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Inhibikase Therapeutics Announces FDA Orphan Drug Designation Granted to IKT-001 for the Treatment of PAH

WILMINGTON, Del., July 23, 2026 (GLOBE NEWSWIRE) -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) ("Inhibikase" or "Company"), a clinical-stage pharmaceutical company developing IKT-001 for Pulmonary Arterial Hypertension ("PAH"), today announced that the U.S. Food and Drug Administration ("FDA") has granted Orphan Drug Designation ("ODD") to its lead product candidate IKT-001, a prodrug of imatinib mesylate, for the treatment of PAH.

"The grant of Orphan Drug Designation for IKT-001 by FDA is another important milestone for Inhibikase and reflects the high unmet medical need among the approximately 50,000 people suffering from PAH in the United States," said Mark Iwicki, Chief Executive Officer of Inhibikase. "PAH is a progressive and life-threatening disease with substantially diminished quality of life which is caused by the abnormal proliferation of vascular cells in the lung. Recently, presentations of IKT-001 pre-clinical data at the American Thoracic Society International Conference in Orlando demonstrated improvements in pulmonary vascular and hemodynamic markers of PAH, together with a lower potential for GI toxicity compared to imatinib mesylate, and we believe that IKT-001's potential to be the first once-daily oral proliferative may offer significant potential benefits to the PAH patient population."

Orphan Drug Designation was granted by the FDA's Office of Orphan Products Development. As noted by the FDA, orphan designation applies to the active moiety of IKT-001, imatinib, rather than a specific formulation. ODD also provides potential development incentives, including eligibility for tax credits on qualified clinical trial costs, exemption from certain FDA user fees, and the potential for seven years of market exclusivity upon regulatory approval.

Orphan Drug Designation is granted to investigational therapies intended to treat rare diseases affecting fewer than 200,000 patients in the United States.

About Inhibikase

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.

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 beliefs about the potential benefits of Orphan Drug Designation. 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 realize any of the potential benefits of Orphan Drug Designation, 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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Source: Inhibikase Therapeutics