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): January 4, 2024

THIRD HARMONIC BIO, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-41498	83-4553503
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1700 Montgomery Street, Suite 210 San Francisco, California	94111
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (209) 727-2457

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:

☐ 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, par value $0.0001 per share	THRD	The Nasdaq Stock Market

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 4, 2024, Third Harmonic Bio, Inc. (the "***Company***"), announced the appointment of Christopher M. Murphy, age 40, as the Company's Chief Financial and Business Officer and principal financial officer, effective as of January 4, 2024.

Prior to joining the Company, Mr. Murphy held positions of increasing responsibility at Horizon Therapeutics PLC ("***Horizon***") from March 2014 to May 2020, serving most recently as Group Vice President, Commercial Operations and Analytics from June 2018 to May 2020, serving as Vice President of Business Development from March 2014 to November 2015, Group Vice President of Corporate Development from November 2015 to October 2017, Group Vice President of Operations, Inflammation Business Unit from October 2017 to June 2018, and most recently as Group Vice President, Commercial Operations and Analytics from June 2018 to May 2020. Prior to Horizon, Mr. Murphy held positions of increasing responsibility in the Life Sciences Investment Banking Group at JMP Securities LLC ("***JMP***") from July 2008 to March 2014, serving most recently as a Director from February 2014 to March 2014. Prior to JMP, Mr. Murphy served as a Consultant in the Litigation and Investigation Group of Navigant Consulting, Inc. from July 2006 to June 2008. Mr. Murphy holds a B.B.A. in Finance from the University of Notre Dame.

There is no arrangement or understanding between Mr. Murphy and any other persons, pursuant to which Mr. Murphy was selected as an officer, no family relationships among any of the Company's directors or executive officers and Mr. Murphy, and Mr. Murphy does not have any direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

In connection with his appointment as Chief Financial and Business Officer, Mr. Murphy and the Company entered into an Offer Letter (the "***Offer Letter***"), which includes the following terms: (i) an initial annual base salary of $495,000 per year (the "***Initial Base Salary***"); (ii) an annual discretionary bonus of up to 40% of the Initial Base Salary; and (iii) an option to purchase 410,000 shares of the Company's common stock, par value $0.0001 per share.

Mr. Murphy has also entered into the Company's standard form of Indemnity Agreement and Change in Control and Severance Agreement. The forms of the Indemnity Agreement and Change in Control and Severance Agreement were previously filed by the Company as Exhibits 10.1 and 10.12, respectively, to the Company's Registration Statement on Form S-1, filed with the SEC on September 8, 2022, and are incorporated by reference herein.

The foregoing descriptions of the Offer Letter, Indemnity Agreement and Change in Control and Severance Agreement are qualified in their entirety by reference to the full text of the Offer Letter, Indemnity Agreement and the Change in Control and Severance Agreement, respectively. The Offer Letter will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

Item 7.01 Regulation FD Disclosure.

On January 4, 2024, the Company issued a press release announcing the appointment of Mr. Murphy as Chief Financial and Business Officer of the Company and providing a general business update. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The Company is furnishing its corporate presentation, which it intends to use in conferences and meetings. The full copy of the Company's corporate presentation is filed as Exhibit 99.2 hereto. The corporate presentation will also be available on the Company's website in the Investors & Media section at https://ir.thirdharmonicbio.com.

The information furnished in this Item 7.01, including Exhibits 99.1 and 99.2, 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 into any other filing under the Securities Act of 1934, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Third Harmonic Bio, Inc. dated January 4, 2024
99.2	Corporate Presenation
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.

THIRD HARMONIC BIO, INC.

