June 13, 2022

Inhibikase Therapeutics Announces Advancement of IkT-148009 Phase 2 '201' Program Following FDA Review

Phase 1/1b '101' study terminated early; demonstrated favorable safety, tolerability, and pharmacokinetic profile in single doses up to 325 mg and multiple doses up to 100 mg

Phase 2a '201' study open for enrollment; expect to dose first patient in 2Q 2022

Phase 1/1b trial results to be presented at the Movement Disorders Society Congress in Madrid, Spain September, 2022

BOSTON and ATLANTA, June 13, 2022 /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 it is advancing its Phase 2a study ('201 trial') following review of the study protocol and Phase 1/1b ('101 trial') data by the U.S. Food and Drug Administration (FDA or 'the Agency').

The 101 trial was a single and multiple ascending dose safety, tolerability and pharmacokinetics (PK) trial evaluating once daily administration of IkT-148009, the Company's lead c-Abl inhibitor for the treatment of Parkinson's disease. The study evaluated single doses up to 325 mg per day (the 'SAD study') and multiple doses up to 100 mg (the 'MAD study') in 88 older and elderly healthy adults and subsequently in 13 patients with mild to moderately advanced Parkinson's disease. Clinical pharmacology of IkT-148009 in patients closely paralleled the clinical pharmacology of IkT-148009 in older healthy volunteers. IkT-148009 also demonstrated a favorable safety and tolerability profile up to a dose of 325 mg with no clinically significant adverse events observed.

Following a review of IkT-148009 safety, tolerability and PK data in the first two cohorts of the 101 trial in Parkinson's patients at 50 and 100 mg as well as the 201 trial protocol, the FDA agreed with the Company's view that proceeding with the 201 trial was appropriate without restrictions. Based on this feedback, Inhibikase will continue to advance the 201 trial and end enrollment of the 101 trial.

"The 101 trial was the first in human study of our novel c-Abl inhibitor, IkT-148009, which has been designed to alter the course of Parkinson's disease. The favorable safety, tolerability and PK data of IkT-148009 observed to date supports the continued pursuit of IkT-148009 clinically," commented Milton H. Werner, PhD, President and Chief Executive Officer. "Based on these data and agreement with the FDA, we are very pleased to open enrollment in our 201 trial, just 17 months from the first-in-human dose of IkT-148009. This

study will allow us to further evaluate the long-term safety and potential benefit of IkT-148009 in patients with Parkinson's disease. With our first two trial sites actively screening patients, we expect to dose the first patient in the 201 trial by the end of the second quarter."

"The 101 trial and other early studies represent key milestones that have now laid the foundation for critical trials that will define the clinical efficacy and safety of IkT-148009 over longer time periods," said Robert A. Hauser, MD, Director of the Parkinson's Disease and Movement Disorders Center of the University of South Florida.

The 201 trial is a 3:1 randomized, double-blind, twelve-week dosing trial that will measure the safety, tolerability and steady-state PK of IkT-148009 in untreated Parkinson's patients (Hoehn & Yahr < 2.0) as primary endpoints. The trial will also measure a hierarchy of Parkinson's-related disease assessments in the brain and gut as secondary or exploratory endpoints. Inhibikase expects that at least 7 of 40 total sites will be open by the end of the second quarter this year.

"Parkinson's disease is an inexorably progressive disorder and a disease-modifying therapy that slows or halts progression remains a major unmet need in the management of this disorder," said C. Warren Olanow, M.D., FRCPC, Professor Emeritus in the Department of Neurology and Department of Neuroscience at the Mount Sinai School of Medicine in New York, and Interim Chief Medical Officer of Inhibikase Therapeutics. "IkT-148009 has shown a good safety profile in initial SAD and MAD clinical studies as well as encouraging results in relevant humanized animal models of PD. We are excited to begin enrolling patients in our double blind placebo controlled 201 trial, which will evaluate the safety and potential disease modifying effects of IkT-148009 in a longer term setting for untreated Parkinson's patients."

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. 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 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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