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Inhibikase Therapeutics Announces Publication Highlighting Mechanism of Disease and the Potential of Oral c-Abl Kinase Inhibitor Therapy for the Treatment of Parkinson's Disease

- Publication describes role of c-Abl and misfolded alpha-synuclein proteins in the initiation and progression of neurodegeneration

- Preclinical research and clinical safety and tolerability data supports continued development of IkT-148009 to potentially slow or halt progression of Parkinson's disease

BOSTON and ATLANTA, Nov. 29, 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 the publication of a paper describing the biochemical rationale and potential benefit of Abelson Tyrosine Kinase (c-Abl) inhibition as a potential disease-modifying therapy for Parkinson's Disease. The article, titled *"Parkinson's Disease Modification Through Abl Kinase Inhibition: An Opportunity"* was published online in the journal *Movement Disorders* on November 24, 2021 (DOI: 10/1002/mds.28858).

The publication analyzes the role of both c-Abl, a non-receptor tyrosine kinase, as well as misfolded alpha-synuclein in the initiation and progression of Parkinson's disease (PD). Early research in PD hypothesized that misfolded alpha-synuclein was the primary driver in initiating the disease process. However, novel humanized preclinical mouse models of progressive, alpha-synuclein-dependent disease, indicate that while the presence of misfolded alpha-synuclein is necessary, it is not sufficient to initiate the disease. The internalization of misfolded alpha-synuclein within the affected neurons activates c-Abl, which in turns modifies the internalized misfolded protein to create a toxic form of alpha-synuclein and triggering effectors that drive the neurodegenerative disease processes. Therapeutic administration of IkT-148009, a highly selective c-Abl kinase inhibitor, demonstrated the ability to clear alpha-synuclein aggregates from the brain and GI tract, promote regeneration of neurons, and induce substantial functional recovery in measures of motor and non-motor function. These studies support that the inhibition of c-Abl could have disease modifying effects and further support the continued clinical development of IkT-148009.

"Parkinson's disease affects an estimated one million people in the U.S. and remains a significant unmet medical need. Today's publication provides a detailed mechanistic understanding of the early steps in the disease process and the role c-Abl plays in neurodegeneration. Our lead candidate, IkT-148009, a selective c-Abl kinase inhibitor, has demonstrated the potential to halt and reverse disease progression in animal models," stated Milton H. Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics and principal author of the manuscript published today along with co-author and Interim Chief Medical Officer Dr. Warren Olanow. "IkT-148009 is currently in a Phase 1b extension study in Parkinson's patients, which we believe will give us an early look into safety and tolerability of IkT-148009 in patients and evaluate potential improvements across motor and non-motor aspects of the disease in patients over 7-day dosing. We anticipate completing this extension study in 2022, and expect to present data from our Phase 1 and possibly Phase 1b studies at the AD-PD Meeting to be held March 15-20, 2022 in Barcelona, Spain."

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

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^{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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