UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 14, 2025

INHIBIKASE THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39676**	**26-3407249**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1000 N. West Street, Suite 1200 **Wilmington, DE**	**19801**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (302) 295-3800

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	IKT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On August 14, 2025, Inhibikase Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2025 and other corporate updates. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure

On August 14, 2025, Inhibikase Therapeutics, Inc. updated its corporate presentation for use in meetings with investors, analysts and others from time to time. A copy of the presentation is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.2 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release issued by Inhibikase Therapeutics, Inc., dated August 14, 2025, furnished herewith.
99.2	Corporate Presentation of Inhibikase Therapeutics, Inc., dated August 14, 2025, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 14, 2025

INHIBIKASE THERAPEUTICS, INC.

By: /s/ Mark Iwicki
Mark Iwicki
Chief Executive Officer

Inhibikase Therapeutics Announces Second Quarter 2025 Financial Results and Highlights Recent Activity

August 14, 2025 — 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 reported financial results for the quarter ended June 30, 2025 and highlighted recent developments.

"During our second quarter of 2025, we continued to position the Company to advance IKT-001 toward a late-stage clinical trial in PAH," said Mark Iwicki, Chief Executive Officer of Inhibikase. "We have now finalized our study protocol, and we expect to initiate our Phase 2b clinical study of IKT-001, our re-engineered prodrug of imatinib mesylate, in PAH in the second half of 2025."

Multiple studies including both Phase 2 and the Phase 3 IMPRES study previously demonstrated that imatinib mesylate ("imatinib"), an anti-proliferative tyrosine kinase inhibitor, was highly efficacious in PAH. Notably in the IMPRES study, patients that maintained 400 mg of imatinib for greater than 50% of the treatment period showed a placebo adjusted 45-meter improvement in 6-minute walk distance ("6MWD") which represents best-in-class improvements for patients afflicted by PAH. More recently, a contemporary study in the *American Journal of Respiratory and Critical Care Medicine* demonstrated that higher exposures of imatinib were associated with a larger improvement in total pulmonary resistance ("TPR"). The 400 mg dose of imatinib exhibited the greatest impact on TPR and, even though the majority of patients completed the study at 200 mg or less, the magnitude of the hemodynamic change for the study was noted to compare favorably with recent studies of novel therapies added to background treatment. The Company believes this supports its thesis that IKT-001 has the potential to minimize GI side effects while maximizing the highly efficacious outcomes observed at 400 mg across multiple studies.

Recent Developments:

- Advancement of IKT-001 as a therapy in PAH:
  - During the first half of 2025, the Company evaluated potential study designs and obtained feedback from various key opinion leaders before finalizing a clinical study protocol for its forthcoming Phase 2b study, known as IMPROVE-PAH.
  - IMPROVE-PAH is a multi-center, randomized, double-blind, placebo-controlled study of approximately 150 PAH participants. Participants under IMPROVE-PAH will be randomized 1:1:1 to receive 300 mg IKT-001, 500 mg IKT-001, or placebo once daily for 26 weeks, in addition to stable background PAH therapy. The Company's bioequivalence studies previously confirmed that 500 mg of IKT-001 has comparable exposure in humans to 380 mg of imatinib. The primary efficacy endpoint is change in pulmonary vascular resistance at Week 26. Secondary endpoints include 6MWD, World Health Organization functional class, and pharmacokinetics. The study protocol also includes an interim safety review for study continuance by the Data Safety Monitoring Board with at least 50 patients at 12-weeks of follow-up.
  - The Company expects to initiate IMPROVE-PAH in the second half of 2025.

Financial Results

Cash Position: As of June 30, 2025, cash, cash equivalents and marketable securities were $87.7 million as compared to $97.5 million as of December 31, 2024.

Net Loss: Net loss for the quarter ended June 30, 2025, was $9.9 million, or $0.11 per share, compared to a net loss of $5.0 million, or $0.66 per share in the quarter ended June 30, 2024. Net loss for the six months ended June 30, 2025, was $23.6 million, or $0.26 per share, compared to a net loss of $9.6 million, or $1.38 per share, for the six months ended June 30, 2024.

R&D Expenses: Research and development expenses were $5.3 million for the quarter ended June 30, 2025, compared to $3.1 million for the quarter ended June 30, 2024. Research and development expenses were $15.8 million for the six months ended June 30, 2025, which includes a non-cash write-off of in-process research and development of $7.4 million and $1.0 million of stock-based compensation expense, both associated with the Company's acquisition of CorHepta in February 2025, compared to $5.8 million for the six months ended June 30, 2024.

SG&A Expenses: Selling, general and administrative expenses for the quarter ended June 30, 2025 were $5.9 million, compared to $2.0 million for the quarter ended June 30, 2024. Selling, general and administrative expenses for the six months ended June 30, 2025 were $11.2 million, which includes $1.0 million of severance expenses resulting from the transition of senior executives in the Company during the year, compared to $4.0 million for the six months ended June 30, 2024.

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 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 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 initiation of the Company's Phase 2b trial of IKT-001 in PAH 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 commence and execute a Phase 2b 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.

