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Inhibikase Therapeutics Announces Selection of the Bioequivalent Dose of IkT-001Pro and Provides Update on the '501' Bioequivalence Study

- 600 mg dose of IkT-001Pro selected as the bioequivalent dose relative to standard of care 400 mg imatinib mesylate -

- On-track to complete pivotal clinical phase of the 501 study by the end of 2Q22 -

BOSTON and ATLANTA, June 22, 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 announced that it has selected the bioequivalent dose 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) and provided an update on its '501' bioequivalence study.

The '501' bioequivalence study has evaluated IkT-001Pro at four single ascending doses of 300, 400, 500 and 600 mg, leading to the selection of 600 mg IkT-001Pro as the bioequivalent dose to 400 mg imatinib mesylate. The pivotal phase of the study was dosed with bioequivalent IkT-001Pro in 31 healthy volunteers; one subject was excluded pre-dose due to aberrant clinical laboratory values. The Company expects to complete the pivotal clinical phase of the study by the end of the second quarter.

"Based on the safety signals we have seen at the 600 mg dose of IkT-001Pro relative to 400 mg imatinib mesylate, we believe that we have identified the appropriate go-forward dose for standard-of-care treatment with IkT-001Pro," stated Dr. Milton Werner, President and Chief Executive Officer of Inhibikase Therapeutics. "We plan to add an additional cohort to the '501' trial in the third quarter to evaluate bioequivalence of IkT-001Pro relative to 600 mg imatinib mesylate with repeat dosing. 600 mg imatinib mesylate is commonly used to treat CML, but is poorly tolerated by up to 50% of patients. We believe IkT-001Pro may overcome the poor tolerability of high dose imatinib experienced by many patients, further differentiating the advantage of IkT-001Pro over current standard-of-care."

Following the completion of the '501' trial, Inhibikase will 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 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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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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