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Inhibikase Therapeutics Receives FDA Clearance To Begin Evaluation of IkT-148009 in Parkinson's Patients

ATLANTA, July 26, 2021 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or "Company"), a clinical-stage pharmaceutical company developing therapeutics to modify the course of Parkinson's disease and related disorders, today announced that, after a review of safety, tolerability and pharmacokinetic data from the Company's Phase 1 clinical trial of IkT-148009 in healthy volunteers, the United States Food and Drug Administration (FDA) has given the Company clearance to begin a Phase 1b extension study to evaluate its lead drug candidate IkT-148009 in Parkinson's patients.

The randomized Phase 1 study investigated the safety, tolerability and pharmacokinetics (PK) of IkT-148009 in healthy volunteers aged 45 to 70 years old, with the objective of evaluating the safety, tolerability and the PK profile of IkT-148009 in single and multiple ascending dose settings. Forty-two patients were dosed with IkT-148009 between 12.5 and 100 mg with no clinically significant adverse events reported. High drug exposures were achieved in this dose range and were consistent with exposures observed in animal efficacy studies of inherited and sporadic progressive Parkinson's disease. Following the review, the Agency met with the Company on July 22, 2021, and granted the company permission to begin evaluation of IkT-148009 in Parkinson's patients.

"The extension of our Phase 1 study of IkT-148009 for the treatment of Parkinson's disease into patients is an important milestone for Inhibikase. IkT-148009 is a highly selective, potent inhibitor of the Abelson Tyrosine Kinase, or c-Abl, which plays a critical role in driving neurodegeneration and neuroinflammation in Parkinson's disease," stated Milton Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "In validated preclinical animal models, IkT-148009 was able to drive functional recovery in the brain and gastrointestinal tract, clear pathologic alpha-synuclein aggregates, and block neurodegeneration and neuroinflammation. With the initiation of our Phase 1b extension study in Parkinson's patients, we are excited that we may be closer to finally impacting this devastating disease that affects millions of people worldwide."

About IkT-148009
IkT-148009 is a selective c-Abl kinase inhibitor that uniquely inhibits c-Abl and the closely related Abl2/Arg enzyme without inhibition of other members of the Abl-kinase family, namely c-Kit or PDGFRa/b. It has nearly 20x the potency of the anticancer agent Imatinib against c-Abl in enzyme inhibition assays. The extension of the Company's Phase 1 study into the patient population, a Phase 1b, will focus on safety, tolerability and pharmacokinetics measured over 7 to 14 days. The Company is completing 13-week pivotal toxicology studies that will be submitted to the U.S. FDA for review in August, 2021. Following Agency review and agreement, the Company may be able to dose patients out to 3 months. Cognitive, motor function and gut motility tests will all be assessed as exploratory

endpoints in this Phase 1b study, to include measures of alpha-synuclein aggregate clearance in multiple compartments as a consequence of treatment.

About Parkinson's Disease
Parkinson's disease (PD) is the second most prevalent neurodegenerative disorder, affecting approximately 1,000,000 persons in the United States, with 60,000 new cases and 38,000 deaths annually. PD is a progressive neurodegenerative disease that initiates with misfolding of a small, non-essential protein known as alpha-synuclein inside and outside of the brain. The common features of PD include tremors at a resting state, slowing or lack of control of movement and postural instability. These features of the disease arise from degeneration of neurons that secrete dopamine to transmit neurological signals. The degeneration of these dopaminergic neurons in nigrostriatal area of the brain near the brainstem, coupled with the accumulation of alpha-synuclein protein aggregates in cell bodies and terminals known as Lewy bodies, have long been thought to be the cause of the disease. Less well known are the features of this disease can affect serotonin levels, cholinergic, and norepinephrine neurons and nerve cells in the olfactory system, cerebral hemisphere, brain stem, spinal cord, and peripheral autonomic nervous system such as in the GI tract. Currently, these non-dopaminergic features are not properly controlled with dopamine-replacement or levodopa therapy.

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. Inhibikase is currently evaluating the safety, tolerability and pharmacokinetics of IkT-148009 in older and healthy subjects and Parkinson's patients. 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, or MSA, and drug delivery technologies for kinase inhibitors such as IkT-001Pro, a prodrug of the anticancer agent Imatinib that the Company believes will provide a better patient experience with fewer on-dosing side-effects. The Company's RAMP^{TM} medicinal chemistry program has identified a number of follow-on compounds to IkT-148009 to be 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 are set forth in Inhibikase's filings with the SEC, including its registration statement on Form S-1, as amended (File No. 333-240036), 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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