Contacts:
Investor Relations:
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LifeSci Advisors
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—tables to follow—

Inhibikase Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2025 (unaudited)	December 31, 2024 (Note 3)
Assets		
Current assets:		
Cash and cash equivalents	$ 77,742,669	$ 56,490,579
Marketable securities	9,923,100	41,052,949
Prepaid research and development	138,855	81,308
Deferred offering costs	307,373	—
Prepaid expenses and other current assets	682,628	826,473
Total current assets	88,794,625	98,451,309
Equipment and improvements, net	23,687	47,100
Right-of-use asset	34,918	101,437
Total assets	$ 88,853,230	$ 98,599,846
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,703,554	$ 943,019
Lease obligation, current	37,944	110,517
Accrued expenses and other current liabilities	3,145,888	2,680,030
Contingent consideration liability	2,912,159	—
Total current liabilities	8,799,545	3,733,566
Total liabilities	8,799,545	3,733,566
Commitments and contingencies (see Note 16)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 500,000,000 and 100,000,000 shares authorized; 74,516,635 and 69,362,439 shares issued and outstanding (including 4,149,252 and 0 contingently issuable shares—see Note 10) at June 30, 2025 and December 31, 2024, respectively	74,516	69,362
Additional paid-in capital	197,996,982	189,254,777
Accumulated other comprehensive loss	(2,944)	(37,248)
Accumulated deficit	(118,014,869)	(94,420,611)
Total stockholders' equity	80,053,685	94,866,280
Total liabilities and stockholders' equity	$ 88,853,230	$ 98,599,846

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

	Three Months Ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Costs and expenses:				
Research and development	$ 5,270,967	$ 3,075,830	$ 15,784,546	$ 5,827,109
Selling, general and administrative	5,919,731	1,974,705	11,169,022	4,005,786
Change in fair value contingent consideration	(358,420)	—	(1,523,284)	—
Total costs and expenses	10,832,278	5,050,535	25,430,284	9,832,895
Loss from operations	(10,832,278)	(5,050,535)	(25,430,284)	(9,832,895)
Interest income	916,755	90,927	1,836,026	223,652
Net loss	(9,915,523)	(4,959,608)	(23,594,258)	(9,609,243)
Other comprehensive income (loss), net of tax				
Unrealized gain (loss) on marketable securities	(1,977)	776	34,304	(1,901)
Comprehensive loss	$ (9,917,500)	$(4,958,832)	$(23,559,954)	$(9,611,144)
Net loss per share – basic and diluted	$ (0.11)	$ (0.66)	$ (0.26)	$ (1.38)
Weighted-average number of shares – basic and diluted	90,009,625	7,535,667	89,774,703	6,939,779

Inhibikase Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six months ended June 30,	
	2025	2024
Cash flows from operating activities		
Net loss	$(23,594,258)	$(9,609,243)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	36,812	13,137
Stock-based compensation expense	6,250,938	84,131
Write-off of in-process research and development	7,357,294	—
Change in fair value of contingent consideration	(1,523,284)	—
Changes in operating assets and liabilities:		
Operating lease right-of-use assets	66,519	58,465
Prepaid expenses and other assets	7,526	30,719
Prepaid research and development	(57,547)	(86,483)
Accounts payable	1,592,656	875,701
Operating lease liabilities	(72,573)	(62,389)
Accrued expenses and other current liabilities	258,156	(225,430)
Net cash used in operating activities	(9,677,761)	(8,921,392)
Cash flows from investing activities		
Purchases of equipment and improvements	(13,399)	—
Purchases of investments—marketable securities	—	(9,209,545)
Maturities of investments—marketable securities	31,350,103	8,440,958
Acquired in-process research and development	(438,624)	—
Net cash provided by (used in) investing activities	30,898,080	(768,587)
Cash flows from financing activities		
Proceeds from issuance of common stock, pre-funded warrants and warrants, net of issuance costs	150	3,611,255
Issuance of common stock form exercise of stock options	31,621	—
Net cash provided by financing activities	31,771	3,611,255
Net increase (decrease) in cash and cash equivalents	21,252,090	(6,078,724)
Cash and cash equivalents at beginning of period	56,490,579	9,165,179
Cash and cash equivalents at end of period	$ 77,742,669	$ 3,086,455
Supplemental disclosures of cash flow information		
Issuance costs	$ —	$ 1,203,350
Non cash investing and financing activities		
Non-cash financing costs	$ —	$ (181,930)
CorHepta transaction costs	$ 175,000	$ —
Contingent consideration	$ 2,912,159	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ 307,373	$ —

Exhibit 99.2

Inhibikase Therapeutics

Corporate Overview

August 2025

Disclaimer

This presentation contains information that may constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Inhibikase Therapeutics, Inc. (the "Company" or "we") intends for the forward-looking statements to be covered by the safe harbor provisions for forward-looking statements in those sections. Generally, we have identified such forward-looking statements by using the words "believe," "expect," "intend," "estimate," "anticipate," "project," "target," "forecast," "aim," "should," "will," "may", "continue", "assume", "contemplate", "could", "design", "due", "goal", "hope", "might", "plan", "opportunity", "predict", "possible", "potential", "seek", "strategy", "would" and similar expressions that are predictions or indicate future events and future trends, or the negative of these terms or other comparable terminology. Such statements are subject to a number of assumptions, risks and uncertainties which may cause actual results, performance or achievements to be materially different from those anticipated in these forward-looking statements. You should read statements that contain these words carefully because they discuss future expectations and plans which contain projections of future clinical studies or trials, regulatory approvals, product candidate development, results of operations or financial condition or state other forward-looking information. However, the absence of these words or similar expressions does not mean that a statement is not forward-looking. Forward-looking statements are not historical facts, but instead represent only the Company's beliefs regarding future events, many of which, by their nature, are inherently uncertain and outside of the Company's control. It is possible that the Company's actual results and financial condition may differ, possibly materially, from the anticipated results and financial condition indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as of the time made. However, caution should be taken not to place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the Company's historical experience and our present expectations or projections. This presentation should be read in conjunction with the Company's filings with the Securities and Exchange Commission, including its annual report on Form 10-K, its quarterly Form 10-Q and any subsequent filings with the SEC (collectively, the "SEC Filings"). Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in the Company's SEC filings, including under the caption "Risk Factors".

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party studies, publications, surveys and other data to be reliable as of the date of this presentation, we have not independently verified , and make no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third-party sources. In addition, no independent sources has evaluated the reasonableness or accuracy of our internal estimates or research and no reliance should be made on any information or statements made in this presentation related to or based on such internal estimates and research.

