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Inhibikase Therapeutics Advancing IKT-001 to Global Phase 3 Study in Pulmonary Arterial Hypertension

Phase 3 Study initiating in First Quarter of 2026

Single Pivotal Study Accelerates Potential FDA Approval Timeline by Approximately 3 Years

BOSTON and ATLANTA, Nov. 20, 2025 (GLOBE NEWSWIRE) -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or "Company"), a clinical-stage pharmaceutical company developing therapeutics to modify the course of cardiopulmonary diseases namely, Pulmonary Arterial Hypertension ("PAH"), today announced that it expects to advance IKT-001 to a global pivotal Phase 3 clinical study in PAH. The Phase 3 study, 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 expected to be initiated in the first quarter of 2026.

IKT-001 is an investigational novel pro-drug of imatinib mesylate ("imatinib"). Imatinib is an anti-proliferative tyrosine kinase inhibitor, TKI, with potential best-in-class improvements in pulmonary vascular resistance ("PVR") and 6-minute walk distance ("6MWD") of 45 meters[(1)] based on Phase 3 IMPRES and Phase 2 studies[(2)]. Despite the IMPRES Phase 3 study of imatinib demonstrating improved exercise capacity and hemodynamics in patients with advanced PAH, high discontinuations impacted the results. IKT-001 is a prodrug of imatinib which is engineered to realize the potential of imatinib in PAH and lower discontinuations in the forthcoming Phase 3 study.

The Company previously planned to initiate a Phase 2b study in 150 subjects in PAH prior to advancing to a pivotal Phase 3 study. However, the Company submitted a Type C Meeting request to the U.S. Food & Drug Administration ("FDA") to, among other things, obtain feedback on an immediate transition to a pivotal Phase 3 study design.

Following receipt from the FDA of the Written Response from the Type C interaction, the Company now plans to initiate a two-part adaptive Phase 3 study. We expect Part A of IMPROVE-PAH will be a double blind, placebo-controlled study in 140 patients with a primary endpoint of PVR at Week 24. We expect Part B will adopt an identical format to Part A except the primary endpoint will be 6MWD at Week 24 in 346 patients. We believe this adaptive Phase 3 study design has important advantages including; (1) permitting a 12-week dose-titration phase designed to get patients to the highest tolerable dose of IKT-001; (2) uninterrupted enrollment between Part A and Part B; and (3) the ability to, if necessary, undertake a sample size re-estimation for Part B based on Part A findings. Given the Company was well-advanced in initiating the previous Phase 2b study design, the Company expects to initiate IMPROVE-PAH in the first quarter of 2026, with this study expected to be conducted in up to approximately 180 sites around the world.

“Our revised study plan for IKT-001 in PAH permits a single pivotal study format and thereby has the potential to advance our timeline to Phase 3 topline data readout and a potential NDA filing by approximately three years. We are excited about the recent progress we have made,” said Mark Iwicki, Chief Executive Officer of Inhibikase. “Importantly, the written responses from FDA will allow the Company to adopt a 12-week dose-titration phase which we believe will potentially allow patients to get to the higher tolerable doses where imatinib has previously demonstrated the greatest benefit in exercise capacity and hemodynamics. With over two decades of imatinib clinical experience, together with IKT-001’s expected improved gastrointestinal tolerability profile and adaptive study design for IMPROVE-PAH, we believe this supports a potential higher probability of success and we are looking forward to study initiation next quarter.”

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, PAH, that arise from aberrant signaling through the Abelson Tyrosine Kinase, and type III receptor tyrosine kinases including platelet derived growth factor receptors and c-KIT. Our lead product candidate is IKT-001, a prodrug of imatinib mesylate, for PAH which is an orphan indication. PAH is a progressive, life-threatening disease characterized by pulmonary vascular remodeling and elevated pulmonary vascular resistance that affects approximately 50,000 Americans.

Social Media Disclaimer

Investors and others should note that the Company announces material financial information to investors using its investor relations website, press releases, SEC filings and public conference calls and webcasts. The Company intends to also use LinkedIn 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 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; expectations regarding the Company’s Phase 3 trial of IKT-001 in PAH, including design, timing of initiation and its impact on the Company’s timeline; and the Company’s future activities, 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 initiate and execute a global Phase 3 trial 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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(1) Placebo-adjusted 6MWD improvement of 45 meters at week 24 in patients at 400 mg for >50% of treatment. See Hoeper et al; Circulation 2013 Suppl. Appendix. (2) The referenced Phase 3 IMPRES and Phase 2 Studies were conducted by Novartis Pharmaceutical Corporation

Source: Inhibikase Therapeutics