

June 5, 2024



Inhibikase Therapeutics Announces Expansion to its Therapeutic Pipeline and Updates its Research and Development Programs

- Company positioning multiple assets for late-stage development across its therapeutic pipeline –

BOSTON and ATLANTA, June 05, 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 ("PD"), Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today announced expansion of its therapeutic pipeline and multiple updates to its Research and Development programs.

“At Inhibikase we have let fundamental scientific discoveries drive identification of new product candidates that could transform the lives of patients. We first began clinical development of our product candidates in 2021. In 2025, we anticipate having multiple late-stage ready assets across our therapeutic pipeline,” commented Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. “The 201 Trial in untreated Parkinson’s disease has reached 94% enrollment and we anticipate enrolling the last patient in mid-June. In parallel, we are seeking grant funding for the 202 trial in Multiple System Atrophy through The National Institute of Neurological Diseases and Stroke (NINDS). Finally, following our pre-IND meeting with the U.S. Food and Drug Administration (FDA) in April, 2024, we have made the decision to redirect our efforts with IkT-001Pro into cardiopulmonary disease, opening a new therapeutic area for the Company. Taken together, we believe we are on track to advance our clinical assets into late-stage trials in the coming year.”

Upcoming Milestones and Strategic Updates:

- **Complete The 201 Trial in untreated Parkinson’s disease.** The Company anticipates that the last patient will complete the 12-week treatment period before the close of the third quarter of 2024. The Company expects to report biomarker and outcome data to support the Company’s pursuit of an End of Phase 2 and Phase 3 protocol discussion with the FDA by the end of 2024.
- **Expansion into cardiopulmonary disease.** Following the Company’s pre-IND meeting with the FDA, the Company will submit its IND application to the FDA for IkT-001Pro as a treatment for Pulmonary Arterial Hypertension (PAH) early in the third quarter of 2024, opening a new therapeutic area for the Company. The active ingredient in IkT-001Pro, imatinib, has previously been shown to be disease-modifying for PAH. The Company believes that 001Pro could have a more favorable safety and tolerability profile compared to imatinib for this indication. If approved, IkT-001Pro

could be a branded product with all the value drivers of a novel treatment for indication of high unmet need. The IND for 001Pro in PAH represents the seventh the Company has filed since 2019.

- **Scaling manufacturing of IKT-001Pro.** Following the Company's pre-NDA meeting with the FDA in January, 2024, the Company is scaling its process development efforts for IKT-001Pro to support late-stage clinical development and NDA batch requirements. These activities include development of new dosage forms to differentiate 001Pro tablets from generic imatinib mesylate in alignment with FDA feedback.
- **Seeking support for the 202 Trial in Multiple System Atrophy through the Other Transaction Authority of NINDS.** The National Institute of Neurological Diseases and Stroke (NINDS) is initiating a new funding mechanism for clinical development in neuroscience beginning June, 2024. Through this new program, termed the Other Transaction Authority (OTA), the Company is seeking to support its Phase 2 '202 Trial' in MSA trial using a dedicated U.S. trial network set-up by the Institute.
- **Discontinuing antiviral development for Progressive Multifocal Leukoencephalopathy (PML):** As part of the Company's strategy to focus on late-stage clinical assets in neurodegeneration, cancer and cardiopulmonary disease, Inhibikase will discontinue development of treatments for PML.

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 several 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.

Social Media Disclaimer

Investors and others should note that the Company announces material financial information to investors using its 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 enroll and complete the 201 Trial evaluating Risvodetinib in untreated Parkinson's disease, to successfully apply for and obtain FDA approval for IkT-001Pro in blood and stomach cancers or other indications, to successfully conduct clinical trials that are statistically significant and whether results from our animal studies may 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

Precision AQ

alex.lobo@precisionaq.com



Source: Inhibikase Therapeutics