We do not intend our use or display of other entities' names, trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

This presentation shall not constitute an offer to sell or a solicitation of an offer to buy any securities, nor shall there be any sale of such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Experienced Leadership with Deep Expertise in PAH

MARK IWICKI
Chief Executive Officer

CHRIS CABELL, MD MHS FACC
Head of R&D, Chief Medical Officer

DAVID McINTYRE BEC CPA LLB MBA
Chief Financial Officer

JEFF KAGY
Chief Human Resource Officer

JOHN ADAMS, PHD
Chief Scientific Officer

CHAD OREVILLO, MPH
EVP, Development Operations

ALLISON WIDLITZ, MS, PA
VP, Clinical Development

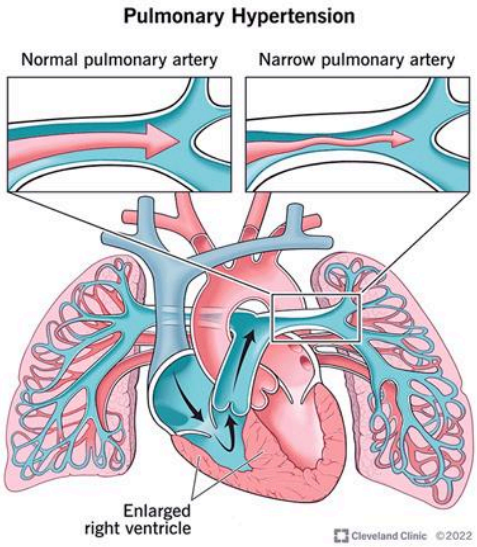
Inhibikase and IKT-001: Pulmonary Arterial Hypertension (PAH)

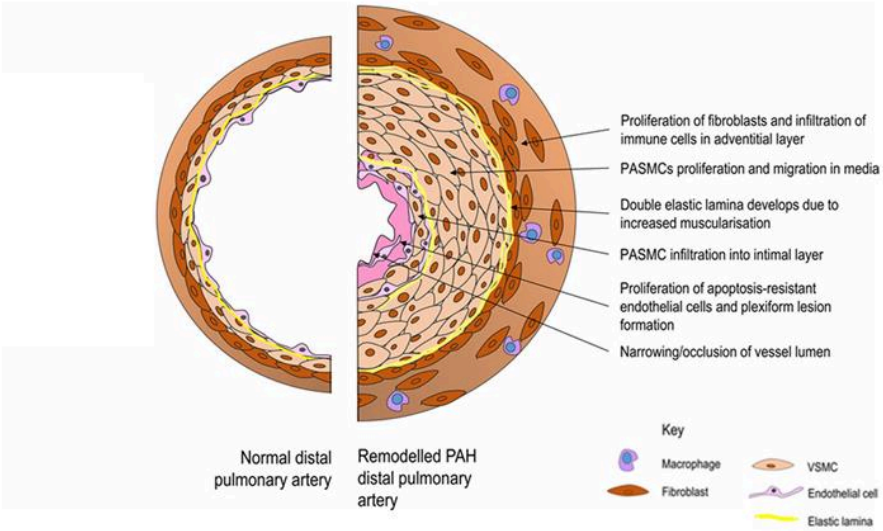
Major unmet need with high mortality, poor QoL and high cost	• PAH is a rare, progressive and life-threatening disease with significant unmet need • ~30% 5-year mortality(1), reduced quality of life and high economic burden • $7.6 Billion market with limited treatments that address the underlying etiology
Imatinib has proven efficacy in Phase 3 in PAH	• Imatinib is an anti-proliferative TKI with potential best-in-class improvements in PVR and 6MWD (45 meters*) based on Phase 3 IMPRES and Phase 2 studies • Imatinib hit primary efficacy endpoints in IMPRES but was not well tolerated at 400mg
Potential to be the 1st oral anti-proliferative agent	• IKT-001 is a pro-drug engineered to realize the potential of imatinib in PAH • IKT-001 releases imatinib in the blood with potential to minimize GI side effects maximizing potential to achieve highly efficacious doses
Strong Leadership Executing Near Term Development	• IKT's Phase 2b is on track to initiate in the second half of 2025 • Long intellectual property runway through 2044 • Team with extensive PAH / CV experience

(1) Hoeper M, et al. Eur Respir J. 2017
TKI = tyrosine kinase inhibitor; QoL= Quality of Life; PVR = pulmonary vascular resistance; 6MWD = 6-minute walk distance; GI= Gastrointestinal; CV = cardiovascular
* See Page 17

PAH is a Progressive Disease Driven by Uncontrolled Cell Proliferation

Proliferation of vascular cells drive vascular remodeling, raising pulmonary artery pressure and leading to progressive right ventricular heart failure and ultimately death





PASMCs = Pulmonary artery smooth muscle cells; Vascular smooth muscle cells

PAH: An Orphan Disease with ~30% 5-Year Mortality Despite Aggressive Treatment

~50,000
People with PAH in the US[1]

52 years
Average age at diagnosis[2]

~26,000
People with PAH in the EU5[1]

15
Approved vasodilators
(across the prostacyclin, nitric oxide, and endothelin pathways)

~80%
Female[2]

1
Approved anti-proliferative

High Unmet Medical Need

Progressive and Life Threatening

- ~30% 5-year mortality[3] despite aggressive treatment with vasodilator therapies
- Progressively worsening symptoms

Reduced Quality of Life

- Chronic breathlessness, and fatigue
- Significant limitation on activities of daily living
- Dizziness, chest pain, anxiety and depression

High Economic Burden[4]

- Average monthly healthcare costs ~$6,850-$15,650
- Acute all cause hospitalization rate of 700 per 1000 patients per year among Medicare or Medicaid patients
- Substantial indirect costs due to work loss, caregiver time and disability

(1) CVrG Market Strategies report Jun 2025; (2) Badlam et al; CHEST 2021; (3) Hoeper M, et al. Eur Respir J. 2017; (4) Watzger et al; Pharmacoeconomics 2025

PAH: Patient and Treatment Journey

Progressive pulmonary vasculopathy driving right heart failure (RHF)