Date: January 4, 2024

By: */s/ Natalie Holles*
Natalie Holles
Chief Executive Officer

Exhibit 99.1

Third Harmonic Bio Appoints Christopher Murphy as Chief Financial and Business Officer and Provides Business Update

Chris brings extensive enterprise-level leadership experience in business development, commercial operations, and corporate strategy

IND-enabling toxicology studies of THB335 nearing completion; Pre-IND interaction with the U.S. FDA now complete

Program remains on track to file a U.S. IND and initiate a Phase 1 study of THB335 during the first half of 2024

SAN FRANCISCO, CA, January 4, 2024 (GLOBE NEWSWIRE) — Third Harmonic Bio, Inc. (Nasdaq: THRD), a biopharmaceutical company focused on advancing the next wave of medicine for inflammatory diseases, today announced the appointment of Christopher Murphy as Chief Financial and Business Officer. Chris brings extensive experience in business development, commercial operations, corporate strategy and investment banking in the biopharmaceutical industry to the company's leadership team. In his role, Chris will be responsible for strategic leadership and direction of the company's finance, corporate strategy, and business development functions.

"We are very excited to welcome Chris, a high-caliber enterprise leader with a clear track record of translating thoughtful corporate strategy into meaningful shareholder value," said Natalie Holles, Chief Executive Officer at Third Harmonic Bio. "I look forward to Chris' thought partnership as we advance THB335 for the treatment of mast-cell mediated inflammatory diseases and evaluate opportunities to expand our work through strategic business development opportunities."

Chris Murphy most recently served as a member of the leadership team that transformed Horizon Therapeutics PLC from a primary care-focused specialty pharmaceutical company with a market capitalization of approximately $800 million to a fully integrated, highly profitable rare disease-focused biopharmaceutical company, which was acquired by Amgen Inc. for $28 billion in October 2023. While at Horizon, he served in roles of increasing responsibility in business development and commercial operations. In business development, Chris was most recently Group Vice President, where he oversaw a number of strategic transactions and integrations. In commercial operations, Chris most recently served as Group Vice President, overseeing market access, sales and marketing operations, and analytics across Horizon's portfolio of medicines, including during the preparation and initial launch of TEPEZZA® (teprotumumab-trbw) for the treatment of thyroid eye disease. Earlier in his career, Chris held positions of increasing responsibility in the Life Sciences Investment Banking Group at JMP Securities LLC.

Third Harmonic Bio also provided a business update on its lead program, THB335, a potent, highly selective oral small molecule KIT inhibitor in development for the treatment of chronic spontaneous urticaria and other mast-cell mediated inflammatory disorders. IND-enabling toxicology studies of THB335 are nearing completion, and the company recently completed its pre-IND written correspondence with the U.S. FDA. The company is on track to file a U.S. IND and initiate a Phase 1 SAD/14-day MAD study of THB335 during the first half of 2024.

The company maintains a strong financial position with cash and cash equivalents totaling $273.9 million as of September 30, 2023.

About Third Harmonic Bio, Inc.

Third Harmonic Bio is a biopharmaceutical company focused on advancing the next wave of medicine for inflammatory diseases through the development of novel highly selective, small-molecule inhibitors of KIT, a cell surface receptor that serves as the master regulator of mast cell function and survival. Early clinical studies demonstrate that KIT inhibition has the potential to revolutionize the treatment of a broad range of mast-cell-mediated inflammatory diseases, and that a titratable, oral, intracellular small molecule inhibitor may provide the optimal therapeutic profile against this target. Third Harmonic Bio's lead product candidate, THB335, is a titratable, oral, intracellular small molecule inhibitor expected to enter clinical trials during the first half of 2024. For more information, please visit the Third Harmonic Bio website: www.thirdharmonicbio.com.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, the roles and responsibilities of Chris Murphy, the timing of Third Harmonic Bio completing IND-enabling studies of THB335, the filing a U.S. IND application for THB335, and the expected timing for clinical activities. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties, including risks and uncertainties related to Third Harmonic Bio's cash forecasts, ability to advance its product candidates, the receipt and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, our ability to protect our intellectual property, the timing and results of preclinical and clinical trials, changes to laws or regulations, market conditions, geopolitical events, and further impacts of pandemics or health epidemics, that could cause actual results to differ materially from what Third Harmonic Bio expects. Further information on potential risk factors that could affect Third Harmonic Bio's business and its financial results are

detailed under the heading “Risk Factors” included in Third Harmonic Bio’s Quarterly Report on Form 10-Q for the nine months ended September 30, 2023, filed with the U.S. Securities and Exchange Commission (“SEC”) on November 9, 2023, and in Third Harmonic Bio’s other filings filed from time to time with the SEC. Third Harmonic Bio undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

TEPEZZA® is a registered trademark of Amgen Inc.

