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Inhibikase Therapeutics Files Two Investigational New Drug Applications for IkT-148009, a Disease-Modifying Therapy for Parkinson's Disease

ATLANTA and BOSTON, Feb. 26, 2019 (GLOBE NEWSWIRE) -- Inhibikase Therapeutics, Inc., a pharmaceutical company developing protein kinase inhibitors for treatment of neurological infections and neurodegenerative diseases, today announced that it has filed two Investigational New Drug (IND) applications with the U.S. Food and Drug Administration (FDA) to initiate human clinical trials of IkT-148009, a cellular Abelson tyrosine kinase (c-Abl) inhibitor for Parkinson's Disease (PD) and related disorders.

The first IND filed will seek to treat PD using standard measures such as the Unified Parkinson's Disease Rating Scale as a primary readout of treatment benefit. The second IND will use novel diagnostic tools and natural history patient data to evaluate treatment benefit by IkT-148009 using new primary endpoints in the GI tract. The second IND builds upon prior work completed by the Company that demonstrates many PD patients suffer from severe constipation, difficulties swallowing and failure to properly process food along the GI tract related to alpha synuclein accumulation. The Company believes disease-modification can be more easily demonstrated and proven in the GI tract using these new primary measures of GI function. Following FDA review and clearance, the Company anticipates first-in-human studies will commence in 2Q19.

"These IND applications for IkT-148009 represent important regulatory milestones for Inhibikase," said Milton Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "Our novel c-Abl inhibitor therapy for Parkinson's Disease has demonstrated compelling promise in preclinical studies, and we are excited by IkT-148009's new approach to potentially both halt and reverse Parkinson's Disease. We look forward to providing further updates on the program."

"The greatest unmet need of the millions of people with Parkinson's is a treatment to slow or stop disease progression. C-Abl inhibitors are a promising route to that goal, but important data on safety and efficacy are still needed. We are glad to see more opportunities to test this strategy in human volunteers," said Brian Fiske, Ph.D., Senior Vice President of Research Programs at The Michael J. Fox Foundation, which supported preclinical studies of this compound.

IkT-148009 is a novel, orally delivered, once-a-day c-Abl inhibitor therapy for Parkinson's Disease that has been shown to both halt and reverse the disease course in animal models that mimic progressive disease in the brain or gastrointestinal tract. IkT-148009 builds upon

the Company's research on the mechanism by which alpha-synuclein dysfunction leads to PD and related disorders. This research has demonstrated that the pathway(s) governing the disease course pass through c-Abl as a checkpoint, showing that PD may be better described as a disease of kinase activation. Mimicry of the progressive disease process in both the brain and gastrointestinal tract suggests that the process of neurodegeneration is very similar inside and outside of the brain. The Phase 1 studies will evaluate the human safety, tolerability and pharmacology of IkT-148009 in newly diagnosed and early stage Parkinson's patients.

About Parkinson's Disease

Parkinson's disease (PD) is the second most prevalent neurodegenerative disorder, affecting approximately 1,000,000 persons in the United States, with 60,000 new cases annually. PD is a progressive neurodegenerative disease that initiates with dysfunction of a small protein known as alpha-synuclein, inside and outside of the brain. The common features of PD include tremors at a resting state, slowing or lack of control of movement and postural instability. These features of the disease arise from degeneration of neurons that secrete dopamine to transmit neurological signals. The degeneration of these dopaminergic (DA) neurons in nigrostriatal area of the brain near the brainstem, coupled with the accumulation of alpha-synuclein protein aggregates in cell bodies and terminals known as Lewy bodies (LBs), have long been thought to be the cause of the disease. Less well known are the features of this disease can affect serotonin levels, cholinergic, and norepinephrine neurons and nerve cells in the olfactory system, cerebral hemisphere, brain stem, spinal cord, and peripheral autonomic nervous system such as in the GI tract. Currently, these non-dopaminergic features are not properly controlled with dopamine-replacement or levodopa therapy.

About Inhibikase Therapeutics

Inhibikase Therapeutics, Inc. is a pharmaceutical company focused on the development of protein kinase inhibitors for treatment of neurological infections and neurodegenerative diseases. The Company's pipeline includes multiple products developed from its proprietary RAMP drug innovation and prodrug technology engines, using the same clinically validated kinase target. The Company is headquartered in Atlanta, Georgia and operates out of Boston, Massachusetts.

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