August 17, 2023

Inhibikase Therapeutics Announces Completion of the 501 Bioequivalence Study of IkT-001Pro

- 600 mg IkT-001Pro demonstrated bioequivalence to Standard-of-Care 400 mg Dose of Imatinib mesylate -

- Minimal adverse events with consistent drug delivery seen across 31 subjects in the pivotal trial -

- Company to submit FDA meeting request to discuss regulatory approval pathway -

BOSTON and ATLANTA, Aug. 17, 2023 /PRNewswire/ -- 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 the completion of its bioequivalence study of IkT-001Pro compared to 400 mg imatinib mesylate.

"We are pleased to announce the completion of the pivotal phase of our 501 study evaluating IkT001Pro," stated Dr. Milton Werner, President and Chief Executive Officer of Inhibikase Therapeutics. "The study met expectations and demonstrated that the 600 mg dose of IkT-001Pro was equivalent to standard-of-care 400 mg imatinib mesylate. IkT-001Pro demonstrated a favorable safety and tolerability profile that we are planning to further differentiate from standard of care by establishing the bioequivalent dose for high dose 600 mg imatinib mesylate, a dose that is poorly tolerated in patients. We are preparing to submit a meeting request to the FDA in the near term to discuss the requirements for approval under the 505(b)(2) pathway."

The '501' bioequivalence study evaluated IkT-001Pro at four single ascending doses of 300, 400, 500 and 600 mg in 27 healthy subjects ranging in age from 18 to 55, followed by a pivotal phase comparing the 600 mg of IkT-001Pro to 400 mg imatinib mesylate in 31 healthy volunteers. In total, fifty adverse events were observed following treatment with IkT-001Pro or commercial 400 mg imatinib mesylate, 24 of which were possibly or probably related to the administration of either study drug to the participants in the trial. All adverse events were of mild severity, with the most common adverse events being muscle aches or pains, headache, insomnia or a feeling of bloatedness. Imatinib delivered by IkT-001Pro demonstrated a slower rise time to maximum plasma concentration (T_{max}) of 6 hours, compared to the 4-hour T_{max} of 400 mg imatinib mesylate, but displayed lower inter-patient variability relative to standard-of-care. Mean and median maximum plasma concentration

(C_{max}) and overall exposure ($AUC_{0\text{-}infinity}$) were approximately 16% higher for IkT-001Pro relative to 400 mg imatinib mesylate, consistent with higher total imatinib delivery by 600 mg IkT-001Pro.

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 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 non-human 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 Chronic Myelogenous Leukemia

Chronic myeloid leukemia[1] is a slowly progressing cancer that affects the blood and bone marrow. In CML, a genetic change takes place in immature myeloid cells — the cells that make most types of white blood cells. This change creates an abnormal gene product called BCR-ABL which transforms the cell into a CML cell. Leukemia cells increasingly grow and divide in an unregulated manner, eventually spilling out of the bone marrow and circulating in the body via the bloodstream. Because they proliferate in an uncontrolled manner, the excessive production of myeloid cells acts like a liquid tumor. In time, the cells can also settle in other parts of the body, including the spleen. CML is a form of slow-growing leukemia that can change into a fast-growing form of acute leukemia that is difficult to treat.

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 focuses on neurodegeneration and its lead program IkT-148009, 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 offices in Boston, Massachusetts.

Social Media Disclaimer

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 Twitter, 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 satisfactorily address the issues raised by the FDA in order to have the clinical hold on our IkT-148009 programs removed, 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
SternIR, Inc.
alex.lobo@sternir.com

[1] 1 Also known as chronic myelogenous leukemia, chronic myelocytic leukemia, and chronic granulocytic leukemia (CGL).

View original content to download multimedia:https://www.prnewswire.com/news-releases/inhibikase-therapeutics-announces-completion-of-the-501-bioequivalence-study-of-ikt-001pro-301903289.html

SOURCE Inhibikase Therapeutics, Inc.