

June 2025

# Innovating for Everyone

Clinical-stage biopharmaceutical company  
focused on next generation therapeutics  
meeting unmet patient needs.



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## Our Mission

At Hoth Therapeutics, we strive to develop innovative, impactful, and ground-breaking treatments with a goal to improve patient quality of life. We are a catalyst in early-stage pharmaceutical research and development, elevating promising drugs from the bench to pre-clinical and clinical testing. Utilizing a patient-centric approach, we collaborate and partner with a team of scientists, clinicians, and key opinion leaders to seek out and investigate medications that hold immense potential to create breakthroughs and diversify treatment options. Our mission is to bring value to both our shareholders and our patient populations.



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# Key Investment Highlights

 HOTH THERAPEUTICS



**Clinical Programs**



**Robust Pre-Clinical  
Development  
Programs**

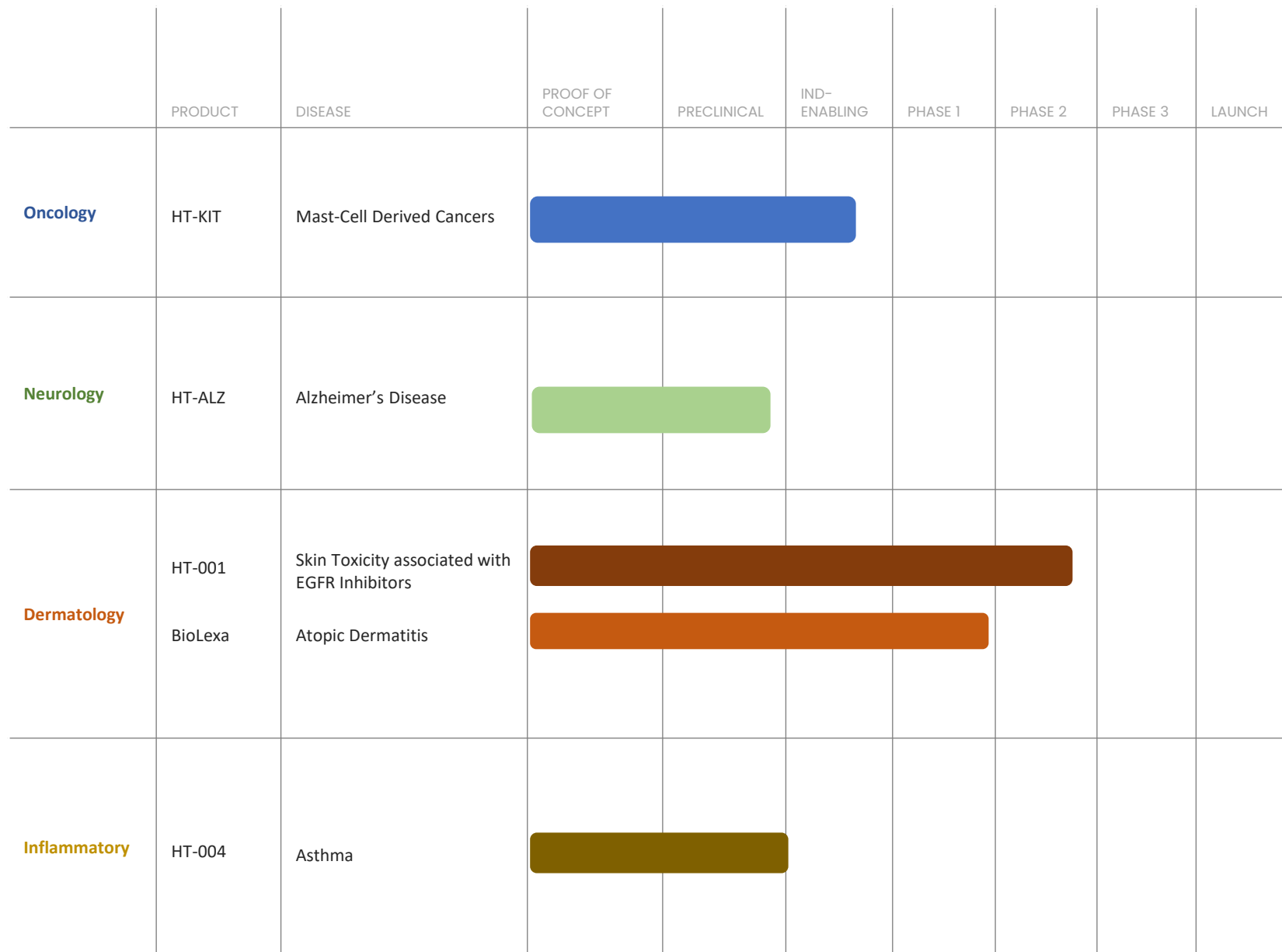


**Targeting Unmet  
Medical Needs to  
Address Broad Market**



**Experienced  
Management and  
Advisory Board**

# Pipeline: Multiple Shots on Goal



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# Primary Development

 HOTH THERAPEUTICS

**HT-001 Topical Gel**

**HT-KIT Injection**

**HT-ALZ Oral Soluble Film**

**BioLexa Lotion**

## HT-001:

### Value Proposition

**Market Growth:** EGFR Inhibitor Skin Toxicity market predicted to grow from \$52M in 2018 to \$391M by end of 2030\*

**Mechanism of Action:** 