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Inhibikase Therapeutics Announces Preliminary Outcomes of its Pre-NDA Meeting with the FDA on the Pathway for Approval for IkT-001Pro in Blood and Gastrointestinal Cancers

- The Company continues to progress the 201 Trial evaluating risvodetinib in untreated Parkinson's disease -

BOSTON and ATLANTA, Feb. 07, 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 preliminary outcomes of the Company's discussion with the U.S. Food and Drug Administration (FDA) on the path to approval of IkT-001Pro in blood cancers, the Company's prodrug of the anticancer agent imatinib mesylate.

"We were pleased with the discussion we had with the FDA as we begin the process of building our first NDA package needed for approval," said Dr. Milton Werner, President and Chief Executive Officer of Inhibikase. "Our bioequivalence studies were presented to the FDA and we were given specific guidance on the manufacturing requirements necessary to complete the NDA. The FDA acknowledged that the appropriate approval path appears to be 505(b)(2) and we plan to seek all 11 indications for which imatinib mesylate has been approved, including its use in children. There is significant work ahead of us as we discuss these details with potential commercialization partners and carry out the work needed for the NDA submission," noted Dr. Werner.

On January 19, 2024, members of the Company along with its medical oncology consultants met with the FDA Review Team from the Division of Hematologic Malignancies to discuss the Company's bioequivalence studies of IkT-001Pro. During the meeting Inhibikase inquired whether additional clinical studies may be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appears to be the appropriate pathway for approval of IkT-001Pro and indicated that, pending formal review of the Company's clinical data, clinical studies completed to date indicate that 600 mg and 800 mg IkT-001Pro provides similar exposures to 400 mg and 600 mg imatinib mesylate, respectively. These preliminary outcomes from the meeting are subject to formal review of the NDA package. In addition, given that imatinib mesylate is approved for use between 300 mg and 800 mg once

daily for a variety of blood and gastrointestinal cancers, the Review Team advised that if the Company intends to seek approval across all currently approved indications, Inhibikase should evaluate additional doses as needed to measure the safety, tolerability and bioequivalent dose of IkT-001Pro that would deliver up to 800 mg, the highest approved dose of imatinib mesylate. The Review Team also discussed the possible difference between IkT-001Pro and imatinib mesylate absorption in the gut and recommended the Company evaluate whether IkT-001Pro and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. Inhibikase is in alignment with the FDA and is initiating the necessary pre-clinical tests to evaluate this further to ensure that delivery of imatinib by IkT-001Pro mimics imatinib mesylate in all respects. Finally, a number of recommendations were discussed to prevent the mix-up between 001Pro and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. A comprehensive use-related risk analysis will be conducted as part of the manufacturing and quality control development program to identify ways to discriminate the two drugs by appearance, pill size and dosage. The Company will request milestone-based meetings as it completes the manufacturing and quality control processes to ensure are it is meeting the manufacturing requirements for approval.

The Company has continued to make progress in its evaluation of risvodetinib in the 201 Trial in Untreated Parkinson's disease. As of February 7, 2024, 32 sites are open and actively evaluating prospective trial participants. 51 participants have been enrolled, 19 prospective participants are in medical screening and 46 potential participants are being evaluated for suitability to initiate medical screening. Twenty-three participants have completed the 12 week dosing period. Nine mild and one moderate treatment-related adverse events have been reported across all enrolled participants taking risvodetinib.

About IkT-001Pro

IkT-001Pro is a prodrug formulation of imatinib mesylate and has been developed to improve the safety of the first FDA-approved Abelson (Abl) kinase inhibitor, imatinib (marketed as Gleevec®). Imatinib is commonly taken for hematological and gastrointestinal cancers that arise from Abl kinase mutations found in the bone marrow or for gastrointestinal cancers that arise from c-Kit and/or PDGFRa/b mutations in the stomach; c-Kit, PDGFRa/b and Abl are all members of the Abelson Tyrosine Kinase protein family. IkT-001Pro has the potential to be a safer alternative for patients and may improve the number of patients that reach and sustain major and/or complete cytogenetic responses in Stable-Phase Chronic Myelogenous Leukemia ("Stable-Phase CML") and/or reduce the relapse rate for these patients. In preclinical studies, IkT-001Pro was shown to be as much as 3.4 times safer than imatinib in primates, reducing burdensome gastrointestinal side effects that occur following oral administration. Imatinib delivered as IkT-001Pro was granted Orphan Drug Designation for Stable-Phase CML in September, 2018.

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 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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Investors and others should note that we announce material financial information to our investors using our 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, our ability to successfully apply for and obtain FDA approval for IkT-001Pro in blood cancers and whether the FDA's signed meeting minutes differ from written pre-meeting comments or oral discussion that occurred during our pre-NDA meeting for IkT-001Pro. Additional factors include our ability to successfully conduct pre-clinical and clinical studies, and whether results of our animal studies translate to a clinical benefit in humans, as well as our need for additional financing and other such factors that are discussed 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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