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Inhibikase Therapeutics Highlights 2022 Pipeline Goals and Milestones

BOSTON and ATLANTA, Jan. 5, 2022 /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 highlighted recent developments and anticipated milestones for 2022.

Key Business and Clinical milestones expected in 2022:

- **Continue Phase 1 dose escalation of IkT-148009 in older and elderly healthy volunteers:** IkT-148009 continues to be evaluated at higher single doses in older and elderly healthy volunteers as part of the Phase 1 study, which was initiated in February 2021. To date, no clinically significant adverse events have been observed at doses up to 175 mg. Although total drug exposures measured in blood are very high compared to other drugs approved in the c-Abl inhibitor class, few laboratory abnormalities have been observed. The large systemic exposure and the absence of significant adverse events provides the opportunity to evaluate a wide dosing range in future Phase 2 and Phase 3 studies. Inhibikase expects to continue dosing patients up to a single dose of 250 mg to identify a Maximum Tolerated Dose in the first quarter of 2022 and may increase the dose beyond 250 mg subject to safety committee review.

- **Complete first two cohorts in Phase 1b study of IkT-148009 in patients with Parkinson's Disease**: The Phase 1b study is a 3:1 randomized, placebo-controlled dose escalation trial evaluating the safety, tolerability, and pharmacokinetics of seven-day dosing of IkT-148009 at three escalating dose levels. Inhibikase expects to complete enrollment and analysis of the first two cohorts of 8 patients with mild to moderate Parkinson's disease in the first quarter of 2022, with the third cohort completed in the second quarter of 2022. The study is also assessing motor and non-motor function, gut motility, and measures of alpha-synuclein aggregate clearance as exploratory endpoints.

- **Submit complete chronic toxicology data for IkT-148009 to the U.S. Food and Drug Administration (FDA) in the first quarter of 2022:** In October 2021, Inhibikase reported that it had submitted interim 13-week results from its ongoing chronic toxicology studies of IkT-148009 in rats and non-human primates to the FDA. Inhibikase expects to submit the full chronic toxicology dataset, including nine-month toxicology outcomes in non-human primates, to the FDA in the first quarter of 2022. Previously submitted interim data indicated that the toxicology profile of IkT-148009 improves with extended daily oral dosing and supports evaluation in Parkinson's patients for three months or longer, subject to review by and agreement with the U.S.

FDA.

- **Meet with the FDA to discuss the development program of IkT-148009 as a treatment for Parkinson's disease:** The Company's Fast-Track Designation request has not been granted by the FDA but remains under further consideration. As part of the review, the FDA requested that Inhibikase meet with the Agency to review the Company's near and long-term development plans and proposed efficacy measures for IkT-148009 as a treatment for Parkinson's disease. It is expected this meeting will take place in the first quarter of 2022.

- **Initiate Phase 2a clinical study for IkT-148009 in patients with Parkinson's Disease:** Inhibikase expects to dose the first patient in a Phase 2a study of IkT-148009 in untreated Parkinson's Disease in the second quarter of 2022, subject to agreements with the FDA. The 3:1 randomized, double-blind, twelve-week trial will evaluate the safety and tolerability of three doses of IkT-148009 in up to 120 patients diagnosed with Parkinson's disease who have not yet progressed to the need for symptomatic treatment. The trial will also measure motor and non-motor function inside and outside of the brain as secondary endpoints and evaluate whether treatment with IkT-148009 leads to a reduction or clearance of pathogenic alpha-synuclein aggregates inside and outside of the central nervous system as exploratory endpoints.

- **Complete preclinical studies evaluating IkT-148009 in animal models ofMultiple System Atrophy (MSA) in preparation for Phase 2 clinical studies:** Inhibikase expects to report preclinical data studying IkT-148009 in at least one of two animal models of MSA in the second quarter of 2022. The studies are evaluating whether inhibition of the Abelson Tyrosine Kinase, or c-Abl, could have a therapeutic benefit in MSA. The potential role of c-Abl in the disease process was highlighted in the Company's recent publication published in the peer reviewed journal *Neurobiology of Disease*[1]. Based on the preclinical results from these studies and subject to agreement with the FDA and equivalent regulatory bodies in the European Union, Inhibikase expects to advance IkT-148009 into a Phase 2a clinical study by the third quarter of 2022.

- **Submit Investigational New Drug application (IND) for IkT-001Pro for stable-phase Chronic Myelogenous Leukemia (CML) in the first quarter of 2022:** Commercially viable large-scale manufacturing of IkT-001Pro has been under development and resulted in the production of the first clinical batch at the close of 2021. As a result, Inhibikase expects to submit the IND for IkT-001Pro in the first quarter of 2022 and commence bioequivalence studies in accordance with the 505(b)(2) regulatory pathway following receipt of a Study May Proceed letter and other agreements with the FDA.

- **Medicinal chemistry insights into the selectivity, potency and brain penetration of IkT-148009 and related inhibitors lead to a library of potential second generation molecules:** New insights into the origins of IkT-148009's selectivity, safety, toxicology and potency have let to improved designs for c-Abl inhibitors. These new designs could build on the discoveries into how IkT-148009 and other molecules in Inhibikase's portfolio cross the blood-brain barrier, remain in the central nervous system for extended periods of time and reduce the likelihood of efflux transport back

into the systemic circulation. These insights and discoveries could lead to long-acting product offerings with less frequent dosing and improved safety profiles.

"2021 was a transformational year for Inhibikase, as we became a clinical stage Company, advanced multiple programs forward in the clinic, and reinforced our balance sheet to support our growth over the coming years," commented Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "In 2022, we will continue to work diligently to advance our programs in multiple therapeutic areas that include Parkinson's disease, MSA, and stable phase CML as we seek to treat these devastating diseases. In addition, through our research and publications, we will continue to shape the conversation around Parkinson's disease and the potential role of alpha-synuclein in disease initiation and progression, as we recently described in a peer-reviewed publication in *Movement Disorders*[2]. We expect 2022 to be another significant year for the Company and look forward achieving our outlined milestones as we seek to improve the lives of millions of patients."

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. 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, or MSA, and drug delivery technologies for kinase inhibitors such as IkT-001Pro, a prodrug of the anticancer agent Imatinib 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 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 are set forth in Inhibikase's filings with the SEC, including its registration statement on Form S-1, as amended (File No. 333-240036), including under the caption "Risk Factors." 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.

[1] doi: 10.1016/j.nbd.2020.105184
[2] doi: 10.1002/mds.28858

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