

Inhibikase Therapeutics Reports First Quarter Financial Results and Highlights Recent Period Activity

Company to host conference call on Tuesday, May 16, 2023 at 8:00 a.m. ET

BOSTON and ATLANTA, May 15, 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 ("PD"), Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today reported financial results for the first quarter ended March 31, 2023 and highlighted recent developments.

"With a clear clinical path ahead, we are focused on executing across our pipeline portfolio in 2023," said Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "Our recent industry presentations and publications have highlighted the exciting promise of our lead IkT-148009 program in neurodegenerative disease. We began screening patients in April at 7 sites for our Phase 2 '201' trial for Parkinson's disease and anticipate up to fourteen sites to be screening patients by the end of May. In addition, we are rapidly advancing our '501' bioequivalence study for IkT-001Pro for Stable-Phase CML and anticipate commencing the confirmatory analysis portion of the study in June 2023. We look forward to providing updates on both our clinical and preclinical efforts later this year."

Recent Developments and Upcoming Milestones:

• Actively screening patients across multiple sites in the Phase 2 '201' Clinical Trial of IkT-148009 for the Treatment of Parkinson's Disease: The '201' trial is a 1:1:1:1 randomized, double-blind, twelve-week dosing trial intended to assess the safety, tolerability and steady-state pharmacokinetics of IkT-148009 as primary endpoints. Inhibikase plans to enroll 120 patients with untreated Parkinson's Disease (Hoehn & Yahr < 3.0) who have yet to require symptomatic therapy. The study will evaluate three doses of IkT-148009 on a staggered schedule with 50 and 100 mg doses preceding 200 mg enrollment. The trial will also measure a hierarchy of fifteen Parkinson's-related disease assessments in the brain and gut as secondary or exploratory endpoints. Thirty-six clinical sites have now been selected with 27 fully contracted. Up to 14 sites could be actively screening patients by the end of May 2023.

In March 2023, Inhibikase completed an evaluation of safety and steady-state pharmacokinetic (PK) profile of the 200 mg dose of IkT-148009 in six healthy volunteers and submitted the data to the FDA in April 2023. The Company is completing an ethics committee review at all sites to add this dose into the '201' trial.

- Completed Dose escalation portion of the '501' bioequivalence study of lkT-**001Pro**: IkT-001Pro is the Company's prodrug formulation of imatinib mesylate intended to enhance the safety and efficacy of imatinib (marketed as Gleevec®) in patients with Chronic Myelogenous Leukemia (CML). In May 2023, Inhibikase completed dosing of the four dose escalation cohorts evaluating 300, 400 and 500 and 600 mg lkT-001Pro. As the Company completes the pharmacokinetic analysis of these four cohorts, Inhibikase anticipates identifying the dose of IkT-001Pro that delivers the equivalent dose of commercial 400 mg imatinib mesylate. IkT-001Pro has shown a favorable safety profile, with fewer adverse events observed relative to 400 mg imatinib mesylate and none of clinical significance. Inhibikase anticipates commencing the confirmatory analysis of the bioequivalent dose of IkT-001Pro in thirty-two additional healthy volunteers using a two-period crossover design in June 2023. The Company expects to complete this confirmatory analysis by the end of the second guarter 2023. Inhibikase is also considering the addition of a cohort that will measure bioequivalence for high-dose imatinib delivered by prodrug that is equivalent to 600 mg imatinib mesylate to further explore the safety benefit of IkT-001Pro over standard-ofcare, subject to agreement with the FDA.
- Advancing preclinical development of lkT-148009 in MSA: In March 2023, Inhibikase announced that the Investigational New Drug (IND) application for the Phase 2 trial of lkT-148009 in MSA was opened. An ongoing MSA animal model study has shown that pre-exposure prophylaxis of lkT-148009 precludes loss of function in a transgenic model of MSA; an independent model is running concurrently with the transgenic model to confirm the apparent functional benefit of lkT-148009 treatment. These studies will form the basis for determining the timing for initiation of a planned Phase 2 clinical study of lkT-148009 in MSA.

