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Inhibikase Therapeutics Provides Update to FDA Clinical Hold of IkT-148009 Programs

BOSTON and ATLANTA, Dec. 7, 2022 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or the "Company"), a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of Parkinson's disease ("PD"), Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, announced that it has received the U.S. Food and Drug Administration's (FDA) clinical hold letter in regards to the Company's IkT-148009 programs in Parkinson's disease and Multiple System Atrophy.

The FDA raised several points, summarized below, in their explanation of the basis for the clinical hold:

- Further evaluation of the existing safety and pharmacokinetic ("PK") data and justification supporting the use of the 200 mg dose used in the Phase 2a '201' clinical trial.
- A better understanding of how the clinical trial will monitor the potential for detecting adverse events that could affect vision in trial participants and whether those adverse events are reversible.
- Need for material additions to the disclosures made to investigators and patients related to the clinical and safety measures completed to date, including the potential risks to vision in trial participants.

"We have reviewed the FDA's clinical hold letter and we will be responding to the issues cited in the letter in the coming days," said Milton Werner, Ph.D., President and Chief Executive Officer. "The FDA is seeking additional supportive information for the selection of the 200 mg dose in the '201' trial. In addition to the Phase 1b '101' trial data and the rationale for dose selection and vision monitoring in the '201' trial we reviewed with the FDA, the FDA will also receive the unblinded safety, tolerability and pharmacokinetic data from the first 11 patients in the '201' trial, including safety and pharmacokinetic data from three patients dosed at 200 mg in the '201' trial. We believe that the safety, tolerability and pharmacokinetic data measured to date support the continued development of IkT-148009 and restart of the '201' trial. We look forward to a resolution with the FDA and lifting of the clinical hold 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 Ableson 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.

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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's 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.

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