ESC/ERS 4 Risk Strata (Risk of 1 year Mortality)[1]

	Low (0-3%)		Intermediate Low (2-7%)	Intermediate High (9-19%)	High (>20%)
WHO Functional Class	**Class 1** No limitation of physical activity	**Class 2** Slight limitation of physical activity. Ordinary physical activity causes dyspnea, fatigue, chest pain, or near syncope		**Class 3** Marked limitation in physical activity. Less than ordinary activity causes undue dyspnea, fatigue, chest pain or near syncope	**Class 4** Inability to carry out any physical activity without symptoms. Signs of RHF. Discomfort increased by any physical activity. Dyspnea and fatigue present at rest
6MWD	>440 meters		320 – 440 meters	165 - 319 meters	<165 meters
NT-ProBNP	<300ng.L^{-1}		300-649ng.L^{-1}	650-1100ng.L^{-1}	>1100ng.L^{-1}

1st Line of Therapy ← → **Add On Therapy With Declining Health Status**

Initiate PDE-5i +ERA Combo		Oral/Inhaled Prostacyclin	Activin Signaling Inhibitor	Infused Prostacyclin
PDE-5i or *NO Pathway Sildenafil; Tadalafil; Riociguat*	**ERA's** Bosentan; Ambrisentan Macitentan	Selexipag; Oral Remodulin; Tyvaso, Tyvaso DPI; Yutrepia	Sotatercept	Remodulin IV; Remodulin Sub-Q; Flolan, Veletri

ERS=European Respiratory Society; ESC=European Society of Cardiology; WHO=World Health Organization; 6MWD= 6 Minute Walk Distance Test; NT-ProBNP= Biomarker of cardiac strain; NO = Nitric Oxide; * Riociguat is a soluble guanylate cyclase stimulator (sGC)

(1) Humbert et al; ERJ 2023

$7.6B Market Driven by Vasodilators Which Don't Treat Underlying Causes of PAH

Novel antiproliferative agents with disease modifying properties expected to revolutionize treatment

Vasodilators

Prostacyclin Pathway ($3.7B)

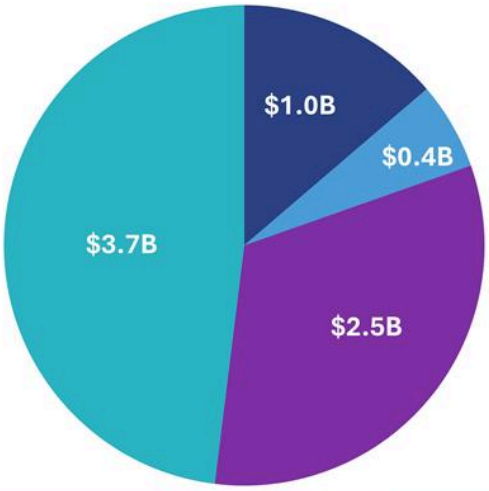
Epoprostenol, Treprostinil, Iloprost, Selexipag

Endothelin Pathway ($2.5B)

Ambrisentan, Bosentan, Macitentan

Nitric Oxide Pathway ($1.0B)

Sildenafil, Tadalafil, Riociguat



Anti-proliferative Agents

Activin Signaling Pathway ($0.4B)

Sotatercept - subcutaneos injection (FDA approval March 2024)

IKT-001 has the potential to be the first oral anti-proliferative agent for the treatment of PAH

2024 annual reports from Janssen, United Therapeutics, Bayer, and Merck

Our Solution: An Oral Pro-Drug of Imatinib Optimized for PAH

Engineered to realize imatinib's best-in-class efficacy potential in PAH

Gleevec (Imatinib)

NOVARTIS

IKT-001 (Imatinib Pro-Drug)

IKT

History
First Approved in 2001; 25 years of real-world experience
Indicated for: Leukemia, Soft Tissue Sarcoma, Myelodysplastic Syndromes, Mastocytosis and GIST

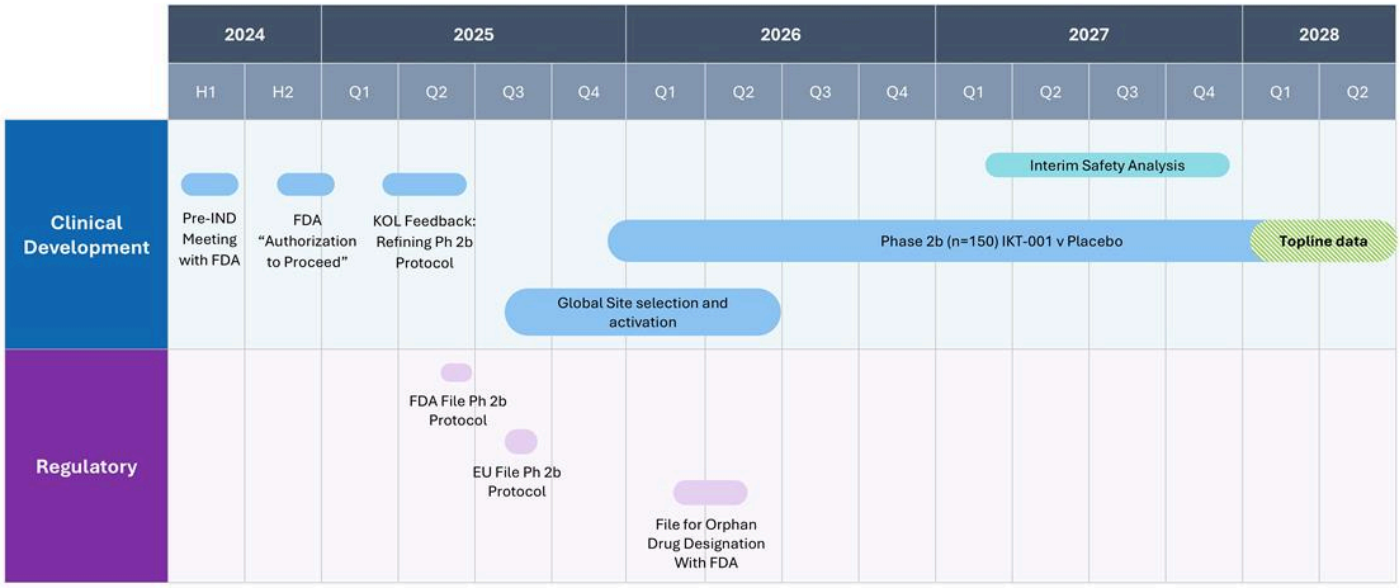
IKT-001 is a novel pro-drug of imatinib designed for better GI tolerability allowing optimal efficacy

