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Inhibikase Therapeutics Announces FDA Clinical Hold on IKT-148009 Programs

BOSTON and ATLANTA, Nov. 7, 2022 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or "Company"), a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of Parkinson's disease, Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today announced that the Company was informed via e-mail communication that the U.S. Food and Drug Administration (FDA) has reviewed its Investigational New Drug (IND) application for IKT-148009 for the treatment of Multiple Systems Atrophy (MSA) and has issued a Clinical Hold on the IKT-148009 201 program in Parkinson's disease (PD) and the use of IKT-148009 in MSA. The FDA indicated it will provide an official clinical hold letter to Inhibikase within 30 days.

"We have not seen any serious adverse events in the ongoing 201 trial and we remain committed to our mission to improve the lives of patients suffering from devastating neurodegenerative diseases," commented Milton H. Werner, Ph.D., President and Chief Executive Officer. "Given the safety, tolerability and pharmacokinetics data observed in clinical trials with IKT-148009 to date, we are actively working with the FDA to understand the agency's concerns and to resolve them as soon as possible."

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 Kinases. 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 offices in Lexington, 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 include our ability to satisfactorily address the issues raised by the FDA in order to have the clinical hold on our IND removed, as well as such other factors that are included 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.


Contacts:

Company Contact:

Milton H. Werner, Ph.D.
President & CEO
678-392-3419
info@inhibikase.com

Investor Relations:

Alex Lobo
SternIR, Inc.
alex.lobo@sternir.com

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