Investor & Media Contact:

Lori Murray
lori.murray@thirdharmonicbio.com

Exhibit 99.2


Third Harmonic Bio
FOCUSED
On advancing the next wave of medicine for inflammatory diseases
JANUARY 2024
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Forward Looking Statements

This presentation contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. Any statements made in this presentation that are not statements of historical fact, including statements about our beliefs and expectations, are forward-looking statements and should be evaluated as such. Forward-looking statements include information concerning the anticipated profile, efficacy and target indications of THB335, the expected timing of completing IND-toxicology studies for THB335, the expected development and timeline for clinical and non-clinical studies of THB335 candidate, and the expected timing of filing an IND application for THB335. These statements often include words such as "anticipate," "expect," "suggests," "plan," "believe," "intend," "estimates," "targets," "projects," "should," "could," "would," "may," "will," "forecast" and other similar expressions. These forward-looking statements are contained throughout this presentation. We base these forward-looking statements on our current expectations, plans and assumptions that we have made in light of our experience in the industry, as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances at such time. As you read and consider this presentation, you should understand that these statements are not guarantees of future performance or results. The forward-looking statements are subject to and involve risks, uncertainties and assumptions, and you should not place undue reliance on these forward-looking statements. Although we believe that these forward-looking statements are based on reasonable assumptions at the time they are made, you should be aware that many factors could affect our actual results or results of operations and could cause actual results to differ materially from those expressed in the forward-looking statements. Factors that may materially affect such forward-looking statements include: our limited operating history and that we have not completed any clinical trials beyond Phase 1 and have not had any product candidates approved for commercial sale; our significant net losses incurred since inception and the likelihood of incurring additional losses for the foreseeable future; our need for substantial additional funding; the early stage of development of our programs and the possibility they may fail in development; our future performance is substantially dependent on our ability to identify and develop future product candidates; legal and regulatory risks; and intellectual property-related risks, among others. Additional risks and uncertainties that could affect our financial results and business are more fully described under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the three months ended September 30, 2023, filed with the SEC on November 9, 2023, and our other SEC filings, which are available on the Investor & Media page of our website at https://ir.thirdharmonicbio.com/ and on the SEC's website at www.sec.gov. These cautionary statements should not be construed by you to be exhaustive and are made only as of the date of this presentation. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by applicable law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these 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.

Recent Highlights

Appointed Chris Murphy as Chief Financial and Business Officer

IND-enabling toxicology studies of THB335 nearing completion

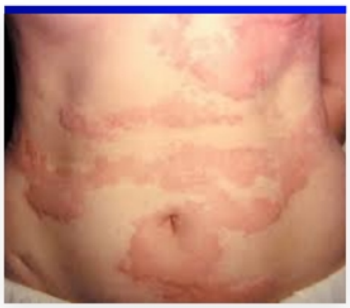
Completed Pre-IND interaction with the U.S. FDA

On track to file a U.S. IND and initiate a Phase 1 study of THB335 during 1H'24

Strong financial position with cash and cash equivalents totaling $273.9 million as of September 30, 2023

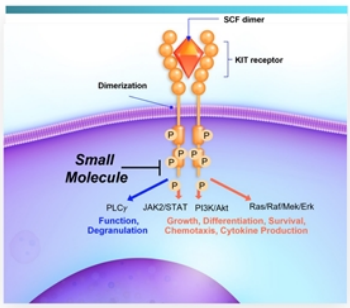
Third Harmonic Bio: Focused on KIT Inhibition to Treat Mast Cell-Mediated Inflammatory Diseases

LARGE ESTABLISHED MARKETS WITH HIGH UNMET NEED



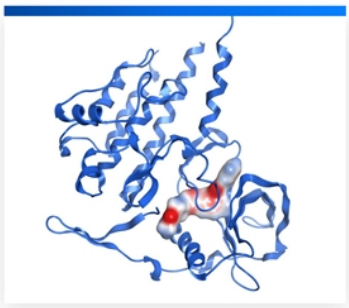
Millions of patients living with severe mast cell-mediated diseases; high residual need despite multiple approved products

