March 8, 2023

Inhibikase Therapeutics Announces FDA has Lifted the Full Clinical Hold on IkT-148009 in Multiple System Atrophy

- Advancing model studies of IkT-148009 in MSA; early data has shown a substantial neuroprotective benefit in response to c-Abl inhibition by IkT-148009 –

- MSA IND Opened, the 5th in the Company's history –

- Planned Phase 2a '202' clinical trial will evaluate therapeutic benefit of IkT-148009 over 6 months-

BOSTON and ATLANTA, March 8, 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, the Company's c-Abl inhibitor, in Multiple System Atrophy (MSA) allowing the Company to proceed with its plans for a future Phase 2 clinical trial in MSA.

"We are grateful for the expeditious review by the FDA of our response to the Clinical Hold on IkT-148009 in MSA," stated Milton H. Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "As with our work in Parkinson's, preclinical models have highlighted the therapeutic potential of IkT-148009 in MSA. One of two ongoing model studies has shown a substantial neuroprotective benefit in response to c-Abl inhibition by IkT-148009. With the clinical hold lifted and the IND now open, we look forward to completing these studies prior to initiation of the Phase 2a trial in this patient population.

IkT-148009 is a potent, selective, brain penetrant c-Abl tyrosine kinase inhibitor that has been shown to halt disease progression, protect and restore lost neurons and clear the underlying protein pathology in animal studies of Parkinson's disease. [1]MSA is a rare form of Parkinsonism, which occurs in a different part of the brain and advances three times faster than ordinary Parkinson's disease. In previously published work, [2]Inhibikase has demonstrated that MSA may also be initiated by c-Abl modification of alpha-synuclein aggregates in the brain. In ongoing animal models of MSA, Inhibikase has observed that IkT-148009 shows a substantial neuroprotective benefit, preventing functional loss in mice following 7 week, once-daily dosing. The Company will continue to evaluate the functional benefit of IkT-148009 for an additional 3 months in order to assess whether IkT-148009 leads to clearance of alpha-synuclein aggregate pathology in the treated animals.

The planned '202' trial will evaluate the safety, tolerability and pharmacokinetics of IkT-148009 in MSA patients over 6 months of once daily dosing at one of two oral doses. Secondary and exploratory endpoints will evaluate clinical benefit using a modification of the Total Unified MSA Rating Scale (UMSARS), assessment of quality of life. severity of symptoms arising from orthostatic hypotension, and the levels of neurofilament light chain in peripheral blood and spinal fluid. Additionally, biomarkers of treatment benefit will be explored by measuring levels of phosphorylated alpha-synuclein in spinal fluid, peripheral blood and skin. Clinical effect on the progression of atrophy will be monitored in the trial using MRI.

About Multiple System Atrophy

Multiple System Atrophy (MSA) is a rapidly progressive orphan disease affecting the central and autonomic nervous systems. MSA is characterized by pathological alpha-synuclein aggregation, which may lead to cell dysfunction and degeneration of neurons. Although it is significantly debilitating and fatal, it is classified as a rare disease, with approximately three individuals per 100,000 individuals per year aged 50 years or older diagnosed with the disease. MSA affects men and women equally, with onset of symptoms typically occurring in the fifth or sixth decade of life. Rapid progression of the disease results in patients becoming wheelchair bound in many cases, with varying combinations of extrapyramidal dysfunction, cerebellar ataxia, dysautonomia and parkinsonism. Currently, no disease-modifying or symptomatic therapies exist for MSA.

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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