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Inhibikase Therapeutics Announces Dosing of First Parkinson's Patient in its Phase 1b Clinical Trial of IkT-148009

ATLANTA, Oct. 19, 2021 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) (Inhibikase), a clinical-stage pharmaceutical company developing therapeutics to modify the course of Parkinson's disease and related disorders, today announced dosing of the first Parkinson's patient in its Phase 1b clinical trial of IkT-148009, an Abelson Tyrosine Kinase, or c-Abl, inhibitor for the treatment of Parkinson's disease.

The Phase 1b extension study is a 3:1 randomized, placebo-controlled trial investigating the safety, tolerability and pharmacokinetics of IkT-148009. The trial will enroll a total of 24 patients with Parkinson's disease across 3 escalating doses (8 patients per cohort). The study will also assess cognitive, motor function, gut motility and measures of alpha-synuclein aggregate clearance in multiple compartments, as exploratory endpoints. The Company previously reported results from its Phase 1 study of IkT-148009 in older and elderly healthy volunteers, which achieved high drug exposure between 12.5 and 100 mg with no clinically significant adverse events across 56 patients. These results were consistent with exposures observed in animal efficacy studies of inherited and sporadic progressive Parkinson's disease.

"We are pleased to begin dosing patients in our Phase 1b study. This is the first time we will assess our selective c-Abl kinase inhibitor in Parkinson's patients, which could give us an early look into the potential efficacy of this treatment in slowing or possibly halting disease progression and even partly restoring functional loss in Parkinson's disease," commented Milton Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "As we look ahead, we anticipate completing this study and advancing into a Phase 2a study in 2022."

c-Abl is a clinically validated target that is activated once plaques of alpha-synuclein are internalized by the affected neurons in the brain and gut. C-Abl drives biochemical pathways and processes that lead to degradation of the neurons affected in Parkinson's disease. Inhibition of c-Abl may restore functional loss for neurons that have not fully degraded in the brain and remodel neurons in the gastrointestinal tract, two major organ systems affected by the disease.

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 reported interim 13-week toxicology study outcomes to the FDA in October, 2021. Following Agency review and agreement, the Company plans 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 has completed its Phase 1 studies evaluating the safety, tolerability and pharmacokinetics of IkT-148009 in older and healthy subjects and has commenced a Phase 1b study in 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™ 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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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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