KIT: A NOVEL, CLINICALLY VALIDATED TARGET



Clinical validation of KIT as potentially transformative target for mast cell-mediated diseases

SELECTIVE ORAL KIT INHIBITORS



Highly selective oral small molecule with opportunity to optimize therapeutic index and offer patient convenience over injectables

"PIPELINE-IN-A-TARGET" POTENTIAL

Potential to be an attractive treatment option for a range of dermal, airway and GI inflammatory diseases

Third Harmonic Bio

Mast Cells are a Fulcrum of Inflammation

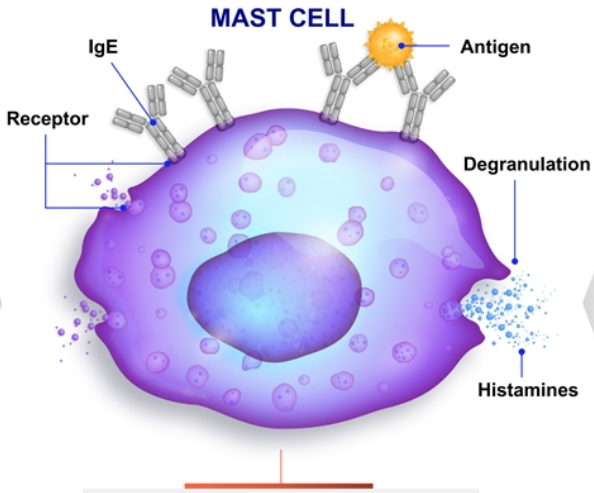
Current therapeutic approaches are mechanistically limited

MANY ACTIVATORS

Receptor-binding agonists
Omalizumab ~~*IgE*~~
Complement
Neuropeptides
Microbial products
Cytokines
Tezepelumab ~~*TSLP*~~
Chemokines

Physical activators
Temperature
Pressure

Cell-cell contact



OPTIMAL INTERVENTION POINT
The Mast Cell Itself

MANY MEDIATORS

Pre-formed mediators
~~*Histamine*~~ *Anti-histamines*
~~*IL-4, IL-13*~~ *Dupilumab*
TNF, GM-CSF
Proteases
Serotonin
Heparin

Newly synthesized mediators
Prostaglandins
~~*Leukotrienes*~~ *Anti-leukotrienes*
Cytokines
Chemokines
Neuropeptides
PAF, free radicals

Lymphocyte ligands

KIT is the Master Regulator of Mast Cell Function and Survival

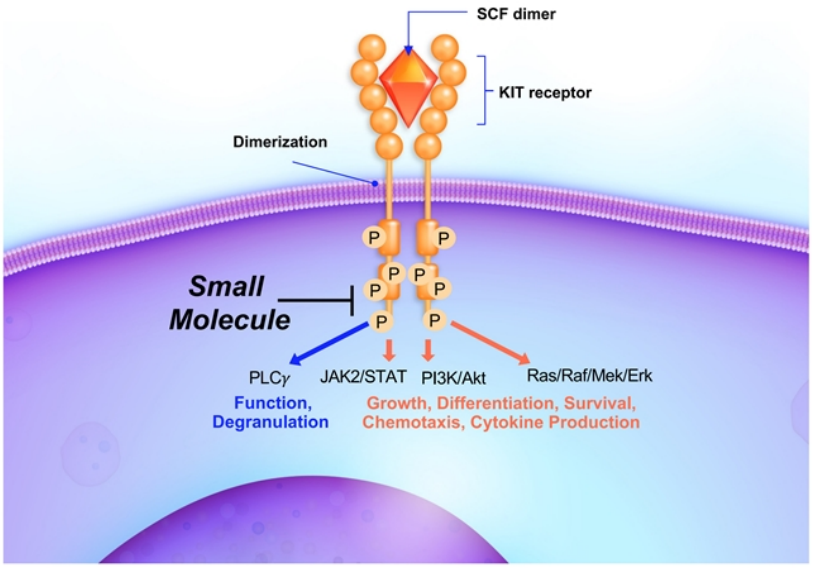
Intracellular small molecule approach to KIT inhibition offers multiple potential therapeutic advantages

