December 19, 2023

Inhibikase Therapeutics Issues Letter to Shareholders and Provides Update on Development Programs

BOSTON and ATLANTA, Dec. 19, 2023 (GLOBE NEWSWIRE) -- 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 ("PD"), Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today issued a Letter to Shareholders.

Dear Fellow Shareholders of Inhibikase Therapeutics:

What a ride it has been in 2023. The year began with a quick recovery in January from a brief clinical hold for risvodetinib as well as the successful closing of a $10 million equity raise to support the advancement of our neurodegenerative and cancer therapeutics programs. Despite the market volatility experienced this year, we approach the end of the year with our stock price up 68% since its low point of $0.81 on October 9. We have made great strides across our multi-therapeutic pipeline as the year comes to a close.

In neurodegeneration, we continue to advance our 201 trial evaluating risvodetinib in untreated Parkinson’s disease and began actively enrolling patients in the second quarter. As of today, all 32 sites are consenting, screening and enrolling patients with 35 participants enrolled, 50 potential participants scheduling or reviewing informed consent forms and 11 potential participants undergoing medical evaluations necessary to be considered for enrollment. Thus far, only three mild treatment-related adverse events have been reported across all enrolled patients. Based on the current pace of enrollment, we expect to report results from this trial in the second half of 2024. Our approach with Multiple System Atrophy, an aggressive form of Parkinson’s disease, has seen similar success in 2023. We have opened an IND for direct entry into a Phase 2 clinical trial and have received Orphan Drug Designation for risvodetinib as a treatment for MSA from the FDA, although the trial start date is yet to be determined. We plan to submit complementary regulatory documents for risvodetinib to European Union authorities in 2024. Additionally, our internal and external medical chemistry pursuits have identified four second generation molecules that will begin pharmacokinetic and therapeutic animal model studies in early 2024.

Our cancer therapeutics program has also made significant progress throughout 2023. IkT-001Pro, our prodrug of imatinib, was evaluated in 66 healthy subjects, ages 18 to 55, to measure bioequivalence to 400 mg or 600 mg imatinib mesylate. With these studies complete, we will have a pre-NDA teleconference with the FDA in early 2024 to discuss the requirements of approval of IkT-001Pro for up to nine cancer indications. Recently, we requested to amend our Orphan Drug Designation for imatinib delivered by IkT-001Pro by

adding eight additional indications. We are also evaluating the market potential of IkT-001Pro in non-oncology indications to which imatinib has already been shown to have meaningful benefit. We look forward to providing updates on this progress in the first half of 2024.

Across our therapeutic pipeline, we have developed technologies that will advance clinical development and may augment commercial success. For risvodetinib, a commercial tablet formulation was developed that doubles drug exposure at the same dose. We believe this formulation significantly improves oral drug absorption. For IkT-001Pro, the prodrug has shown early signals of safety improvements relative to imatinib mesylate, but more work will be required before we know the scope of these safety improvement across a range of patients.

2023 was a year of growth: growth of our clinical and chemistry teams as well as rapid advancement of our clinical programs. We believe 2024 will be the year of transformation. We believe our efforts are leading to transformative treatments in neurodegeneration, and, if successful, will provide benefit for millions of patients worldwide. We appreciate the resilience and enduring support from our shareholders through what has been a difficult year for micro-cap biotech. With the recent improvement in macroeconomic conditions, M&A activity, and the enthusiasm for CNS drug development that we've started to see, we look to 2024 to be a transformative year scientifically, medically and for our shareholders. As always, our transparency remains a core principle.

Everyone at Inhibikase wishes you a happy and healthy holiday season and wonderful New Year.

Sincerely,

Milton H. Werner, PhD.
President & CEO

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 risvodetinib, 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 an office in Lexington, Massachusetts.

Social Media Disclaimer
Investors and others should note that we announce material financial information to our investors using our investor relations website, press releases, SEC filings and public

conference calls and webcasts. The Company intends to also use X, 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 successfully conduct clinical trials, that results in our animal studies may not be replicated in humans, and our need for additional financing 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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Source: Inhibikase Therapeutics