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Inhibikase Therapeutics Announces FDA Clearance of Investigational New Drug Application for IkT-001Pro for the Treatment of Chronic Myelogenous Leukemia

BOSTON and ATLANTA, Aug. 26, 2022 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) (Inhibikase), 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 the U.S. Food and Drug Administration (FDA) has reviewed its Investigational New Drug (IND) application for IkT-001Pro for the treatment of Chronic Myelogenous Leukemia (CML) and issued a Study May Procced (SMP) letter.

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 occur 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. 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.

"We are excited to have received the SMP letter from the FDA for IkT-001Pro for CML. This represents the first program to emerge from our novel prodrug platform, which aims to improve the safety and tolerability of approved and novel therapeutics," commented Milton H. Werner, Ph.D., President and Chief Executive Officer. "Based on preclinical studies, we believe that IkT-001Pro has the potential to significantly improve the safety profile of oral imatinib, which may enhance patient adherence and quality of life, potentially leading to better rates of complete cytogenetic response. We look forward to initiating a bioequivalence study in the second half of 2022."

IkT-001Pro will be evaluated in a single ascending dose bioequivalence study and will enroll approximately 64 male and female healthy volunteers aged 25 to 55 who will receive IkT-001Pro at one of four doses. The study is designed to evaluate the safety profile of IkT-

001Pro as well as identify a dose with a similar systemic exposure and pharmacokinetic profile compared to 400 mg imatinib mesylate at 96 hours post administration. Following this study, Inhibikase will conduct a superiority study comparing the selected dose of IkT-001Pro to 400 mg imatinib mesylate, the current standard-of-care for stable-phase Chronic Myelogenous Leukemia and evaluate the adverse event profile and patient reported outcomes as a measure of superiority over standard-of-care.

About Chronic Myeloid Leukemia

Chronic myeloid leukemia (CML)[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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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 are set forth in Inhibikase's filings with the SEC, including its annual report on Form 10-K for the year ended December 31, 2021, including under the caption "Risk Factors." 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] Also known as chronic myelogenous leukemia, chronic myelocytic leukemia, and chronic granulocytic leukemia (CGL).

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