KIT

- Master regulator of mast cell proliferation, migration, activation and survival
- KIT inhibition drives both mast cell inactivation **and** depletion

INTRACELLULAR SMALL MOLECULE INHIBITION

- Potential for therapeutic index optimization
- Patient and medical practice convenience
- Avoids risk of MAb-mediated mast cell activation/anaphylaxis



Third Harmonic Bio

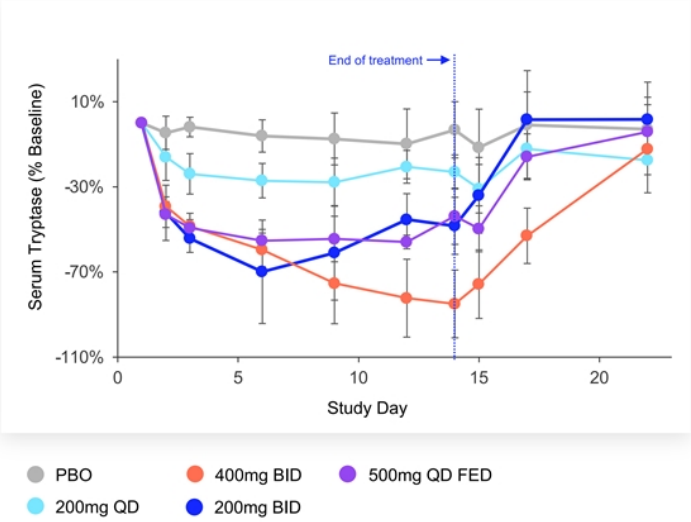

Third
Harmonic
Bio
THB001
Clinical results from first generation
oral KIT inhibitor
7

First-Generation Product Candidate: THB001

Early results support the potential of oral KIT inhibition and inform next-gen development

- THB001 demonstrated high potency and selectivity for KIT → mast cell depletion and disease model efficacy in multiple nonclinical studies
- Phase 1a 14-day healthy volunteer study completed
  - Dose-dependent increases in THB001 plasma exposure and decreases in serum tryptase
  - Mild decreases in hematologic parameters and hair color change consistent with on-target effects of KIT inhibition
- 14-day study results largely predictive of serum tryptase and hematologic effects seen in 12-week study

THB001 PHASE 1 STUDY RESULTS:
Rapid and dose-dependent drops in serum tryptase



PBO = placebo; Mean percent change from baseline calculated using "0" for values <LLOQ (1.0)

THB001 Discontinued Phase 1b Chronic Inducible Urticaria[1] Study Overview

Dose escalation study designed to interrogate potential for therapeutic index optimization

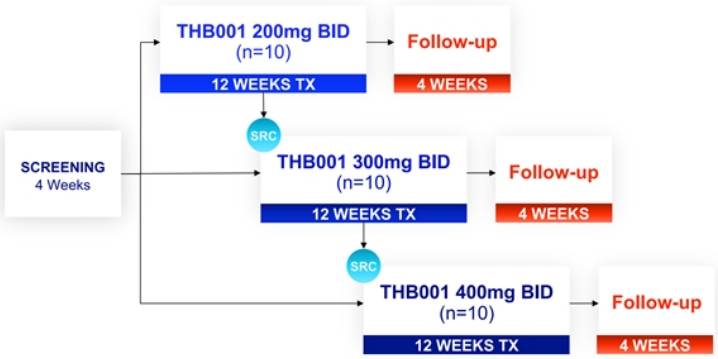
DESIGN AND OBJECTIVES

- 3 doses (1:1:1) of THB001 (total N=30) for 12 weeks
- Pharmacokinetics and serum tryptase levels
- Mean reduction in critical temperature threshold (CTT)

STUDY DISPOSITION

- Enrolled 5 subjects in 200mg BID dose cohort before study discontinuation
- 1 subject completed 12 weeks of treatment
- 2 subjects discontinued at week 8 due to drug-induced liver injury (DILI) AEs
- 2 remaining subjects were discontinued from study drug at weeks 3 and 4 and were followed for safety

