October 4, 2023

Inhibikase Therapeutics Receives FDA Orphan Drug Designation for Risvodetinib for the Treatment of Multiple System Atrophy

BOSTON and ATLANTA, Oct. 04, 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 announced that risvodetinib (IkT-148009) has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of Multiple System Atrophy (MSA).

“We are pleased to receive orphan drug designation for risvodetinib in MSA underscoring the high unmet medical need in this patient population. There are currently no approved symptomatic or disease-modifying therapies for MSA on the market. MSA is an aggressive form of Parkinsonism, leading to death four times faster than a diagnosis of Parkinson’s disease and we believe that risvodetinib could potentially slow or halt the progression of disease. As we look ahead, we are advancing our ongoing animal model studies of risvodetinib to determine its therapeutic potential to block progression and correct functional loss in MSA. These studies will form the basis of our planned Phase 2 clinical study and we look forward to providing further updates on the potential timing of the Phase 2 trial in the coming quarters. We believe proof that risvodetinib is clinically beneficial in MSA will form a basis for potential success in other forms of Parkinsonism,” noted Dr. Milton Werner, Chief Executive of Inhibikase Therapeutics.

In 2022, Inhibikase published data demonstrating that c-Abl is activated in the brains of patients diagnosed with MSA and that c-Abl modifies alpha-synuclein aggregates as part of the disease process. In March 2023, the Company received IND clearance for its planned Phase 2 clinical studies in MSA and presented preclinical data in August 2023, showing that risvodetinib could be therapeutically active in models of disease, at the Movement Disorder Society Congress in Copenhagen, Denmark.

The FDA’s Orphan Drug Designation program provides orphan status to drugs or biologics intended for the prevention, diagnosis, or treatment of diseases that affect fewer than 200,000 people in the United States. Sponsors of medicines that are granted Orphan Drug Designation are entitled to certain incentives and regulatory assistance, including tax credits for qualified clinical trials, prescription drug user-fee exemptions, and potential seven-year marketing exclusivity upon FDA approval.

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 organ dysfunction and degeneration of neurons. Although it is significantly debilitating and fatal, it is classified as a rare disease, with a prevalence of 3.6 to 4.9 cases per 100,000 people in the U.S. population. 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 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 Abelson 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 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 and that results in our animal studies may not be replicated in humans, 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.

Contacts:

Company Contact:
Milton H. Werner, PhD
President & CEO
678-392-3419
info@inhibikase.com

Investor Relations:
Alex Lobo
SternIR, Inc.
alex.lobo@sternir.com

Source: Inhibikase Therapeutics