Kinnate Biopharma Inc. Details Two-Part Phase 1 Trial Design for its Lead RAF Kinase Inhibitor Program at the AACR-NCI-EORTC Virtual International Conference

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First in human, multicenter, non-randomized, open-label trial has expanded to three sites and is actively recruiting

SAN FRANCISCO and SAN DIEGO, Oct. 07, 2021 (GLOBE NEWSWIRE) -- Kinnate Biopharma Inc. (Nasdaq: KNTE) ("Kinnate"), a biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers, will be presenting design and rationale details of a Phase 1 trial (KN-8701; NCT04913285) evaluating KIN-2787 during the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics.

KIN-2787, Kinnate's most advanced product candidate, is an orally available small molecule pan-RAF inhibitor being developed for the treatment of patients with lung cancer, melanoma, and other solid tumors. KIN-2787 has been designed to target both monomeric and dimeric forms of the mutant BRAF kinase and minimize paradoxical activation, a liability often observed with other RAF inhibitors that can adversely impact tolerability and require addition of a MEK inhibitor to suppress pathway activation. Unlike currently available treatments that target only Class I BRAF kinase mutations, KIN-2787 targets Class II and Class III BRAF alterations, where it has the potential to be a first-line targeted therapy, in addition to covering Class I BRAF mutations. In pre-clinical studies, KIN-2787 has shown favorable pharmaceutical properties, achieves substantial systemic exposures in toxicology studies and induces regressions in human cancer xenograft models driven by BRAF Class I, II or III alterations.

"Approved BRAF inhibitors have limited clinical activity in diverse solid tumors driven by BRAF Class II or III alterations, highlighting the urgency to develop effective next-generation targeted therapies for these patients who currently have limited options," said the trial's co-investigator and presenter Meredith McKean, MD, MPH, Associate Director, Melanoma and Skin Cancer Research Program, Sarah Cannon Research Institute at Tennessee Oncology. "We are pleased to share additional details of this two-part trial with this year's conference attendees."

KN-8701 (NCT04913285) is a first-in-human, multicenter, non-randomized, open-label, Phase 1 trial of KIN-2787 in adult patients with BRAF mutant advanced and metastatic solid tumors (AMST). KIN-2787 is given orally bid continuously in 28-day cycles until drug intolerance or disease progression. Planned sample size is approximately 115 patients in two parts: Part A is a trial of dose-escalation to maximum tolerated dose open to patients with AMST driven by BRAF Class I, Class II or Class III genomic alterations. Part B will evaluate a selected dose of KIN-2787 in three cohorts of patients with melanoma, NSCLC, or other AMST, each driven by BRAF Class II or Class III alterations. Standard Phase 1 enrollment criteria are required, and key exclusion criteria include known clinically active brain metastases from non-brain tumors, and prior receipt of BRAF-, MEK-, or MAPK-directed inhibitor therapy (except for cases in which these inhibitors were used in FDA-approved indications).

"We are pleased with the progress of this first-in-human trial of KIN-2787 and grateful to all the trial participants. With poorer prognosis observed in NSCLC and melanoma patients harboring tumors driven by BRAF Class II or III alterations, there is a dire need for more effective and better tolerated therapies," said Richard Williams, MBBS, Ph.D., Chief Medical Officer of Kinnate. "We are proud to collaborate with the Sarah Cannon Research Institute and all the other sites participating in this important trial."

The KN-8701 trial is currently recruiting across three centers in the United States. For more information, please visit www.kinnate.com/patients.

The poster (#P226), titled "Design and rationale of a first in human (FIH) Phase 1/1b study evaluating KIN-2787, a potent and highly selective pan-RAF inhibitor, in adult patients with BRAF mutation positive solid tumors," was presented by Dr. McKean and can be accessed online at: https://www.aacr.org/meeting/aacr-nci-eortc-international-conference-on-molecular-targets-and-cancer-therapeutics.

About Kinnate
Kinnate is focused on the discovery and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers. Kinnate's mission is to expand the reach of targeted therapeutics by developing products for underserved populations. Kinnate utilizes its deep expertise in structure-based drug discovery, translational research, and patient-driven precision medicine, which it refers to as the Kinnate Discovery Engine, to develop targeted therapies. Based in San Francisco and San Diego, California, the Kinnate team is composed of drug discovery experts supported by a distinguished group of scientific advisors. For more information, please visit www.kinnate.com.

Forward Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements include, without limitation, statements regarding the potential benefits of our product candidates and the enrollment and conduct of our clinical trials. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are also intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends. Such expectations and projections may never materialize or may prove to be incorrect. These forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors, including risks related to operating as a preclinical-stage biopharmaceutical company with a limited operating history; our ability to raise additional capital to finance our operations; our ability to discover, advance through the preclinical and clinical development of, obtain regulatory approval for and commercialize our product candidates; the novel approach we are taking to discover and develop drugs; our ability to timely file and obtain approval of investigational new drug applications for our planned clinical trials; the potential for any clinical trial results to differ from our preclinical trial results; negative impacts of the COVID-19 pandemic on our business, including planned clinical trials and ongoing and planned preclinical trials; competition in our industry; regulatory developments in the United States and other countries; our ability to attract, hire and retain highly skilled executive officers and employees; difficulties in managing our growth; our ability to protect our intellectual property; reliance on third parties to conduct our preclinical studies and any future clinical trials, and to manufacture our product candidates; general economic and market conditions; and other risks.

These and other risks, uncertainties, assumptions and other factors are further described under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 that we have filed with the Securities and Exchange Commission (the “SEC”), as well as in our subsequent filings we make with the SEC. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Investors 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 future results, levels of activity, performance or achievements. Our forward-looking statements speak only as of the date of this release, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason in the future.

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