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Inhibikase Therapeutics Announces Enrollment of First Patient in IMPROVE-PAH Global Phase 3 Study of IKT-001 in the Treatment of Pulmonary Arterial Hypertension

WILMINGTON, Del., April 07, 2026 (GLOBE NEWSWIRE) -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or "Company"), a clinical-stage pharmaceutical company developing IKT-001 for Pulmonary Arterial Hypertension ("PAH"), announced today that the first patient has been enrolled in the Company's pivotal Phase 3 study IMPROVE-PAH (**I**KT-001 for **M**easuring **P**ulmonary Vascular **R**esistance and **O**utcome **V**ariables in a Phase 3 **E**valuation of **PAH;** NCT07365332).

"Enrollment of the first patient in our IMPROVE-PAH trial is a major milestone for Inhibikase, and the result of many months of work to optimize the IKT-001 study plan to permit a single pivotal global study and significantly accelerate the timeline to potential NDA filing," said Mark Iwicki, Chief Executive Officer of Inhibikase. IKT-001 is a novel oral prodrug of imatinib mesylate designed to reduce gastrointestinal ("GI") side effects commonly observed with imatinib. Under the revised pivotal Phase 3 design, as confirmed in the written responses received from the FDA, Inhibikase has adopted an adaptive study design and a 12-week dose-titration phase to allow for optimized dosing. With over two decades of imatinib clinical experience, together with the potential GI benefits of IKT-001, Inhibikase believes IMPROVE-PAH has a high probability of success.

The global IMPROVE-PAH trial is a two-part adaptive Phase 3 study. Part A of IMPROVE-PAH is a double blind, placebo-controlled study in approximately 140 patients with a primary endpoint of change in Pulmonary Vascular Resistance ("PVR") at Week 24. Part B of IMPROVE-PAH seamlessly begins following the last patient in Part A being enrolled and adopts an identical format to Part A, except the primary endpoint will be change in 6-minute walk distance ("6MWD") at Week 24 in approximately 346 patients. The Company believes this Phase 3 study design has important advantages including permitting a 12-week dose-titration phase designed to get patients to the highest tolerable dose of IKT-001, as well as uninterrupted enrollment between Part A and Part B. The Phase 3 study protocol also permits a sample size re-estimation for Part B based on Part A findings, if necessary. IMPROVE-PAH is expected to be conducted in up to approximately 180 sites around the world.

"The Phase 3 IMPRES study demonstrated that imatinib may improve key parameters associated with PAH, including exercise capacity and hemodynamics," said Dr. Harrison Farber, Co-director of Pulmonary Hypertension Center and Director of the Pulmonary Embolism Response Team (PERT), Tufts Medical Center. "Now, the Phase 3 IMPROVE-

PAH study will help evaluate both hemodynamic and functional improvements, as well as key measures of disease progression, such as time to clinical worsening. Despite the availability of multiple therapies, many patients with PAH continue to experience disease progression, so I am always excited about the potential for a novel antiproliferative agent for the treatment of PAH."

"For patients living with PAH disease progression remains a daily reality even with the therapies we have available today," said Dr. J. Wesley McConnell, M.D., Director of Norton Pulmonary Specialists Pulmonary Hypertension Center in Louisville, Kentucky. "The IMPROVE-PAH trial represents a meaningful step forward because the trial is designed to capture the outcomes that matter most to patients and clinicians alike. I am proud to be part of this program and optimistic about what it could mean for the future of PAH care".

About Inhibikase (www.inhibikase.com)

Inhibikase Therapeutics, Inc. (Nasdaq: IKT) is a clinical-stage pharmaceutical company developing therapeutics to modify the course of cardiopulmonary diseases, namely, Pulmonary Arterial Hypertension ("PAH"), in which aberrant signaling through type III receptor tyrosine kinases, including platelet derived growth factor receptors and a stem cell factor receptor, known as "c-Kit" has been implicated. Our lead product candidate is IKT-001, a prodrug of imatinib mesylate ("imatinib"), for PAH which is an orphan indication. Imatinib was first approved in the United States in 2001 for various cancers and blood disorders and, following more than 20 years of clinical use, has a well-characterized safety profile with the first reported use of imatinib in PAH occurring in 2005. PAH is a progressive, life-threatening disease characterized by pulmonary vascular remodeling and elevated pulmonary vascular resistance that affects approximately 50,000 Americans. Our single pivotal Phase 3 clinical study in PAH in approximately 180 sites around the world, named IMPROVE-PAH (**I**KT-001 for **M**easuring **P**ulmonary Vascular **R**esistance and **O**utcome **V**ariables in a Phase 3 **E**valuation of **PAH**), is actively enrolling patients.

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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 include, but are not limited to, statements that express the Company's intentions, beliefs, expectations, strategies, predictions or any other statements related to the potential effects of IKT-001, the advancement of the Company's global pivotal Phase 3 clinical study of IKT-001 in PAH, including the timing, design, enrollment, conduct and results of the IMPROVE-PAH study and related regulatory submissions, including the potential for NDA submission, the Company's beliefs regarding

the potential advantages of the Phase 3 clinical study of IKT-001, or future events or conditions. 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 commence and execute a Phase 3 study to evaluate IKT-001 as a treatment for PAH, 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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