12-week study conducted at GW suggests the topical application of HT-001 significantly reduces erlotinib-induced cutaneous toxicities applied preventatively or proactively. It supports that HT-001 may be used as a topical intervention to treat EGFR-inhibitor-induced cutaneous toxicity.\*\*

**Addresses Unmet Need:** No current approved product on the market that specifically treats EGFR inhibitor cutaneous toxicities, which occur in up to 90% of patients undergoing EGFR inhibitor therapy.\*\*\*

\*EGFR Inhibitors-Induced Skin Disorders-Market Insights, Epidemiology, and Market Forecast-2030

\*\*<https://ir.hoththerapeutics.com/ht-001>

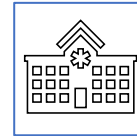
\*\*\*<https://jamanetwork.com/journals/jamadermatology/article-abstract/2767656>

## Recent & Upcoming Milestones: HT-001 Topical Gel



**Q1 2023**

Initiated Phase 2a Clinical  
Trial in Open Label Cohort



**Q4 2024**

All Clinical Sites Active  
and Enrolling in Open  
Label and Double-Blind  
Randomized Cohorts



**Q1 2025**

Initial Interim Open Label  
PK Cohort Data



**Q4 2025**

Full Data Set for Open  
Label PK Cohort



## IND-Opening Trial:

CLEER-001 Phase 2a  
Dose Ranging  
Study

A Randomized, Placebo-Controlled, Parallel Phase 2a Dose Ranging Study to Investigate the Efficacy, Safety, and Tolerability of Topical HT-001 for the Treatment of Cutaneous Toxicities Associated with EGFR Inhibitors

### 2 Parts – Parallel Study Design:

- **Part 1:** Open-label treatment with HT-001 2% for 6 weeks (PK cohort)
- **Part 2:** Randomized double-blind treatment with HT-001 0.5%, 1%, 2% or placebo