First Quarter Financial Results

<u>Net Loss</u>: Net loss for the quarter ended March 31, 2023 was \$4.5 million, or \$0.16 per share, compared to a net loss of \$4.6 million, or \$0.18 per share in the quarter ended March 31, 2022.

R&D Expenses: Research and development expenses were \$2.9 million for the quarter ended March 31, 2023 compared to \$3.0 million in the quarter ended March 31, 2022. The decrease was primarily due to the company restarting its Phase 2 '201' clinical trial.

SG&A Expenses: Selling, general and administrative expenses for the quarter ended March 31, 2023 were \$1.9 million compared to \$1.7 million for the quarter ended March 31, 2022. The increase was primarily the result of legal, consulting fees and promotional related costs.

<u>Cash Position</u>: Cash and cash equivalents and marketable securities were \$25.7 million as of March 31, 2023. This includes the net proceeds from the Company's \$10 million January 2023 concurrent registered direct offering and private placement. The Company expects that existing cash and cash equivalents will be sufficient to fund operations into the fourth quarter of 2024.

Conference Call Information

The conference call is scheduled to begin at 8:00am ET on May 16, 2023. Participants

should dial 1-844-825-9789 (United States) or 1-412-317-5180 (International) with the conference code 8552474. A live webcast may be accessed using the link here, or by visiting the investors section of the Company's website at www.inhibikase.com. After the live webcast, the event will be archived on Inhibikase's website for approximately 90 days after the call.

About Inhibikase (<u>www.inhibikase.com</u>)

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 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 an office in Lexington, 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 forwardlooking statements, including our ability to successfully conduct clinical trials, that results in our animal studies may not be replicated in humans and our ability to maintain our Nasdag listing. Important factors that could cause actual results to differ materially from those in the forward-looking statements include factors that are delineated 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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Inhibikase Therapeutics, Inc. Condensed Consolidated Balance Sheets

	March 31, 2023 (unaudited)		December 31, 2022	
Assets				
Current assets:				
Cash and cash equivalents	\$	3,956,604	\$	7,188,553
Marketable securities		21,761,564		15,861,620
Accounts receivable		64,521		39,881
Prepaid research and development		923,128		1,117,616
Prepaid expenses and other current assets		922,764		163,452
Total current assets		27,628,581		24,371,122
Equipment and improvements, net		231,489		236,532
Right-of-use asset		303,263		328,643
Total assets	\$	28,163,333	\$	24,936,297
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	959,078	\$	1,151,173
Lease obligation, current		146,901		145,836
Accrued expenses and other current liabilities		1,558,221		2,398,436
Total current liabilities	-	2,664,200		3,695,445
Lease obligations, net of current portion		178,110		205,451
Total liabilities	-	2,842,310		3,900,896
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022 Common stock, \$0.001 par value; 100,000,000 shares authorized; 31,056,238 and 25,227,051 shares issued and outstanding at March 31, 2023 and		-		-
December 31, 2022		31,056		25,227
Additional paid-in capital		77,473,765		68,777,298
Accumulated other comprehensive income		165,822		104,718
Accumulated deficit		(52,349,620)		(47,871,842)
Total stockholders' equity	-	25,321,023		21,035,401
Total liabilities and stockholders' equity	\$	28,163,333	\$	24,936,297

Inhibikase Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

Three Months Ended March 31,

	2023		2022	
Revenue:			-	
Grant revenue	\$	64,521	\$	46,031
Total revenue	· · · · · · · · · · · · · · · · · · ·	64,521		46,031
Costs and expenses:	· · · · · · · · · · · · · · · · · · ·			
Research and development		2,854,119		3,016,991
Selling, general and administrative		1,925,351		1,669,636
Total costs and expenses		4,779,470		4,686,627
Loss from operations	((4,714,949)		(4,640,596)
Interest income (expense)		237,171		(5)
Net loss	((4,477,778)		(4,640,601)
Other comprehensive income, net of tax				
Unrealized gains on marketable securities		61,104		_
Comprehensive Loss	\$ ((4,416,674)	\$	(4,640,601)
Net loss per share – basic and diluted	\$	(0.16)	\$	(0.18)
Weighted-average number of common shares – basic and diluted		27,510,077		25,205,454

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