STUDY SCHEMATIC



Third Harmonic Bio

1. CINDU

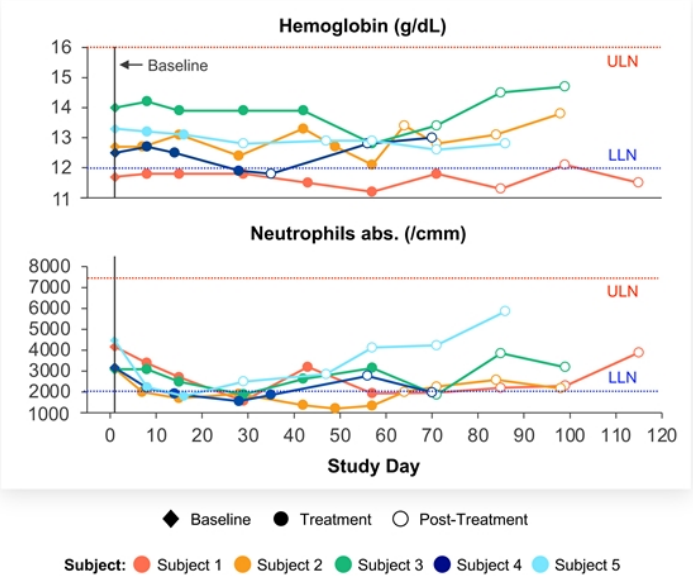
SRC=safety review committee

THB001 in Phase 1b CINDU Study Safety Summary

- No serious or severe adverse events (AEs)
- Two moderate AEs of transaminitis which resolved at weeks 17 and 25 of follow-up
- All other AEs were mild
  - Overall profile consistent with on-target effects of KIT inhibition observed in the Phase 1a study (e.g., hair color change)
  - Hematologic profile similar to Phase 1a and trend toward stabilization of values observed as expected

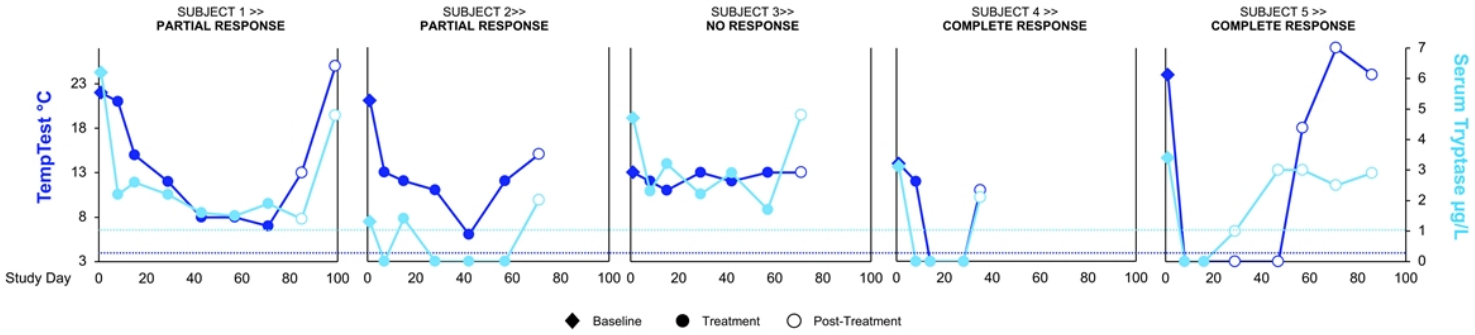
THB001 HEMATOLOGY

Hemoglobin and neutrophil count by subject over time



THB001 Generated Responses at Lowest Planned Dose in Phase 1b Study

4 of 5 subjects reached partial (n=2) or complete (n=2) Critical Temperature Threshold responses



- Rapid tryptase reduction: -83% mean change from baseline by week 1 largely consistent with Phase 1a results
- Strong correlation between serum tryptase reduction and clinical response consistent with other published urticaria clinical data
- 4/5 patients achieved clinical response despite early termination of study

Third Harmonic Bio

Note: Negative TempTest results (complete response) are shown at 3° C.
Serum Tryptase values below lower limit of quantification are shown at 0 µg/L. Empty circles indicate results post treatment.

