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Inhibikase Therapeutics Announces Publication Highlighting Results from its Phase 1 Studies with Risvodetinib

- *Data demonstrated that Risvodetinib was well tolerated up to 7 days of daily dosing with no serious adverse events in healthy volunteers or worsening of symptoms in participants taking anti-PD medications*

BOSTON and ATLANTA, Jan. 29, 2024 (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, Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today announced a publication of Phase 1 clinical studies with risvodetinib ("risvo"), a potential disease-modifying therapy for Parkinson's disease and related disorders. The publication entitled *"A Phase I, Randomized, SAD, MAD, and PK Study of Risvodetinib in Older Adults and Parkinson's Disease"* was published online in the peer reviewed*Journal of Parkinson's Disease* (DOI: 10.3233/JPD-230319) on January 13, 2024.

"Parkinson's disease remains one of the most prevalent neurodegenerative diseases worldwide, affecting more than a million people in the U.S. alone. To date, there are no approved therapies to slow or halt disease progression, however, recently published work by us and our collaborators have pointed to the c-Abl kinase as having an important role in the disease process," said Dr. Milton Werner, President and Chief Executive Officer of Inhibikase. "Our publication in the *Journal of Parkinson's Disease* highlights our early clinical work with risvo, our lead selective inhibitor of c-Abl. In Phase 1 studies, risvo was shown to have a favorable safety profile that was well tolerated by older or elderly healthy subjects and by patients with Parkinson's disease. As we look ahead, we are rapidly advancing our 201 Trial in untreated PD patients and look forward to reporting topline results, possibly as early as the second half of 2024 depending on the enrollment date of the last trial participant."

The publication highlights the safety, tolerability and pharmacokinetics of risvo in 94 healthy volunteers and 14 participants with Parkinson's disease. The multi-part study evaluated risvo in both single ascending dose (SAD) and multiple ascending dose (MAD) studies. Older and elderly healthy participants, aged 45 to 70, in the SAD portion of the study received single doses ranging from 12.5 to 325 mg, while participants in the MAD portion received daily doses between 25 and 200 mg for seven days. In addition, participants with Parkinson's disease who remained on a stable regimen of anti-PD medications were evaluated in the MAD study at either 50 or 100 mg once daily for seven days. Risvo demonstrated a favorable safety and tolerability profile following both single or multiple doses across all trial

participants. Only 11 of the observed adverse events were deemed possibly treatment-related, with none of clinical significance. Single dose pharmacokinetics were approximately linear between 12.5 mg and 200 mg for both C_{max} and $AUC_{0\text{-}inf}$ with no pharmacokinetic difference between healthy volunteers and participants with PD. Exposures at each dose were high relative to other drugs in the same kinase inhibitor class. Of note, voluntary lumbar puncture was used to measure the concentration of risvo in cerebrospinal fluid (CSF) in six participants with or without PD. In these participants, risvo was measured in the cerebrospinal fluid just before dosing on the 7th day, when the concentration of risvo would be at steady-state trough. Measures of the CSF concentration of risvo at trough indicated that risvo crossed the blood-brain barrier and was persistently present in the central nervous system. The concentration of risvo in the brain could not be determined from these measurements in the absence of a brain biopsy.

Inhibikase continues to actively enroll patients in its Phase 2 201 Trial, evaluating risvo in untreated Parkinson's disease. As of January 29, 2024, 32 sites are open and actively evaluating prospective trial participants. 45 participants have been enrolled, 18 prospective participants are in medical screening and 54 potential participants are being evaluated for suitability to initiate medical screening. 19 participants have completed the 12 week dosing period. To date, only seven mild and one moderate adverse event that could possibly have arisen as a result of taking risvo have been reported across all enrolled 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 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 risvodetinib that could potentially be 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 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 transition the chief financial officer role, 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 discussed 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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