluating the Safety and Tolerability of Gamma Delta T Cell Infusions in Combination With Low Dose Radiotherapy in Subjects With Stage 4 Metastatic Non-Small Cell Lung Cancer" (NCT06069570), patients with stage 4 NSCLC will receive two intravenous infusions of Deltacel ™ with four courses of low-dose, localized radiation over a 10-day period. The primary objective of the Deltacel-01 trial is to evaluate safety, while secondary measurements include objective response, progression-free survival, overall survival, time to progression, time to treatment response and disease control rates.

About Deltacel ™

Deltacel ™ (KB-GDT-01) is an investigational gamma delta T-cell (GDT) therapy currently in the Deltacel-01 Phase 1 trial for the treatment of stage 4 metastatic NSCLC. An allogeneic product consisting of unmodified, donor-derived gamma delta T cells, Deltacel ™ is the leading candidate in Kiromic's GDT platform. Deltacel ™ is designed to exploit the natural potency of GDT cells to target solid cancers, with an initial clinical focus on NSCLC, which represents about 80% to 85% of all lung cancer cases. Data from two preclinical studies demonstrated Deltacel ™'s favorable safety and efficacy profile when it was combined with low-dose radiation.

About Beverly Hills Cancer Center

As a private, academic, community-based cancer center, the Beverly Hills Cancer Center not only provides the latest state-of-the-art cancer treatments all under one roof, but also provides leading clinical trials and research, attracting patients globally. By providing access to groundbreaking clinical trials, the Beverly Hills Cancer Center offers patients the opportunity to participate in the most advanced cancer treatments currently in development in the world. Beverly Hills Cancer Center is comprised of an internationally recognized multidisciplinary medical team consisting of medical oncologists, radiation oncologists, radiologists, hematologists and internists who provide exceptional patient care and support services including a robust and highly efficient team of clinical research professionals. More information is available at www.BHCancerCenter.com.

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 tumors. 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, 2023, 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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Source: Kiromic BioPharma, Inc.