TempTest complete response ≤ 4°C
Serum lower limit of quantitation = 1 µg/L

Understanding Hepatic Effects of THB001

Mechanistic understanding allows for differentiation of next-generation candidate

Conducted studies characterizing liver metabolism and phenotypic effects of THB001

Employed a comprehensive approach:

- Assessed evidence for off-target biology liabilities
- Characterized liver metabolism and potential for formation of reactive metabolites
- Identified phenotypic effects associated with THB001 in advanced hepatic testing systems

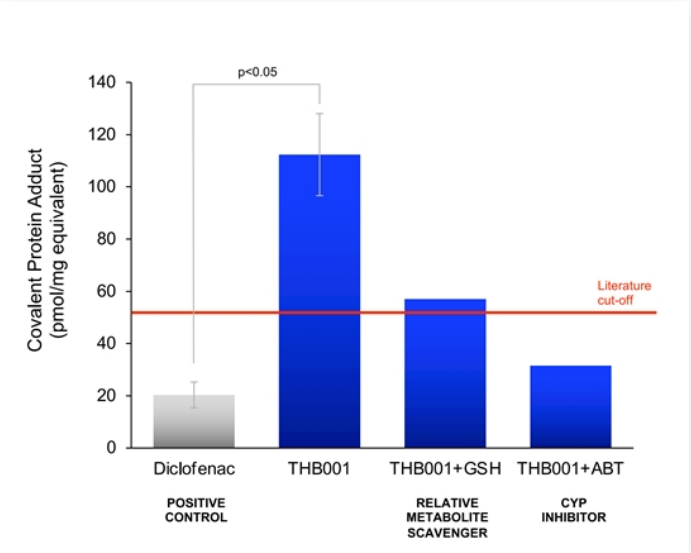
Applied learnings to next-generation compound screening and candidate selection

THB001 Shows Evidence for Formation of a Toxic Reactive Metabolite

Three findings from mechanistic studies provide potential basis for observed transaminitis

- Studies identify major metabolite in human plasma which is formed via a reactive intermediate
  - Metabolite present at higher levels in human plasma than in toxicology animal species
- Detected glutathione (GSH) conjugate metabolites in human urine samples from Phase 1b study
  - Indicates potential to cause oxidative stress
- Measured high levels[1] of protein adduct formation in vitro with radiolabeled THB001
  - Indicates potential to irreversibly inhibit protein function and/or trigger immune response

[^{14}C] THB001 COVALENT PROTEIN ADDUCT FORMATION
in Human Liver Microsomes



Values mean of n=2 or 3 independent donor pools each done in duplicate except ABT that is from a single donor pool.
ABT, 1-aminobenzotriazole.

[1] Published literature cut-off: Evans D.C. et al. *Chem Res Toxicol* 2004


Third
Harmonic
Bio
THB335
Next generation oral KIT inhibitor
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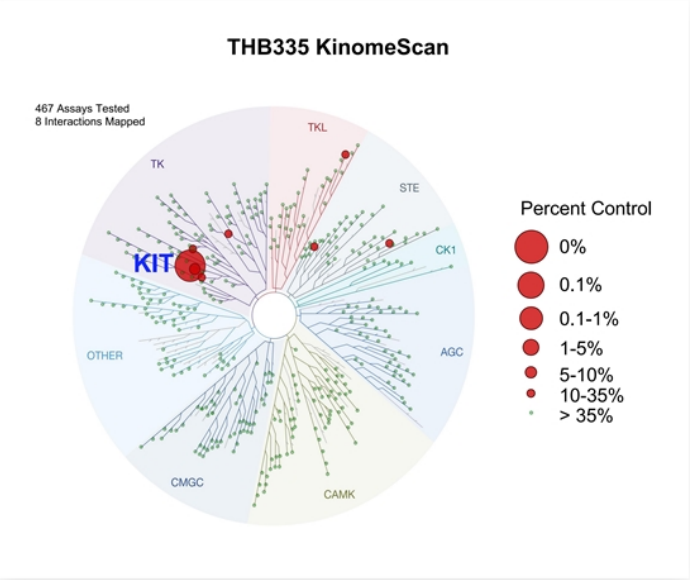
THB335 Potent and Selective Small Molecule KIT Inhibitor

