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Inhibikase Therapeutics Announces Dosing of First Patient in its Phase 2a '201' Clinical Trial of IkT-148009 to Treat Parkinson's Disease

BOSTON and ATLANTA, Aug. 23, 2022 /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 patient in its Phase 2a study ('201 trial') evaluating IkT-148009, the Company's novel Abelson Tyrosine Kinase, or c-Abl, inhibitor for the treatment of Parkinson's disease.

"Dosing of the first patient in our Phase 2a '201' trial represents a major milestone in the development of IkT-148009 for the treatment of Parkinson's disease and related disorders," commented Milton H. Werner, Ph.D., President and Chief Executive Officer. "Parkinson's disease remains one of the most prevalent neurodegenerative disorders and affects nearly one million people in the U.S. annually. Our research continues to validate the critical role that c-Abl, a mechanistically defined target, plays in the initiation and progression of Parkinson's disease, as well as the potential of IkT-148009 as a promising new approach to disease modification. Preclinical data in animal models of human PD suggested that functional recovery could be achieved in less than 8 weeks in animal."

"We are excited to evaluate the safety and tolerability of IkT-148009 in a three-month dosing regimen, which may also have the potential to show preliminary benefits from IkT-148009 inhibition of c-Abl in patients. 12 of up to 40 planned sites have been opened, and as the summer vacation months pass, we anticipate seeing an uptick in screening rates and enrolling patients in this study as we seek to deliver on our mission to improve the lives of patients suffering from devastating neurodegenerative diseases," concluded Dr. Werner.

The 201 trial is a 1:1:1:1 randomized, double-blind, twelve-week dosing trial that will measure the safety, tolerability and steady-state pharmacokinetics of IkT-148009 as primary endpoints. The trial will enroll approximately 120 patients with untreated Parkinson's disease (Hoehn & Yahr < 3.0) who have not yet progressed to the need for symptomatic therapy. Patients will be treated at one of three randomized doses, either 50, 100 or 200 mg given once daily, or to a placebo dose. The trial will also measure a hierarchy of Parkinson's-related disease assessments in the brain and gut as secondary or exploratory endpoints. The 201 trial is currently screening patients across 12 of a planned 40 sites in North America with additional site activations ongoing on a rolling basis.

For more information regarding the trial design please seewww.clinicaltrials.gov (identifier:

NCT05424276).

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 25x the potency of the anticancer agent Imatinib against wild type c-Abl in enzyme inhibition assays. IkT-148009 has been designed to have a predictable low toxicity profile with the ability to cross the blood brain barrier and accumulate in the brain, features that were validated in animal models and extensive toxicology studies. The Company opened its first study site in its Phase 2a clinical trial to evaluate 12-week safety, tolerability and steady-state PK of IkT-148009 in untreated Parkinson's patients on 23 May, 2022.

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.

Social Media Disclaimer
Investors and others should note that the Company announces material financial information to investors using its 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 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

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