

# Inhibikase Therapeutics Receives Grant from U.S. National Institutes of Health to Evaluate IkT-148009 for the Treatment of Multiple System Atrophy

ATLANTA, Sept. 23, 2021 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or "Company"), a clinical-stage pharmaceutical company developing therapeutics to modify the course of Parkinson's disease and related disorders, today announced that the Company has been awarded a \$385,388 research grant from the U.S. National Institute of Neurological Disease and Stroke (NINDS), an Institute of the National Institutes of Health (NIH), to evaluate the therapeutic potential of IkT-148009, the Company's lead c-Abl inhibitor, in a novel preclinical model for Multiple System Atrophy (MSA).

MSA is a rare, rapidly progressive neurodegenerative movement disorder affecting both the central and autonomic nervous systems. MSA is characterized by pathological alphasynuclein aggregation, which may lead to oligodendroglial cell dysfunction and degeneration of neurons. Symptoms of MSA reflect this progressive degeneration and manifest as failures in the autonomic nervous system (i.e. digestion, blood flow and pressure, etc.), Parkinsonism cerebellar ataxia, and pyramidal signs. There are currently no approved therapies to slow or halt the progression of MSA and there is no cure.

In work conducted in collaboration with the Laboratory of Jeffrey Kordower Ph.D., founding director of the Arizona State University Banner Neurodegenerative Disease Research Center, it was established that pathological alpha-synuclein in oligodendroglial cells contains the same hallmarks of c-Abl activation as in Parkinson's disease. Namely, the phosphorylation at a specific tyrosine residue in the pathological alpha-synuclein aggregates<sup>1</sup>. This grant will allow Inhibikase to evaluate the mechanism of the MSA disease process in a novel rodent model to determine if IkT-148009 could have the same therapeutic impact on the disease process as it has in models of Parkinson's disease. A complementary effort is underway in a second rodent model of MSA in collaboration with Erwan Bezard, Ph.D., INSERM Research Director, Institute of Neurodegenerative Diseases at the University of Bordeaux and non-executive director of Motac Neuroscience.

"MSA affects approximately 20,000 people in the U.S. with no meaningful therapies approved to slow or halt the progression of disease," commented Milton Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "This grant will help us to model and understand the mechanisms that drive MSA and we are pleased to be recognized by our scientific peers at NINDS and NIH. Simultaneously, we will work in collaboration with

leading experts in the field to establish the regulatory framework to advance IkT-148009 into clinical development for MSA. We believe that the continued support from government and non-profit organizations serve to further validate the potential of our science and we look forward to advancing our pipeline to treat neurodegenerative disorders."

### **About IkT-148009**

IkT-148009 is a selective c-Abl kinase inhibitor that uniquely inhibits c-Abl and the closely related Abl2/Arg enzyme without inhibition of other members of the Abl-kinase family, namely c-Kit or PDGFRa/b. It has nearly 20x the potency of the anticancer agent Imatinib against c-Abl in enzyme inhibition assays. Clinical development of IkT-148009 advanced into Parkinson's patients just 5 months into the clinical development program with excellent preclinical and clinical safety profiles and no clinically significant adverse events observed to date. The first patient to be dosed with IkT-148009 is anticipated to occur early in the fourth quarter of 2021.

# **About Multiple System Atrophy**

Multiple system atrophy (MSA) is a neurodegenerative movement disorder affecting approximately 20,000 people in the US. It occurs sporadically, usually presenting between the age 35 and 65 with a variable combination of parkinsonian, cerebellar, and autonomic features that rapidly progress to dangerous morbidity. Research toward potential treatments for MSA has been limited, resulting in a paucity of knowledge regarding its underlying causes, and there are no currently approved treatments to halt pathological progression. Initial evidence to the origins of MSA were generated by studying alpha-synuclein and its hallmark histopathology in the brains of patients with MSA. These studies established that MSA is characterized by the presence of glial cytoplasmic inclusions (GCIs) that reside predominantly in oligodendroglial cells. GCIs are comprised of abnormal conformations of alpha-synucelin, the same protein that accumulates in neurons and Lewy Bodies in Parkinson's disease (PD) and Lewy Body Dementia (LBD). Some phenotypes of MSA have little or no clinically pertinent parkinsonism, and instead present with cerebellar ataxia or dysautonomia, most frequently as orthostatic hypotension. As a reflection of the variable clinical spectrum, there is highly variable oligodendrocyte degeneration seen in the basal ganglia (substantia nigra, cardate, putamen), the cerebellum (cerebellar cortex, and Purkinje cells), and the autonomic nuclei (locus caeruleus, dorsal motor nucleus of the vagus, intermediolateral cell column of the spinal cord). Alpha-synuclein inclusions from MSA are capable of propagating to adjacent cells and inducing neurodegeneration when injected into transgenic mice, suggesting that MSA may be a prion disease. Additionally, alpha-synuclein in oligodendrocytes induces deficits in myelination in contrast to what is seen for synuclein aggregates in PD.

## 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. Inhibikase has completed its Phase 1 studies evaluating the safety, tolerability, and pharmacokinetics of IkT-148009 in older and healthy subjects and has

<sup>&</sup>lt;sup>1</sup> (Neurobiology of Disease v. 148, page 105184 (2021). doi: 10.1016/j.nbd.2020.105184).

commenced a Phase 1b study in Parkinson's patients. 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 ondosing side-effects. The Company's RAMP<sup>TM</sup> 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.

### **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 <a href="Twitter">Twitter</a>, <a href="Facebook">Facebook</a>, <a href="LinkedIn">LinkedIn</a> and <a href="YouTube">YouTube</a> 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 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.

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