Maintained kinase inhibition profile to THB001 but lacking evidence for reactive metabolite formation



COMPARISON OF KEY KINASE AND METABOLIC PATHWAY PARAMETERS

	THB001	THB335
KIT IC_{50}	23 nM	9.5 nM
PDGFRα Selectivity	>100-fold	>100-fold
CSF1R Selectivity	65-fold	>100-fold
Off-target cell viability	No effect at 3 μM	
Brain-to-plasma ratio	0.9 to 1.2	<0.1
Reactive intermediate metabolite	Yes	No
Glutathione adduct formation	Yes	No

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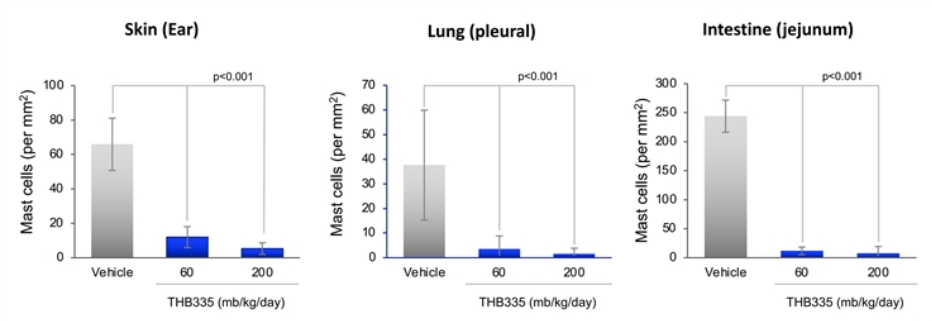
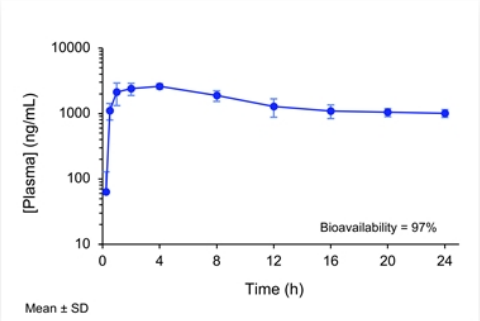
KinomeScan completed at 100 nM THB335
KIT and CSF1R IC_{50} determined by NanoBRET. PDGFRα IC_{50} determined by homogeneous time resolved fluorescence (HTRF). Viability was assessed in cell lines dependent on CSF1R and PDGFRβ, respectively.

THB335 Demonstrated Favorable Nonclinical Profile

THB335 MAST CELL DEPLETION
14-day non-GLP toxicology study



THB335 PK IN NONCLINICAL MODEL
(oral administration)



- Potent mast cell depletion across relevant tissue types
- Favorable nonclinical pharmacokinetic profile, including high oral bioavailability, metabolic stability and long circulating half-life
- Improved solubility and lipophilicity compared to THB001
- No liver toxicity signal observed at high multiples of anticipated clinical exposure in nonclinical models enabled by markedly improved solubility

Third Harmonic Bio Next Steps

Advancing THB335 back toward the clinic with a longer-term view toward franchise expansion

- THB335 U.S. IND filing and clinical trial initiation on track for 1H’24
- Targeting chronic spontaneous urticaria as initial clinical indication
- Planned expansion into additional mast-cell mediated inflammatory disorders at Phase 2
- Medicinal chemistry, next-generation efforts continuing to support pipeline-in-a-target potential
- Selectively evaluating business development opportunities to expand portfolio
- Maintaining focused operational strategy
- Cash and cash equivalents of $273.9M as of September 30, 2023


Third
Harmonic
Bio
ADVANCING
The next wave of medicine for
inflammatory diseases
18