April 3, 2024

Inhibikase Therapeutics Announces Pre-IND Meeting with the FDA for IkT-001Pro in Pulmonary Arterial Hypertension

Meeting to discuss potential of IkT-001Pro as a disease modifying treatment for Pulmonary Arterial Hypertension

BOSTON and ATLANTA, April 03, 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, Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today announced that the Company will meet with the Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) in the Division of Cardiology and Nephrology (DCN) at the U.S. Food and Drug Administration (FDA) for a Pre-IND meeting to discuss IkT-001Pro ("Pro") as a treatment for Pulmonary Arterial Hypertension (PAH). The meeting will be held on April 5, 2024, with meeting results to be reported following receipt of the formal meeting minutes.

"Following our pre-NDA discussion with the FDA related to the path to approval for IkT-001Pro in up to 11 blood and stomach cancers in January, we requested an additional FDA meeting with the Division of Cardiology and Nephrology to discuss Pro as a treatment for Pulmonary Arterial Hypertension," said Dr. Milton Werner, President and Chief Executive Officer of Inhibikase. "PAH is a rare condition that primarily afflicts women between the ages of 30 and 60 and can lead to premature heart failure and death. Previous clinical research with imatinib, the active ingredient in Pro, was shown to be potentially disease-modifying for PAH, however, the adverse event profile of imatinib mesylate in this patient population could not support approval by the FDA. We believe that Pro may be a be a safer and better tolerated therapeutic option for imatinib treatment in PAH. We look forward to the FDA's input on a proposed late-stage trial design and to the FDA's viewpoint on if Pro could be treated as a branded product for this indication."

Pulmonary Arterial Hypertension is a rare disease of the pulmonary microvasculature. PAH can arise spontaneously, or can be caused by genetic mutations, drugs or environmental toxins. PAH is also associated with connective tissue disease (CTD), congenital heart disease, HIV infection and other insults that could affect the right side of the heart. Most treatments for PAH attempt to address symptoms of this progressive disorder, but the recent approval of Winrevair® highlights that disease-modification is possible. There are approximately 30,000 cases of PAH in the U.S. The global PAH market size was valued at $7.66 billion in 2023 and is estimated to grow at a compound annual growth rate of 5.4% between 2024 to 2030.

Imatinib has been shown to have efficacy on par with Winrevair® (doi: 10.1164/rccm.201001-0123OC), however its side effect profile precluded approval in this patient population. Changes in the standard-of-care for these patients suggests that the serious adverse events which arose from treatment with imatinib mesylate in the 2010s may not occur when imatinib is delivered as IkT-001Pro; the Company has yet to conduct any clinical studies to validate this hypothesis. The Pre-IND meeting will review our proposed late-stage trial design to reproduce efficacy and evaluate the safety and tolerability of imatinib delivered by IkT-001Pro in patients with WHO Class I PAH, as well as seek regulatory advice or clarity on FDA orange book exclusivity, approval pathways, special designations. Based on the meeting outcome, the Company will evaluate whether to proceed with filing the IND for IkT-001Pro in this indication and undertake a strategic review and business development initiative to define the Company's path forward with this product.

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 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
Stern Investor Relations, Inc.
alex.lobo@sternir.com

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