PAH Data
Best-in-class improvements in PVR and 6MWD in Phase 2 & 3
Greatest efficacy at 400mg but not clinically tolerated
Contemporary study supports 400mg efficacy/tolerability findings

Potential to be the first and only once-daily oral anti-proliferative tyrosine kinase inhibitor (TKI) for PAH

PVR = Pulmonary Vascular Resistance; 6MWD= 6 Minute Walk Distance test; GI = Gastrointestinal; GIST = Gastrointestinal Stromal Tumor

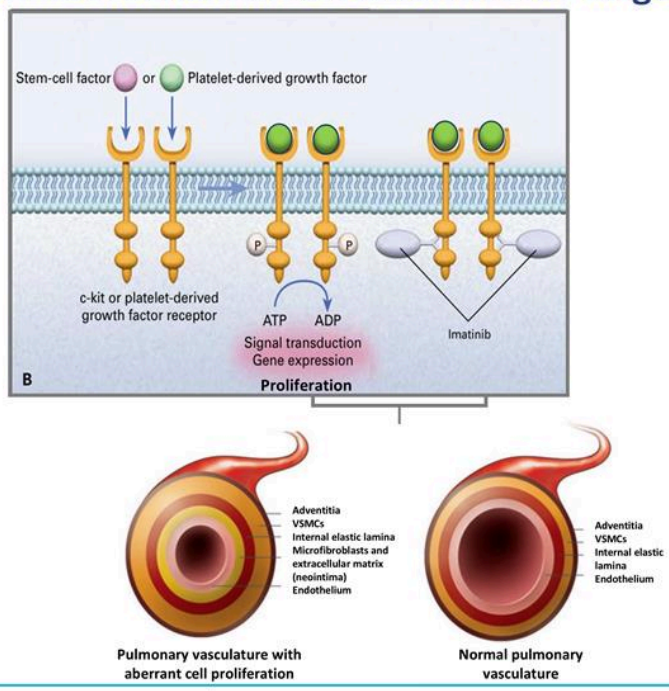
Development and Regulatory Timeline



Inhibikase Therapeutics

Scientific and Clinical Rationale

Imatinib Mechanism of Action in PAH Targets the Underlying Cause of PAH

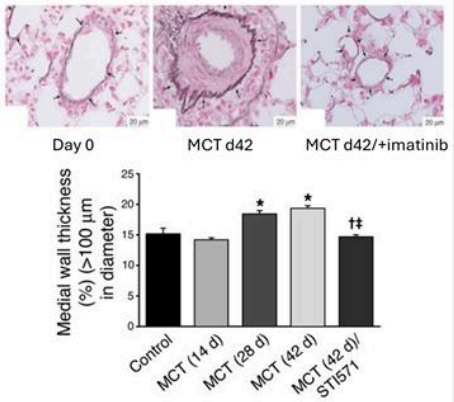


Overactive kinases implicated in aberrant cell proliferation and migration in the pulmonary vasculature

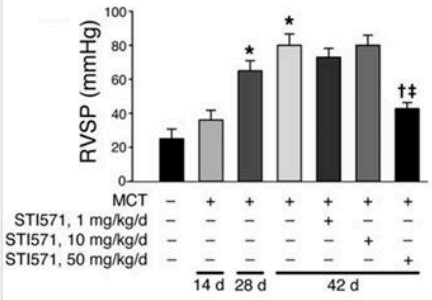
Imatinib inhibits the tyrosine kinase activity of PDGFR and c-kit , blocking cell signaling that drives vascular remodeling

Imatinib Demonstrated Reversal of PAH in Standard Animal Model

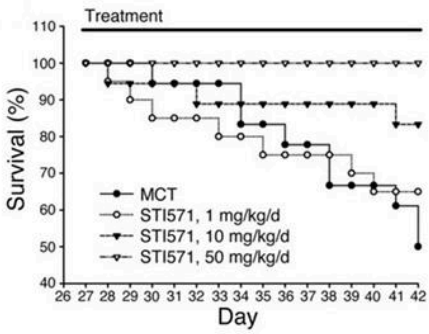
Reversal of vascular remodeling



Reversal of right ventricular pressure



Improved survival

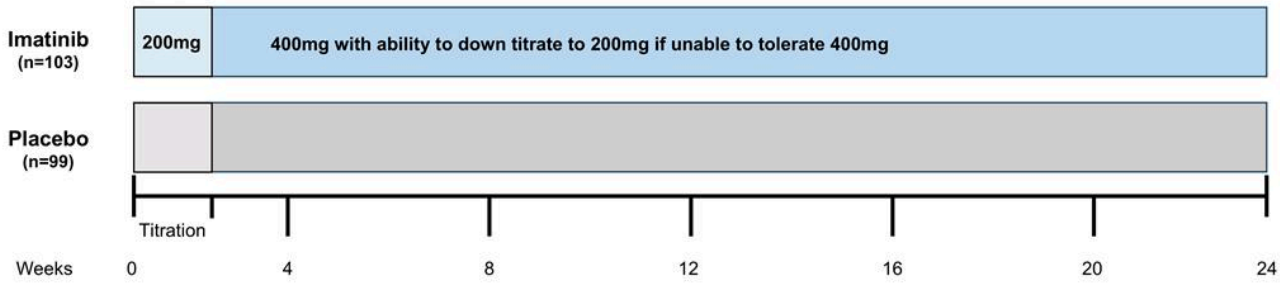


Imatinib reverses pulmonary vascular remodeling, right ventricular pressure / remodeling and improves survival

STI571 = imatinib; MCT = monocrotaline
*P < 0.05 versus control; †P < 0.05 versus MCT at day 28 or hypoxia at day 21; ‡P < 0.05 versus MCT at day 42 or hypoxia at day 35.

