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Inhibikase Therapeutics Provides Safety and Functional Update on its Phase 1/1b 101 Trial and its Phase 2 IkT-148009 201 Trial in Parkinson's Disease

- State-of-the-art biomarker analyses a hallmark of the 201 study -

BOSTON and ATLANTA, April 26, 2023 /PRNewswire/ -- 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 reported updates in the design and execution of its Phase 2 '201' program with IkT-148009 to treat Parkinson's disease.

"We continue to make progress in our '201' program in Parkinson's disease following the clinical hold lift by the FDA earlier this year," remarked Dr. Milton Werner, President & CEO of Inhibikase Therapeutics. "We have worked diligently to implement protocol changes arising from our agreements with the FDA and now have multiple sites screening patients. In addition, we have implemented newly described biomarker analyses in the skin and spinal fluid into the trial to analyze the response to treatment for enrolled patients.[1-2] In parallel, we have completed the evaluation of safety and steady-state pharmacokinetics of the 200 mg dose of IkT-148009 in healthy volunteers. These data have been submitted to the FDA and support the inclusion of the 200mg dose in the '201' trial. We look forward to enrolling the multiple patients the second quarter and will provide additional updates as enrollment progresses."

Recent Developments:

- **Site activation for the '201' trial ongoing:** With 35 sites selected, 11 sites are anticipated to be screening patients by the close of April, 2023. It is anticipated that 30 sites will be screening patients by the end of 2Q23.

- **State-of-the-art biomarker analyses of alpha-synuclein status inside and out of the brain implemented in the '201' trial:** As published on April 12, 2023 and implemented in the 201 trial,[1] the Parkinson's Progression Marker Initiative, or PPMI, published in *Lancet Neurology* a study showing how protein 'seed amplification assays (SAAs)' of spinal fluid can accurately diagnose Parkinson's disease, even in patients who lack disease manifestation. SAAs could form the basis of a spinal fluid biomarker for analysis of treatment benefit in Parkinson's disease. Similarly, skin biopsy analysis

as implemented in the 201 trial has been further validated as a biomarker resource for discriminating patients with different forms of Parkinsonism and for evaluating treatment benefit.[2] Further advancements in the use of skin biopsies in the 201 trial will be announced by our collaborators at the upcoming American Academy of Neurology meeting on April 26, 2023, that includes Inhibikase Director Dr. Roy Freeman.

- **Analysis of Phase 1b data at 50 mg and 100 mg doses**provided further encouragement that these doses should be studied in the 201 trial. Six patients were dosed with 50 mg for 7-days, once daily, while five patients were dosed at 100 mg for 7-days, once daily; across both cohorts, there were three patients given placebo. End-of-study assessments have now been analyzed for all 14 patients which included the two week period following once daily dosing for 7-days. Relative to baseline, MDS-UPDRS Part I declined for the 50 mg and 100 mg dose groups by an average of -4.33 and -1.8 points, respectively, while mean changes in Part II declined -2.0 and -1.4 points, respectively. Pooling the date in the placebo groups either showed no change in Part I or increased by +2.0 points in Part II. Part III MDS-UPDRS changes were small, but increases in Part III were greater for pooled placebos relative to either treatment group. Mean changes from baseline for the Non-Motor Symptom Score (NMSS) declined an average of -10 and -3.6 points for the 50 and 100 mg cohorts, respectively, while the mean score across the pooled placebo group increased by +10 points. Changes from baseline for measures of upper (PAGI-SYM) and lower (PAC-SYM) gastrointestinal tract functionality were small. Given the small cohort size (5 or 6 active, 1 or 2 placebo per dose) and short dosing duration, we don't view these observations as a true measure of clinical response, but they are encouraging observations as the 201 trial gets underway. A future publication will fully describe the outcomes of the single and multiple dose escalation trial of IkT-148009 in healthy subjects and Parkinson's patients, known as the 101 trial.

- **Completed Analysis of the 200 mg dose of IkT-148009 in healthy volunteers:**In March, 2023, Inhibikase completed evaluation of the 200 mg dose given once daily for 7-days in six healthy volunteers to determine the safety and steady-state pharmacokinetic profile of IkT-148009. The pharmacokinetics of the 200 mg dose were consistent with expectations, with steady-state being reached by the fourth day, a 24 hour half-life, and exposures that increased linearly from the 100 mg dose. There were six mild, potentially drug-related adverse events reported, with each event resolved without any adjustment to the dose and none of clinical significance. These data support the inclusion of the 200mg dose in the '201' trial and the Company has submitted the data to the FDA.

[1] DOI:https://doi.org/10.1016/S1474-4422(23)00109-6
[2] DOI: https://doi.org/10.1212/WNL.0000000000206772

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 IkT-148009, 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.

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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

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