Kinnate Biopharma Inc. Receives Fast Track Designation from the U.S. Food and Drug Administration for KIN-3248, an Investigational Pan-FGFR Inhibitor

February 14, 2023

SAN FRANCISCO and SAN DIEGO, Feb. 14, 2023 (GLOBE NEWSWIRE) -- Kinnate Biopharma Inc. (Nasdaq: KNTE) ("Kinnate"), a clinical-stage precision oncology company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for Kinnate's investigational pan-FGFR inhibitor, KIN-3248, for the treatment of patients with unresectable, locally advanced or metastatic cholangiocarcinoma (CCA) harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other alterations, who have received at least one prior systemic therapy.

Cholangiocarcinoma, also known as bile duct cancer, is a rare condition, often diagnosed when it is advanced. Research has shown that FGFR is an actionable alteration in patients with CCA. FGFRs are tyrosine kinases that play a crucial role in cell proliferation, differentiation, migration and survival. FGFR2 gene fusions or other alterations are identified in approximately 16% of intrahepatic cholangiocarcinoma (ICC) tumors.

Fast Track is a process designed by the FDA to facilitate the development and expedite the review of drugs to treat serious conditions and fulfill an unmet medical need. A therapeutic candidate that receives Fast Track designation is eligible for more frequent interactions with the FDA to discuss the candidate's development plan, and if relevant criteria are met, for Accelerated Approval and Priority Review.

About KIN-3248

KIN-3248 is an irreversible, small molecule pan-FGFR inhibitor designed to address primary FGFR2 and FGFR3 oncogenic alterations, including those predicted to drive acquired resistance to current FGFR-targeted therapies, such as gatekeeper, molecular brake, and activation loop mutations observed in cancers such as ICC and urothelial carcinoma (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 an ongoing multi-center, open-label, two-part study of approximately 120 patients to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of KIN-3248 in adults with advanced tumors harboring FGFR2 and/or FGFR3 gene alterations. In dose escalation (Part A), 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. Dose expansion (Part B) 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 advanced or metastatic solid tumors in adults.

This trial is currently enrolling across multiple sites in the U.S. and Taiwan, with additional sites expected globally. Initial dose escalation data is anticipated in the second half of 2023.

The company previously announced that a poster presentation of the design and rationale of the KN-4802 clinical trial will be presented at the upcoming American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium. Details are included below.

ASCO Genitourinary Cancers Symposium, February 16-18, 2023

Title: First-in-Human Phase 1/1b Study Evaluating KIN-3248, a Next-Generation, Irreversible Pan-FGFR Inhibitor, in Patients With Advanced Urothelial Carcinoma and Other Solid Tumors Harboring FGFR2 and/or FGFR3 Gene Alterations
Author: Benjamin Garmezy, MD
Abstract Number: TPS593
Poster Board: P16
Session Type and Track: Trials in Progress Poster Session, Urothelial Carcinoma
Session Date: February 17, 2023, 12:30 p.m. PT / 3:30 p.m. ET

For additional information, visit the ASCO Meeting webpage: https://conferences.asco.org.

About Kinnate Biopharma Inc.

Kinnate Biopharma Inc. is a clinical-stage precision oncology company focused on expanding on the promise of targeted therapies for those battling cancer. The company is developing medicines for known oncogenic drivers where there are no approved targeted drugs and to overcome the limitations of marketed cancer therapies, such as non-responsiveness or acquired and intrinsic resistance. Kinnate has two lead clinical programs being studied in solid tumors with RAF, NRAS and FGFR-driven alterations, and is rapidly progressing a pipeline of additional small molecule drug candidates as part of the Kinnate Discovery Engine. The company is driven by the urgency and knowledge that patients are waiting for new, effective cancer medicines. For more information, visit Kinnate.com and follow us on LinkedIn.

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 expansion of site enrollment in KN-4802, the expected timing of clinical data from KN-4802 and the company's poster presentation of KN-4802. 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 as described under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 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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