IMPRES – Imatinib Phase 3 Study

Randomized, double blind, placebo controlled study to assess the efficacy, safety and tolerability of 400mg imatinib once daily (n=202)



Primary Endpoint

- Change in 6MWD at 24 weeks

Secondary Endpoints

- Changes in hemodynamics (PVR, CO, mPAP, RAP) at 24 weeks
- Time to clinical worsening

Key Inclusion Criteria

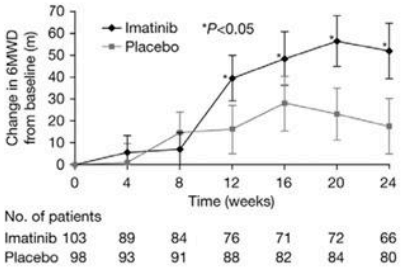
- Functional Class II-IV
- 2 or more background PAH therapies
- PVR ≧ 800 dynes.s.cm^{-5}
- 6MWD ≥150 meters and ≤ 450meters

PVR = pulmonary vascular resistance; CO = cardiac output; mPAP = mean pulmonary arterial pressure; RAP = right arterial pressure; 6MWD = 6-minute walk distance

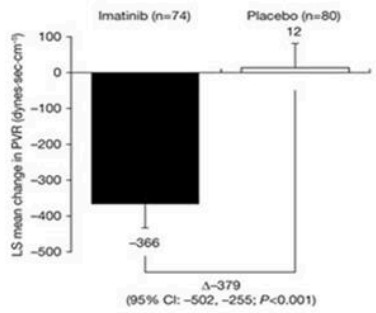
Phase 3 IMPRES: Statistically Significant Improvement in Function & Hemodynamics

32-meter improvement in 6WMD and 32% reduction in PVR at week 24

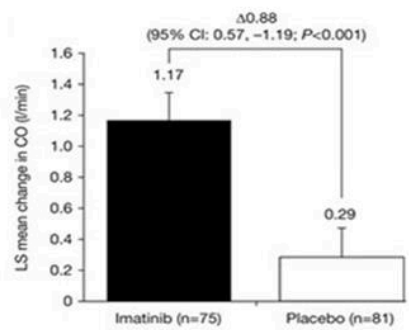
Change in 6MWD



Change in Pulmonary Vascular Resistance



Change in Cardiac Output



Phase 3 IMPRES study hit its primary endpoint along with key clinically relevant secondary endpoints

PVR = Pulmonary Vascular Resistance; 6MWD= 6 Minute Walk Distance test

Hoeper et al; Circulation 2013

Phase 3 IMPRES: 3 of the Top 5 AEs were GI Related

Majority of patients were unable to maintain 400 mg target dose of imatinib

	Imatinib n=103 (%)	Placebo n=98 (%)
Adverse Events	100 (97)	94 (96)
Nausea	57 (55)	23 (24)
Peripheral edema	45 (44)	20 (20)
Diarrhea	36 (35)	19 (19)
Vomiting	31 (30)	10 (10)
Periorbital edema	30 (29)	7 (7)

- The AE profile in IMPRES was similar to the established AE profile of imatinib in other indications
- Poor tolerance prevented most patients from maintaining the target dose of 400 mg of imatinib

Phase 3 IMPRES hit its primary endpoint DESPITE only 48/103 participants maintaining 400mg dose for at least half of the treatment period

IKT-001 is a novel pro-drug of imatinib designed for better GI tolerability allowing optimal efficacy

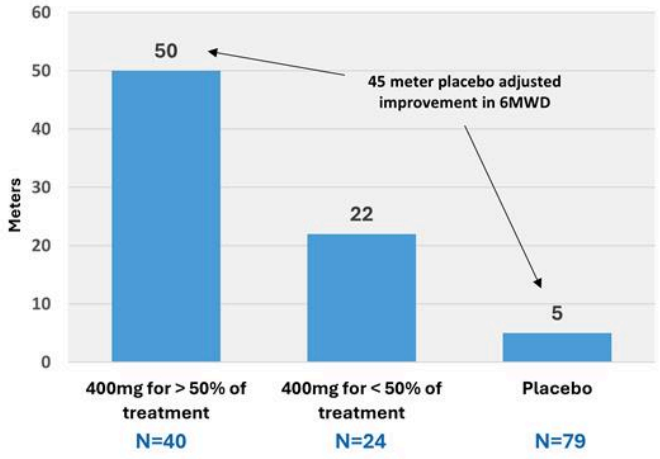
AE = Adverse event; GI = Gastrointestinal

Hoeper et al; Circulation 2013

IMPRES: Efficacy Impacted by Tolerability of 400mg Per Day

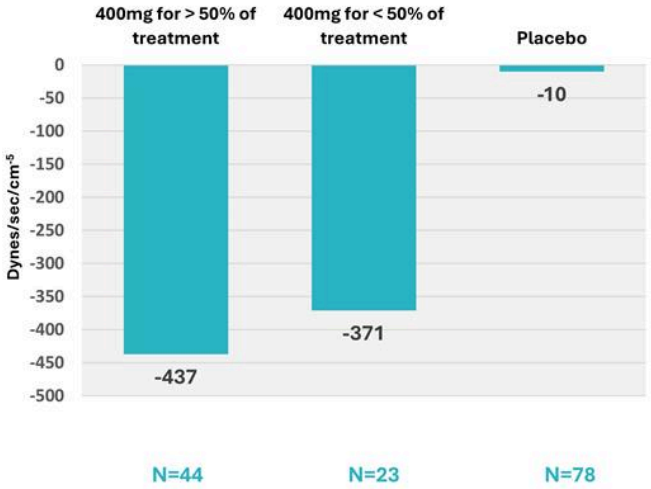
Patients able to sustain 400mg dose showed greater improvements in 6MWD and PVR

