January 25, 2023

Inhibikase Therapeutics Announces FDA has Lifted the Full Clinical Hold on IkT-148009 in Parkinson's Disease

- Phase 2a '201' clinical trial will resume immediately at 50 and 100 mg doses-

-Additional safety and pharmacokinetic information will be measured in healthy subjects at the 200 mg dose prior to implementation in the 201 trial-

BOSTON and ATLANTA, Jan. 25, 2023 /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 the U.S. Food and Drug Administration ("FDA" or "Agency") has lifted the full Clinical Hold on IkT-148009 in Parkinson's disease (PD).

"We are grateful for the expeditious review by the FDA of our response to the Clinical Hold on IkT-148009 in PD," stated Milton H. Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "We believe that we now have clarity on the FDA's expectations as we move forward in the 201 clinical trial for IkT-148009. We are now working to re-open clinical trial sites and initiate screening and enrollment of patients for the trial following agreed upon updates to the Protocol and Informed Consent form. We anticipate completing these restart tasks by the end of the first quarter."

IkT-148009 is a c-Abl tyrosine kinase inhibitor that has been shown to halt disease progression, protect and restore lost neurons and to clear the underlying protein pathology in animal studies that suggests a causal link to the initiation and progression of disease in humans[1]. In lifting the clinical hold, the Agency based their decision on the Company's Complete Response and Amendment dated December 21, 2022, as well as further commitments made on January 20, 2023 regarding ophthalmologic monitoring in the protocol of study IkT-148009-201 and various modifications to the Investigator Brochure. The Agency requested that the Company measure the safety and steady-state pharmacokinetic (PK) profile of the 200 mg dose in six (6) healthy subjects prior to administration of the 200 mg dose in Parkinson's patients. The 201 trial will resume at the 50 mg and 100 mg dose immediately and the safety/PK measurement at 200 mg will be performed simultaneously.

The Agency further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial. This monitoring program is consistent with the monitoring program for ocular pathology of other approved protein kinase inhibitors.

To date, no ocular pathology has been observed in any trial participant administered IkT-148009.

The Agency further requested removal of safety-related data in the Investigator Brochure for the primary metabolites of IkT-148009 to give the Agency time to review the underlying report in support of this safety data.

With agreement on conditions for restart of the 201 trial and the lifting of the clinical hold on IkT-148009, the Company intends to seek a lifting of the Clinical Hold on its program focused on Multiple System Atrophy (MSA).

[1] DOI: 10.1126/scitranslmed.abp9352

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 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 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 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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