#### Part 1

##### Open-Label PK Cohort

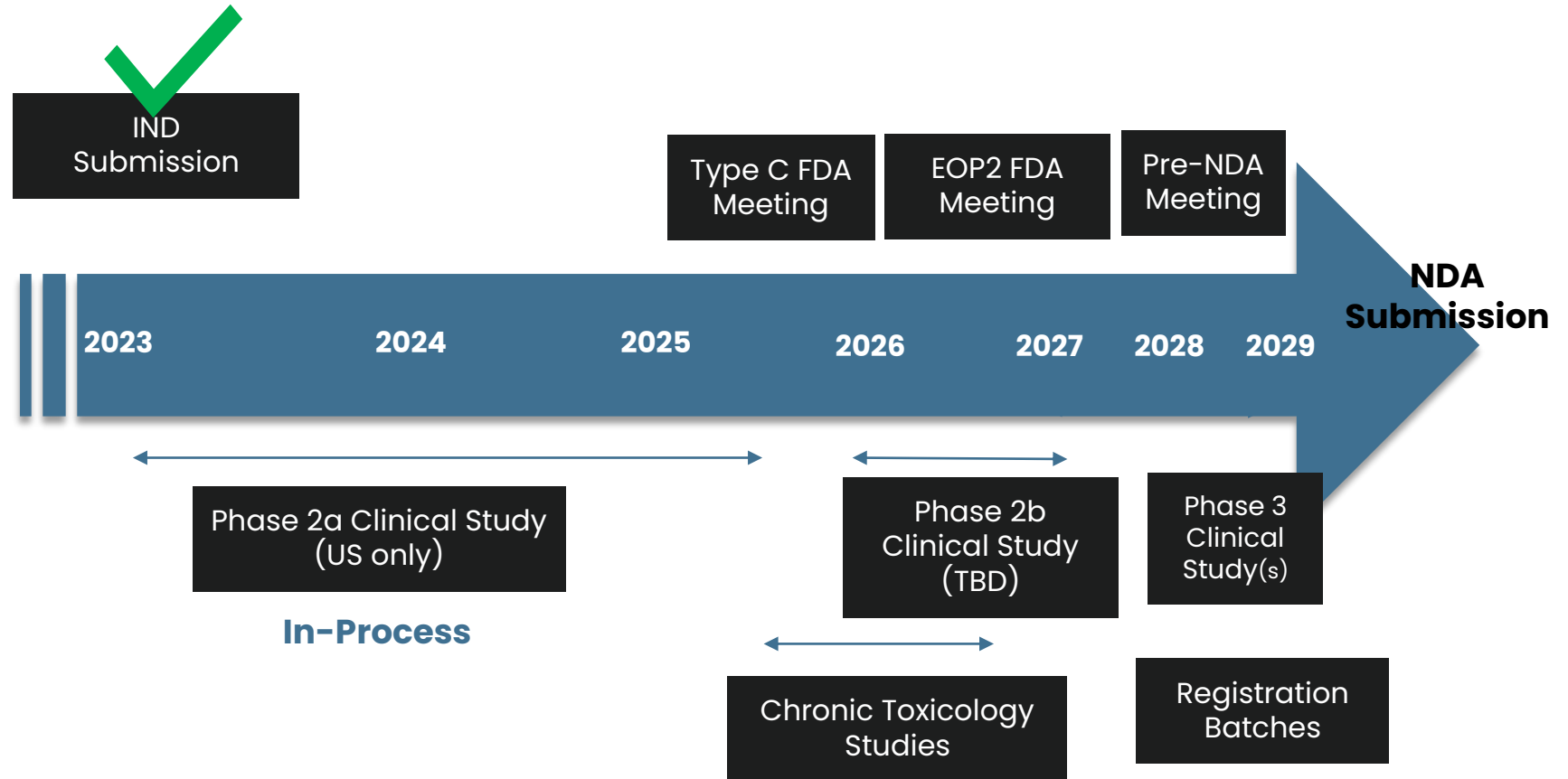
(6 weeks treatment  
+ 2 weeks follow-up)  
N = 12 patients

#### Part 2

##### Randomized, Double Blind Period

(6 weeks treatment  
+ 2 week treatment follow-up)  
N = 140 patients

# HT-001 505(b)(2) Development Pathway



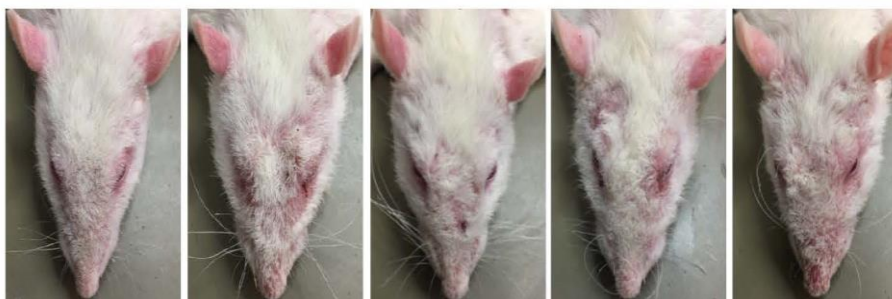
Current estimated dates; pending FDA meetings for phase 2b/phase 3 clinical studies