Changes in 6MWD at Week 24



(Baseline*: 355 meters imatinib; 366 meters placebo)

Changes in PVR at Week 24



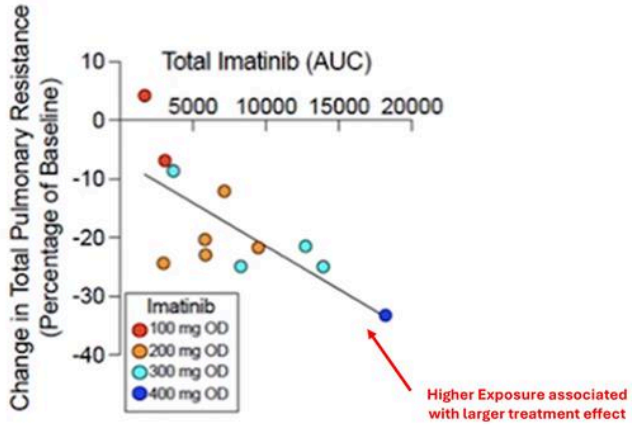
(Baseline*: 1202 dynes/sec/cm^{-5} imatininb; 1181 dynes/sec/cm^{-5} placebo)

* Baseline data is not available for the sub-population of patients on 400mg of imatinib for > 50% of treatment so baseline data above reflects entire study population. PVR= Pulmonary vascular resistance; 6MWD = 6-minute walk distance

Hoeper et al; Circulation 2013 Suppl. Appendix

Contemporary Study of Imatinib Supports 400mg Dose for Best Efficacy

Higher Exposure = Larger Improvement



Percentage change in total pulmonary resistance from baseline at 60 days in relation to plasma level (area under curve in µg*h/L) of imatinib at steady state (red-100md QD, orange-200mgQD, cyan-300mg QD, blue-400mg QD)

Doses over 200mg per day were poorly tolerated

More than 50% of subjects who completed the study were on 200mg per day or less

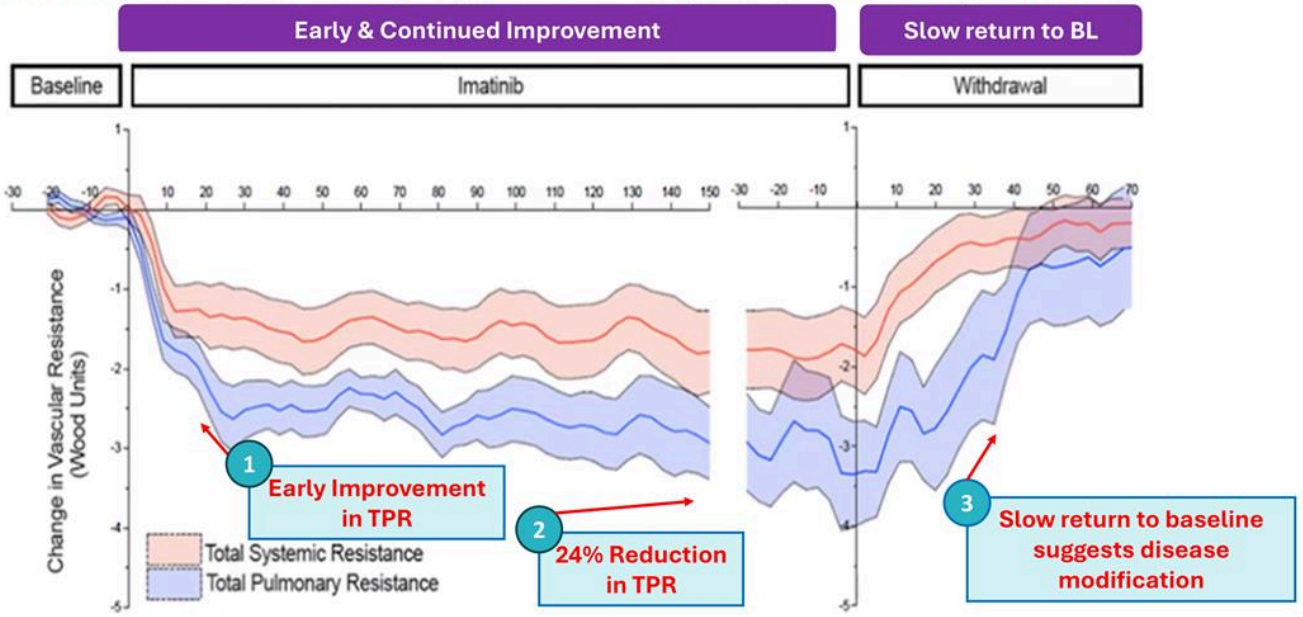
One-third of patients who started the study at either 300mg or 400mg had dose-limiting toxicity at Week 4 and subsequent dose reduction

Only 5 patients completed the study at 300mg or 400mg per day

* Rothman et al., AJRCCM 2025. 17 patient open-label study. Patients were implanted with the CardioMEMS HF System which is a small, wireless sensor implanted in the pulmonary artery to monitor pulmonary artery pressure. Patients remained in the study for up to 24 weeks.

