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Inhibikase Therapeutics Granted Pre-NDA Meeting with the FDA for IKT-001Pro

- Pre-NDA Meeting to discuss requirements for a 505(b)(2) NDA submission for IKT-001Pro in up to eight blood and stomach cancer indications -

- Bioequivalence to 400 mg and 600 mg imatinib mesylate completed with minimal adverse events -

BOSTON and ATLANTA, Dec. 04, 2023 (GLOBE NEWSWIRE) -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or "Company"), a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of Parkinson's disease, Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today announced the U.S. Food and Drug Administration has granted a pre-New Drug Application (pre-NDA) meeting to be held in January 2024 to discuss the requirements for approval of IKT-001Pro and to review the data establishing doses of IKT-001Pro bioequivalent to 400 mg and 600 mg imatinib mesylate. The Company expects to provide an update following the meeting.

"We are pleased that the FDA has granted a pre-NDA meeting to discuss the parameters for approval of IKT-001Pro," stated Dr. Milton Werner, President and Chief Executive Officer of Inhibikase Therapeutics. "Our completed '501' study has identified the bioequivalent doses of IKT-001Pro to 400 mg and 600 mg imatinib mesylate and has demonstrated that there were minimal adverse events observed at all doses. We believe these data support the potential approval of IKT-001Pro and we intend to submit an NDA for up to 8 indications in adults with blood or stomach cancers, similar to the adult indications for imatinib mesylate."

The 501 bioequivalence study evaluated IKT-001Pro at four single ascending doses of 300, 400, 500 and 600 mg in 27 healthy subjects ranging in age from 18 to 55, followed by a pivotal phase comparing the 600 mg of IKT-001Pro to 400 mg imatinib mesylate in 31 healthy volunteers. The study also evaluated an additional cohort of 8 healthy subjects to determine the bioequivalent dose of IKT-001Pro to 600 mg imatinib mesylate, a dose that is poorly tolerated in patients. This additional cohort identified 900 mg of IKT-001Pro as bioequivalent. Across all doses, there were only mild adverse events observed, including just two adverse events for IKT-001Pro at the highest dose comparison. Imatinib delivered by IKT-001Pro demonstrated a slower rise time to maximum plasma concentration (T_{max}) of 6 hours, compared to the 4-hour T_{max} of 400 mg imatinib mesylate. Pharmacokinetic profiles for imatinib delivered by IKT-001Pro and imatinib mesylate were similar at equivalent doses. Imatinib mesylate is currently approved for treatment of Philadelphia chromosome positive chronic myelogenous leukemia and acute lymphoblastic leukemia, adults with myelodysplastic or myeloproliferative disease associated with mutations in the PDGFR genes, mastocytosis associated with mutations in the c-Kit gene and stomach cancers that arise from mutations in the c-Kit or PDGFR genes.

About IKT-001Pro

IKT-001Pro is a prodrug formulation of imatinib mesylate and has been developed to improve the safety of the first FDA-approved Abelson (Abl) kinase inhibitor, imatinib (marketed as Gleevec[®]). Imatinib is commonly taken for hematological and gastrointestinal cancers that arise from Abl kinase mutations found in the bone marrow or for gastrointestinal cancers that arise from c-Kit and/or PDGFRa/b mutations in the stomach; c-Kit, PDGFRa/b and Abl are all members of the Abelson Tyrosine Kinase protein family. IKT-001Pro has the potential to be a safer alternative for patients and may improve the number of patients that reach and sustain major and/or complete cytogenetic responses in stable-phase CML and/or reduce the relapse rate for these patients. In preclinical studies, IKT-001Pro was shown to be as much as 3.4 times safer than imatinib in non-human primates, reducing burdensome gastrointestinal side effects that occur following oral administration. Imatinib delivered as IKT-001Pro was granted Orphan Drug Designation for stable-phase CML in September, 2018.

About Inhibikase (www.inhibikase.com)

Inhibikase Therapeutics, Inc. (Nasdaq: IKT) is a clinical-stage pharmaceutical company developing therapeutics for Parkinson's disease and related disorders. Inhibikase's multi-therapeutic pipeline focuses on neurodegeneration and its lead program IKT-148009, an Abelson Tyrosine Kinase (c-Abl) inhibitor, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. Its multi-therapeutic pipeline is pursuing Parkinson's-related disorders of the brain and GI tract, orphan indications related to Parkinson's disease such as Multiple System Atrophy, and drug delivery technologies for kinase inhibitors such as IKT-001Pro, a prodrug of the anticancer agent imatinib mesylate that the Company believes will provide a better patient experience with fewer on-dosing side-effects. The Company's RAMP[™] medicinal chemistry program has identified a number of follow-on compounds to IKT-148009 to be potentially applied to other cognitive and motor function diseases of the brain. Inhibikase is headquartered in Atlanta, Georgia with offices in Boston, Massachusetts.

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Investors and others should note that we announce material financial information to our investors using our investor relations website, press releases, SEC filings and public conference calls and webcasts. The company intends to also use [X](#), [Facebook](#), [LinkedIn](#) and [YouTube](#) as a means of disclosing information about the company, its services and other matters and for complying with its disclosure obligations under Regulation FD.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking terminology such as "believes," "expects," "may," "will," "should," "anticipates," "plans," or similar expressions or the negative of these terms and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on Inhibikase's current expectations and assumptions. Such statements are subject to certain risks and uncertainties, which could cause Inhibikase's actual results to differ materially from those anticipated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include factors that are discussed in our periodic reports on Form 10-K and Form 10-Q that we file with the U.S. Securities and Exchange Commission. Any forward-looking statement in this release speaks only as of the date of this

release. Inhibikase undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

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