# Proactive Topical HT-001 Significantly Reduces EGFR Inhibitor- Induced Cutaneous Toxicity

Erlotinib (noVeh C) – Week 12



Erlotinib + Topical HT-001 Initiated Week 1 – Week 12



Erlotinib + Topical HT-001 Initiated Week 6 – Week 12



Group	Change Compared to Erlotinib Only Group: Facial Skin Lesions at 12 weeks	Change Compared to Erlotinib Only Group: Hair Loss at 12 weeks
Preventative Topical HT-001 + Erlotinib	58.5% Reduction ( $p < 0.001$ vs Erl and $p < 0.01$ vs control)	56.2% reduction in hair loss ( $p < 0.001$ vs Erl and $p < 0.001$ vs control)
Proactive (week 6) Topical HT-001 + Erlotinib	47.8% reduction ( $p < 0.001$ vs Erl and $p < 0.001$ vs control)	44.4% reduction in hair loss ( $p < 0.001$ vs Erl and $p < 0.001$ vs control)

## HT-KIT: Value Proposition

**Market Growth:** Global systemic mastocytosis treatment revenue is \$128M and projected to grow at 5.8% CAGR through 2031\*

**Mechanism of Action:** HT-KIT is an antisense oligonucleotide that results in non-functional cKIT via mRNA frameshift.\*\*

**Addresses Unmet Need:** KIT D816V mutation found in >80% of adult systemic mastocytosis cases results in conformational changes that make some tyrosine kinase inhibitor drugs ineffective.\*\*

cKIT is also implicated in gastrointestinal stromal tumors, acute myeloid leukemia, and other rare cancers

\*Global Systemic Mastocytosis Treatment Market Research Report, January 2022, Market.US

\*\*Snider et al., Targeting KIT by frameshifting mRNA transcripts as a therapeutic strategy for aggressive mast cell neoplasms, Molecular Therapy (2021), <https://doi.org/10.1016/j.ymthe.2021.08.009>

## Recent & Upcoming Milestones: HT-KIT Injection



**Q4 2023**

Pre-IND Meeting with FDA  
and strategy confirmed



**Q1 2024**

IND-enabling animal  
toxicology studies initiated



**Q1 2025**

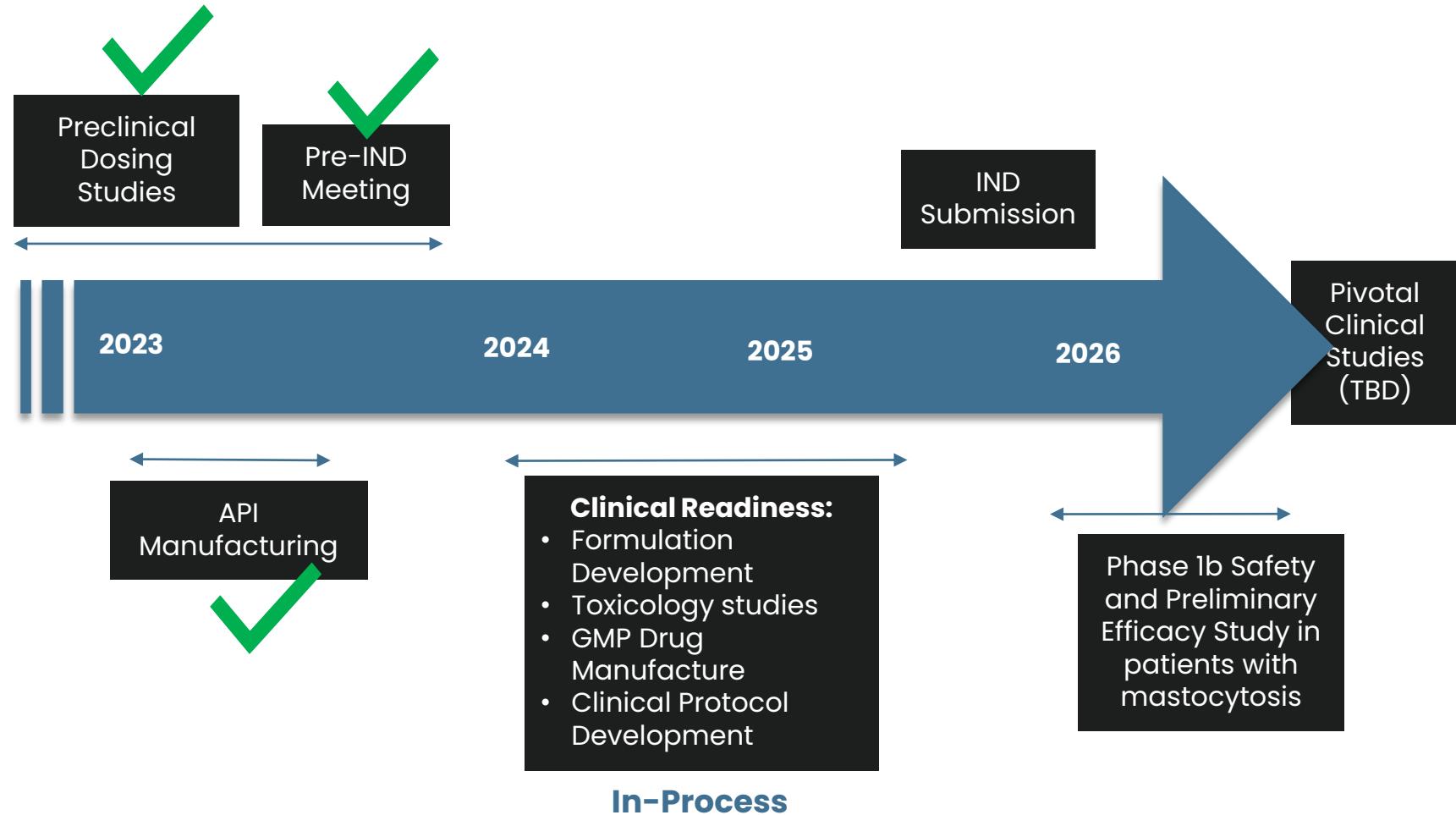
GLP animal studies and  
GMP API manufacturing  
initiation target



