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

BOSTON and ATLANTA, May 16, 2023 /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 that the first patient has been dosed in its Phase 2 '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 '201' trial completes the first milestone in our revamped Phase 2 program evaluating the clinical benefit 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 more than one million people in the U.S. annually. Our research has validated the critical role that c-Abl 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."

The '201' trial is a 1:1:1:1 randomized, double-blind, twelve-week dosing trial intending to assess 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 yet to initiate 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 fifteen Parkinson's-related disease assessments in the brain and gut as secondary endpoints and use state-of-the-art assessments in skin and spinal fluid to measure the effect of treatment on pathological alpha-synuclein.

Additional information about the trial is available at www.clinicaltrials.gov using the identifier [NCT05424276](https://www.clinicaltrials.gov/ct2/show/study?term=NCT05424276).

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 has a primary focus 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 as well as other diseases that arise from Abelson

Tyrosine Kinase. 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 mesylate 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 an office in Lexington, Massachusetts.

Social Media Disclaimer

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, including our ability to successfully conduct clinical trials, that results in our animal studies may not be replicated in humans and our ability to maintain our Nasdaq listing. Important factors that could cause actual results to differ materially from those in the forward-looking statements include factors that are delineated in our periodic reports on Form 10-K and Form 10-Q that we file with the U.S. Securities and Exchange Commission. 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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