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Inhibikase Therapeutics Provides Interim Update on the '501' Bioequivalence Study of IkT-001Pro

Completed dosing of 3 of 4 planned cohorts; expect to complete study in the second quarter of 2023

BOSTON and ATLANTA, March 15, 2023 /PRNewswire/ -- 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 provided an interim update from the dose escalation portion of its '501' bioequivalence study of IkT-001Pro, the Company's prodrug formulation of imatinib mesylate designed to enhance the safety and efficacy of imatinib (marketed as Gleevec®) in patients with Chronic Myelogenous Leukemia (CML).

The 501 trial is evaluating IkT-001Pro at four single ascending doses in the dose escalation portion of the study to select the bioequivalent dose, followed by a dose confirmation portion to confirm the bioequivalent dose. The study will enroll a total of 59 male and female healthy volunteers, aged 25 to 55. The study is designed to evaluate the safety profile of IkT-001Pro as well as compare the pharmacokinetic exposure of IkT-001Pro to the standard of care dose of 400 mg imatinib mesylate in order to identify a bioequivalent dose.

As of March 15, 2023, the Company has enrolled 19 of 27 healthy volunteers in the dose calibration portion of the study, completing 3 of 4 planned escalating doses at 300, 400 and 500 mg IkT-001Pro. To date, IkT-001Pro has shown a favorable safety profile, with only 4 mild adverse events observed, none of clinical significance. IkT-001Pro has high oral bioavailability and a pharmacokinetic profile of delivered imatinib that closely matches the exposure of imatinib delivered as 400 mg imatinib mesylate. Upon completion of the dose escalation phase, the Company will conduct a confirmatory analysis of the bioequivalent dose of IkT-001Pro in 32 additional healthy volunteers using a two-period crossover design. The Company remains on track to complete the 501 trial in the second quarter of 2023.

"We have made great progress in our 501 trial, since dosing the first patients in December," stated Dr. Milton Werner, President and Chief Executive Officer. "To date, our observations in the trial have followed expectations and are in line with our previously reported preclinical data, where we demonstrated that delivery of imatinib as IkT-001Pro was well tolerated. With the rapid completion of the first three dose cohorts, we are on track to complete the 501 trial in the second quarter of 2023."

Following the completion of the 501 trial, Inhibikase plans to initiate a discussion with the

FDA on the parameters for approval of IkT-001pro under the 505(b)(2) statute.

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 Chronic Myelogenous Leukemia
Chronic myeloid leukemia[1] is a slowly progressing cancer that affects the blood and bone marrow. In CML, a genetic change takes place in immature myeloid cells — the cells that make most types of white blood cells. This change creates an abnormal gene product called BCR-ABL which transforms the cell into a CML cell. Leukemia cells increasingly grow and divide in an unregulated manner, eventually spilling out of the bone marrow and circulating in the body via the bloodstream. Because they proliferate in an uncontrolled manner, the excessive production of myeloid cells acts like a liquid tumor. In time, the cells can also settle in other parts of the body, including the spleen. CML is a form of slow-growing leukemia that can change into a fast-growing form of acute leukemia that is difficult to treat.

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 Ableson 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 Twitter, 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 our ability to satisfactorily address the issues raised by the FDA in order to have the clinical hold on our IkT-148009 programs removed, as well as such other factors that are included 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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[1] 1 Also known as chronic myelogenous leukemia, chronic myelocytic leukemia, and chronic granulocytic leukemia (CGL).

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