**Q1 2026**

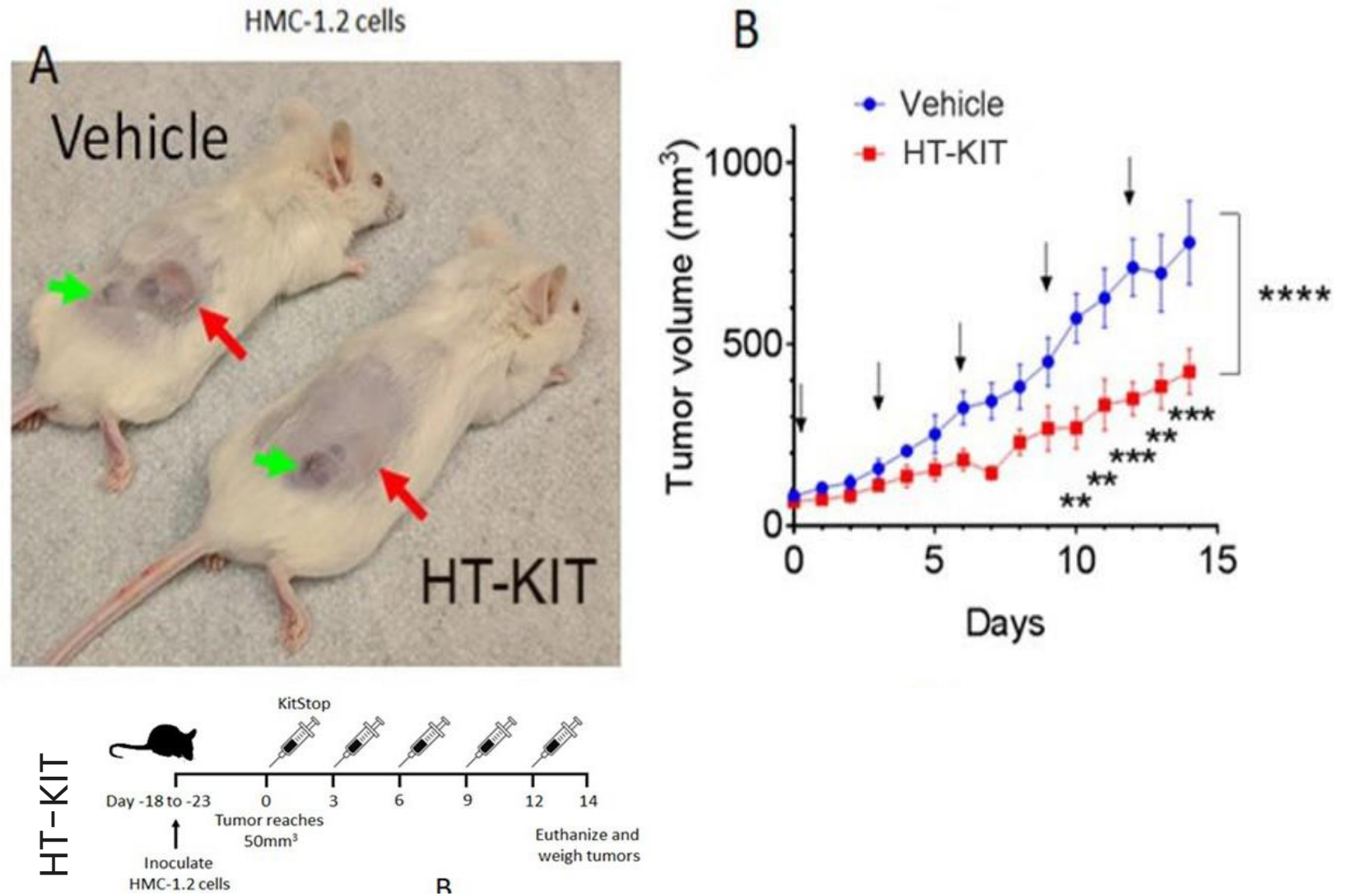
IND Submission target

# HT-KIT Orphan Drug Development Pathway



Current estimated dates; pending FDA meetings for clinical studies.

