Kinnate Biopharma Inc. Announces First Patient Dosed in Phase 1 Clinical Trial of its FGFR Inhibitor Product Candidate, KIN-3248

April 18, 2022

SAN FRANCISCO and SAN DIEGO, April 18, 2022 (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, today announced that the first patient has commenced treatment in its Phase 1 KN-4802 (NCT05242822) clinical trial evaluating its lead Fibroblast Growth Factor Receptor (FGFR) product candidate, KIN-3248. KIN-3248 is a next-generation pan-FGFR inhibitor being developed for the treatment of intrahepatic cholangiocarcinoma (ICC) and urothelial carcinoma (UC), as well as other solid tumors.

"With the dosing of the first patient in our Phase 1 trial of KIN-3248, we are excited to further advance the development of this next-generation therapy which we believe is unique among FGFR inhibitors and has the potential to offer a new targeted therapy option for cancer patients with FGFR-altered tumors," said Richard Williams, MBBS, PhD, Chief Medical Officer of Kinnate. "We are grateful for the contribution of all the participants in this multi-center trial and for the support of our clinical collaborators at each trial site."

KIN-3248 is an irreversible, small molecule pan-FGFR inhibitor that has been developed to address both primary FGFR2 and FGFR3 oncogenic alterations and those predicted to drive acquired resistance to current FGFR-targeted therapies, including gatekeeper, molecular brake, and activation loop mutations observed in cancers such as ICC and UC. In preclinical studies, KIN-3248 demonstrated inhibitory activity across a wide range of clinically relevant mutations that drive primary disease and acquired resistance to other FGFR inhibitors.

The KN-4802 clinical trial (NCT05242822) is a multi-center, open-label, two-part study of approximately 120 patients to evaluate the safety, tolerability, pharmacokinetics (PK), and preliminary efficacy of KIN-3248 in adults with advanced tumors harboring FGFR2 and/or FGFR3 gene alterations. The dose escalation portion (Part A) of the trial will determine the recommended dose and schedule of KIN-3248 for further evaluation in patients with FGFR2 and/or FGFR3 gene alteration-driven cancers. The dose expansion phase (Part B) of the trial will assess the safety and efficacy of KIN-3248 at the recommended dose and schedule in FGFR inhibitor naïve and FGFR inhibitor pretreated patients with cancers driven by FGFR2 and/or FGFR3 gene alterations, including ICC, UC, and other selected adult solid tumors.

"Successfully treating ICC and UC patients with FGFR2 and/or FGFR3 gene alteration-driven cancers remains a significant unmet need in cancer care. KIN-3248 brings a unique approach to potentially address the shortcomings of existing therapies in specific patient populations with primary FGFR2 and/or FGFR3 oncogenic alterations, including those patients with gatekeeper, molecular brake, and activation loop mutations," said Benjamin Garmezy, MD, Assistant Director of Genitourinary Research for Sarah Cannon Research Institute at Tennessee Oncology. "We are proud to be the first site to treat a patient with KIN-3248 and look forward to working with Kinnate to continue enrollment in this important Phase 1 trial."

For additional information about the KN-4802 clinical trial, please visit: clinicaltrials.gov/ct2/show/NCT05242822.

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 that are designed to address significant unmet need. 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 KIN-3248, the conduct of the KN-4802 clinical trial and statements by our Chief Medical Officer and Dr. Garmezy. 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 recently transitioning to operating as a clinical-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 study results; negative impacts of the COVID-19 pandemic on our business, including ongoing and planned clinical trials and ongoing and planned preclinical studies; 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 ongoing or planned 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 Annual Report on Form 10-K for the fiscal year ended December 31, 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.

Contacts:

Investors:
Patti Bank
ICR Westwicke
415-513-1284
investors@kinnate.com

Media:
Colin Sanford
203-918-4347
colin@bioscribe.com