Rapid and Sustained Hemodynamic Effect & Disease Modification of Imatinib in PAH

24% reduction in Total Pulmonary Resistance (TPR); Patients at 200mg or less leaves “efficacy on the table”



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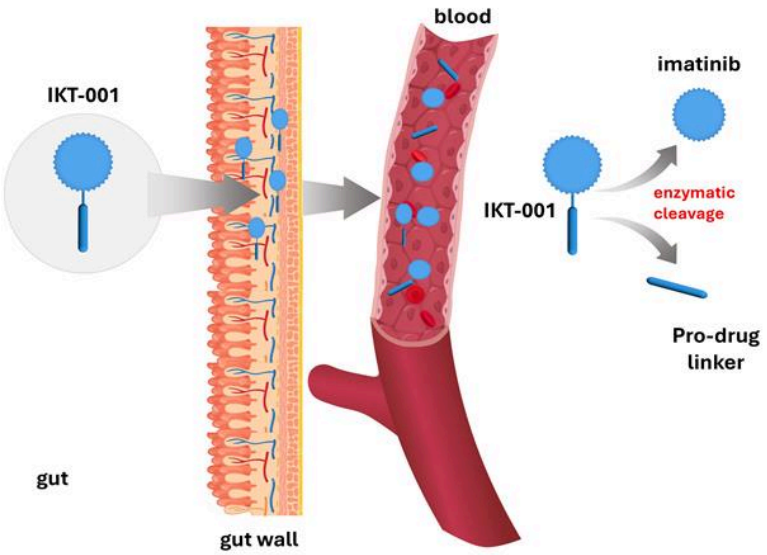
IKT-001

IKT-001 Minimizes GI Imatinib Exposure to Drive Increased Tolerability

28 Day non-human primate study documents improved GI tolerability



>2.5x Improvement in GI Tolerability

Dose Associated with GI Toxicity

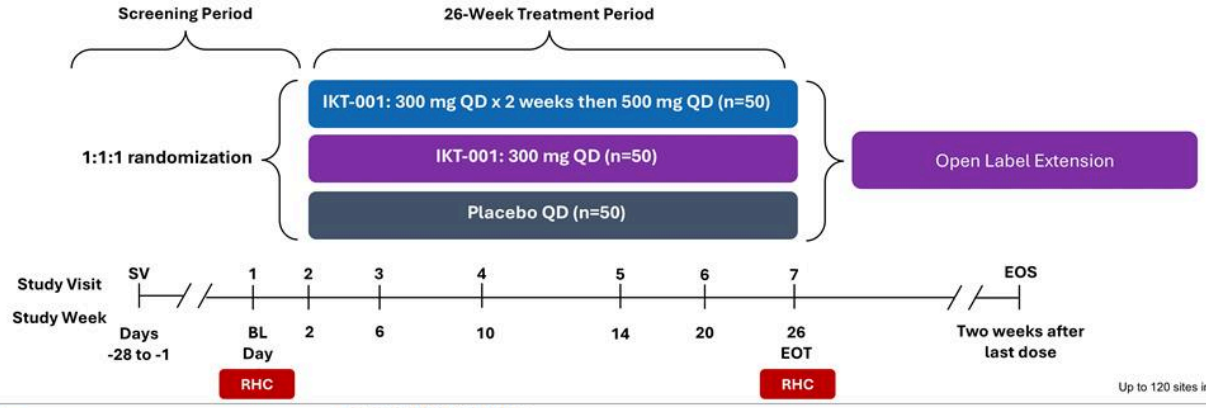
Imatinib: **75 mg per kg per day**

IKT-001: **200 mg per kg per day**

GI = gastrointestinal

IKT-001-201: A Phase 2b Study of IKT-001 in PAH

Randomized double-blind, placebo-controlled study to evaluate efficacy and safety of once daily IKT-001



Up to 120 sites in 18 countries

Primary Endpoints:

PVR at week 26, change from baseline

Safety and tolerability

Secondary Endpoints:

6MWD

WHO Functional Class

Pharmacokinetics

Inclusion / Stratification:

WHO Group 1 PAH with New York Heart Association Functional Class II / III symptoms

Baseline Right Heart Catheter performed during screening period:

- PVR of ≥400 dynes/sec/cm^{-5} ; PCWP ≤15 mmHg; mPAP >20 mmHg
- PVR enrichment criteria to ensure population baseline PVR >700 dynes/sec/cm^{-5}

6MWD ≥100 and ≤500 meters

Previous sotatercept allowed if discontinued 6 months prior to screening and no history of serious bleeding events

Stratification by number of background therapies and ERS/ESC Risk Score

PVR = pulmonary vascular resistance; 6MWD = 6-minute walk distance; RHC = right heart catheter; PCWP = pulmonary capillary wedge pressure; mPAP = mean pulmonary arterial pressure; BL = baseline; SV = screening visit; EOT = end of treatment; EOS = end of study

Inhibikase and IKT-001: Pulmonary Arterial Hypertension (PAH)

Major unmet need with high mortality, poor QoL and high cost	• PAH is a rare, progressive and life-threatening disease with significant unmet need • ~30% 5-year mortality(1), reduced quality of life and high economic burden • $7.6 Billion market with limited treatments that address the underlying etiology
Imatinib has proven efficacy in Phase 3 in PAH	• Imatinib is an anti-proliferative TKI with potential best-in-class improvements in PVR and 6MWD (45 meters*) based on Phase 3 IMPRES and Phase 2 studies • Imatinib hit primary efficacy endpoints in IMPRES but was not well tolerated at 400mg
Potential to be the 1st oral anti-proliferative agent	• IKT-001 is a pro-drug engineered to realize the potential of imatinib in PAH • IKT-001 releases imatinib in the blood with potential to minimize GI side effects maximizing potential to achieve highly efficacious doses
Strong Leadership Executing Near Term Development	• IKT's Phase 2b is on track to initiate in the second half of 2025 • Long intellectual property runway through 2044 • Team with extensive PAH / CV experience

(1) Hoeper M, et al. Eur Respir J. 2017
TKI = tyrosine kinase inhibitor; QoL= Quality of Life; PVR = pulmonary vascular resistance; 6MWD = 6-minute walk distance; GI= Gastrointestinal; CV = cardiovascular
* See Page 17

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Thank You