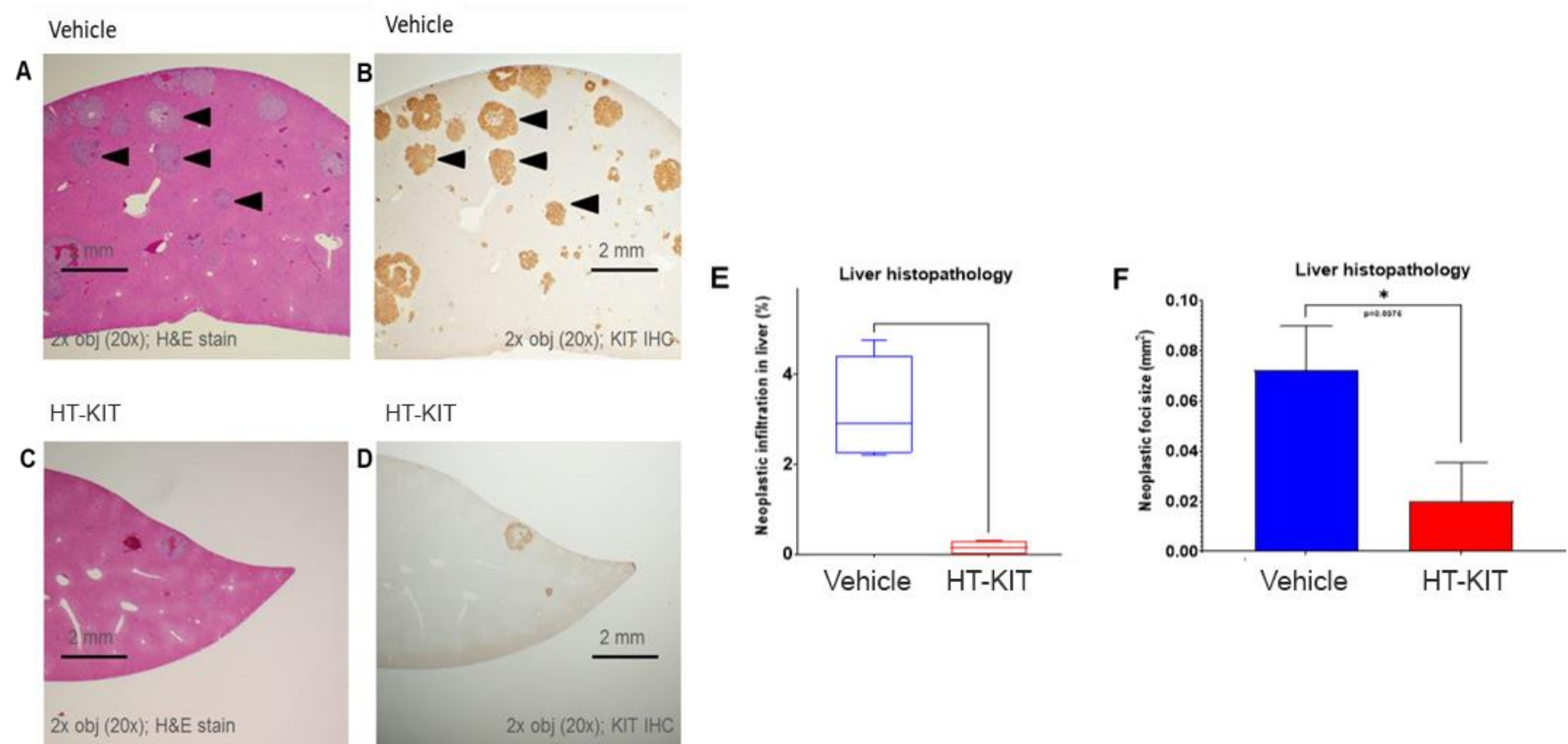
# Systemic delivery of human HT-KIT inhibits tumor growth in a humanized xenograft mast cell neoplasia model



