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Inhibikase Therapeutics Announces Final Pre-IND Meeting Outcomes for IkT-001Pro as a Treatment for Pulmonary Arterial Hypertension

- FDA indicated IkT-001Pro can be considered a New Molecular Entity and is eligible for exclusivity designations in Pulmonary Arterial Hypertension –

BOSTON and ATLANTA, May 09, 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 has received final meeting minutes from its recent pre-IND meeting with the Division of Cardiology and Nephrology of the U.S. Food and Drug Administration (FDA) for IkT-001Pro ("Pro") as a candidate treatment for Pulmonary Arterial Hypertension (PAH). Following review of the final meeting minutes, Inhibikase is preparing the Investigational New Drug (IND) application.

"Following our pre-IND discussion with the FDA related to the chemical entity status and path to approval for Pro as a treatment for Pulmonary Arterial Hypertension, the FDA confirmed in final meeting minutes that Pro would be considered a New Molecular Entity (NME) in PAH," said Dr. Milton Werner, President and Chief Executive Officer of Inhibikase. "This designation opens the path to patent and NME exclusivity for IkT-001Pro even though the FDA agreed that the 505(b)(2) path is appropriate for approval. If approved, IkT-001Pro could be a branded product with all the value drivers of a novel treatment for an indication of high unmet medical need. PAH is a rapidly progressing, often fatal disease affecting primarily women between the ages of 30 and 60. There are several products on the market that address symptoms of the disease, but only one disease-modifying therapy has been approved to date. In previous clinical trial work, imatinib, the active ingredient in Pro, demonstrated that it could be disease-modifying for PAH. We believe that Pro has the potential to be a safer and better tolerated therapeutic option for imatinib treatment and are actively pursuing partnership discussions to advance Pro into clinical development."

In the final minutes from the pre-IND meeting, the FDA agreed that Inhibikase had built a bridge between imatinib's use in blood and gastrointestinal cancers and PAH and supported the Company's Phase 2/3 design as the initial clinical pursuit. The FDA requested the Company complete a pre-clinical cell culture-based study of the hERG ion channel to compare Pro to imatinib as Imatinib has previously been linked with certain cardiovascular abnormalities. The Company intends to complete this 7-day experiment prior to an IND submission. In parallel, the Company has initiated discussions with potential strategic partners in order to advance the development of Pro for Pulmonary Arterial Hypertension.

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 and HIV infection. 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.

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.

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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.

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