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Inhibikase Therapeutics Announces Interim Three-month Results from Chronic Toxicology Studies of its Oral c-Abl Kinase Inhibitor, IkT-148009, in Development for Treatment of Parkinson's Disease

- Interim animal data indicate toxicology profile improves with extended daily oral dosing of IkT-148009; demonstrated selectivity of IkT-148009 may improve safety and tolerability vs. c-Abl inhibitors -

- Results support further clinical evaluation of IkT-148009; pending FDA review, planned Phase 2a study in Parkinson's disease patients expected to initiate in 2022 -

ATLANTA, Oct. 4, 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 interim three-month results from its ongoing chronic toxicology studies of oral IkT-148009 administered in rats and non-human primates (NHPs).

The Company's ongoing toxicology studies of IkT-148009 are designed to meet the regulatory requirements for chronic dosing in humans, which include daily oral administration in rats for six months and in NHPs for nine months. In addition to these requirements, Inhibikase has added three-month dosing cohorts in rats and NHPs to support evaluation in Parkinson's patients for up to three months in its planned Phase 2a study. Today's update includes interim results at three months from both animal species, across which the toxicology profile for IkT-148009 improved the longer the drug was dosed.

"As a highly selective kinase inhibitor, IkT-148009 has demonstrated it is distinct in its ability to discriminate against the target enzyme, c-Abl, without engaging other targets in the Abelson enzyme family, including c-KIT and PDGFRa-b. We believe this property may enable IkT-148009 to offer best-in-class safety, avoiding the most harmful side-effects commonly associated with c-Abl inhibitors the longer they are dosed in patients," stated Milton H. Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "We are pleased to share interim data from ongoing chronic toxicology studies that support this hypothesis, indicating a more favorable profile in rats and non-human primates given extended treatment with IkT-148009. These learnings, coupled with the absence of clinically

significant adverse events in our Phase 1 study, add to our growing confidence in the safety and tolerability of IkT-148009. Taken together with efficacy signals observed preclinically, we look forward to evaluating IkT-148009 in a planned Phase 2a study, subject to FDA agreements, to see how this profile translates into patients with Parkinson's disease."

Inhibikase previously submitted 14-day toxicology data in rats and NHPs to the U.S. Food and Drug Administration (FDA) prior to initiating the Company's Phase 1 trial of IkT-148009 in older healthy subjects. In the 14-day study, the No Adverse Event Level (NOAEL), a measure of drug safety in animals, was determined to be 31.2 mg in NHPs, but could not be determined in rats. Following three months of dosing, NOAEL measurements in rats and NHPs were 50 mg and 75 mg, respectively, representing a 2.4-fold increase in NHPs and establishing a standard for rats.

Following FDA review of these three-month toxicology results, and subject to agreement with the Agency, the Company plans to initiate a Phase 2a study in 2022 to evaluate daily oral administration of IkT-148009 in up to 120 Parkinson's patients out to three months.

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. Following Agency review of 13-week pivotal toxicology data discussed herein and depending on agreement with the U.S. FDA on the clinical path going forward, the Company plans to initiate a Phase 2a study and dose up to 120 patients for up to 3 months of daily dosing at three different doses. Cognitive, motor function and gut motility tests will all be assessed as exploratory endpoints in these Phase 1b and Phase 2a studies, to include measures of alpha-synuclein aggregate clearance in multiple tissues and/or fluids 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 elderly 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™ 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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