February 28, 2024

# Inhibikase Therapeutics Announces Full Outcomes of its Pre-NDA Meeting with the FDA for IkT-001Pro

## Company to pursue eleven indications for IkT-001Pro; all previously approved for treatment with imatinib mesylate

BOSTON and ATLANTA, Feb. 28, 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 and stomach cancers, the Company's prodrug of the anticancer agent imatinib mesylate.

"With the full meeting minutes from the FDA Review Team in hand, we are confident in our approach as we develop the NDA for IkT-001Pro," said Dr. Milton Werner, President and Chief Executive Officer of Inhibikase. "Of note, we may not need to complete a formal risk analysis of the possibility of medication errors following discussion of alternative dosage forms with the FDA, but we will have to provide justification for the selected dosage forms to be proposed in the NDA. Further, we are not restricted from use in children nor restricted to just blood cancer-related approved indications. This opens-up the opportunity to seek all 11 approved indications for IkT-001Pro that were previously approved for imatinib mesylate. We are pleased with the discussions we've had so far with the FDA and look forward to the work ahead of us needed for the NDA submission."

On February 12, 2024, the FDA Review Team from the Division of Hematologic Malignancies issued final meeting minutes from the pre-NDA video conference that took place January 19, 2024. In the minutes, the FDA noted that it may not be necessary to conduct a formal use-related risk analysis of medication errors due to the Company proposing dosage forms that would not overlap with those of imatinib mesylate. In the NDA package, the Company will have to justify why its alternate dosage forms could overcome the risk of dosing errors by physicians and patients. Following the discussion with the Review Team about possible differences in the way IkT-001Pro and imatinib mesylate are absorbed in the gut, the FDA agreed with the Company's assertion that a pre-clinical analysis of gut absorption should be performed to determine whether a food effect clinical study is warranted, since the Company's clinical measures were all performed using an FDA-approved meal prior to taking IkT-001Pro or imatinib mesylate. While the Company will have to supply data and/or rationale for use of IkT-001Pro in any indication for which imatinib mesylate is approved, use in children will need to be accompanied by a statutory

planning document related to dose adjustments and use in children of different ages and/or weights. This planning document is required for any product in which use in children is proposed. All other elements of the pre-NDA meeting remain unchanged from those reported on February 7, 2024.

The Company continues to explore additional indications for which imatinib delivered by IkT-001Pro could be useful and has an upcoming meeting with the FDA to discuss cardiopulmonary applications of IkT-001Pro in April, 2024.

**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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**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 and our ability to successfully apply for and obtain FDA approval for IkT-001Pro in blood and stomach cancers or other indications. 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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