Figures from Douglas B. Snider<sup>1</sup>, Greer K. Arthur<sup>1</sup>, Guido H. Falduto<sup>2</sup>, Ana Olivera<sup>2</sup>, Lauren C. Ehrhardt-Humbert<sup>1</sup>, Emmaline Smith<sup>1</sup>, Cierra Smith<sup>1</sup>, Dean D. Metcalfe<sup>2</sup> and Glenn Cruse<sup>1</sup> (1Department of Molecular Biomedical Sciences, CVM, NC State University 2Laboratory of Allergic Diseases, NIAID, NIH). Targeting KIT by frameshifting mRNA transcripts as a therapeutic strategy for aggressive mast cell neoplasms. Poster presentation at ASCO June 2021.



# HT-KIT Reduces Liver Infiltration of Neoplastic Mast Cells in a Humanized Xenograft Model of Mast Cell Neoplasia



Figures from Douglas B. Snider<sup>1</sup>, Greer K. Arthur<sup>1</sup>, Guido H. Falduto<sup>2</sup>, Ana Olivera<sup>2</sup>, Lauren C. Ehrhardt-Humbert<sup>1</sup>, Emmaline Smith<sup>1</sup>, Cierra Smith<sup>1</sup>, Dean D. Metcalfe<sup>2</sup> and Glenn Cruse<sup>1</sup> (1Department of Molecular Biomedical Sciences, CVM, NC State University 2Laboratory of Allergic Diseases, NIAID, NIH). Targeting KIT by frameshifting mRNA transcripts as a therapeutic strategy for aggressive mast cell neoplasms. Poster presentation at ASCO June 2021.



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## HT-ALZ: Value Proposition



**Market Growth:** The Global Alzheimer's Disease Treatment Market is expected to grow at a CAGR of around 12.8% from 2020 to 2027 and reach the market value of over \$5.2B by 2027.\*

**Mechanism of Action:** HT-ALZ targets the Substance P/Neurokinin-1 Receptor pathway\*\* in the brain, which has both negative (inflammatory) and positive (anti-amyloidogenic, memory, neuroprotective) roles in Alzheimer's disease.

**Addresses Unmet Need:** : There are currently no drugs approved that are considered disease modifying and demonstrate cognitive improvement. Preclinical data with HT-ALZ indicates HT-ALZ may provide reduced neuroinflammation and significant improvements in cognitive functions such as memory and learning.

\*<https://www.acumenresearchandconsulting.com/alzheimers-disease-treatment-market>

\*\*Martinez AN, Philipp MT. Substance P and Antagonists of the Neurokinin-1 Receptor in Neuroinflammation Associated with Infectious and Neurodegenerative Diseases of the Central Nervous System. J Neurol Neuromedicine. 2016;1(2):29-36. doi:10.29245/2572.942x/2016/2.1020

\*\*Severini C, Petrella C, Calissano P. Substance P and Alzheimer's Disease: Emerging Novel Roles. Curr Alzheimer Res. 2016;13(9):964-72. doi: 10.2174/1567205013666160401114039. PMID: 27033058.

## Recent & Upcoming Milestones: HT-ALZ Oral Soluble Film



**Q2 2024**

HT-ALZ Formulation Work  
initiated



**Q3 2024**

US Patent Office Awarded  
HT-ALZ Patent



**Q3 2024**

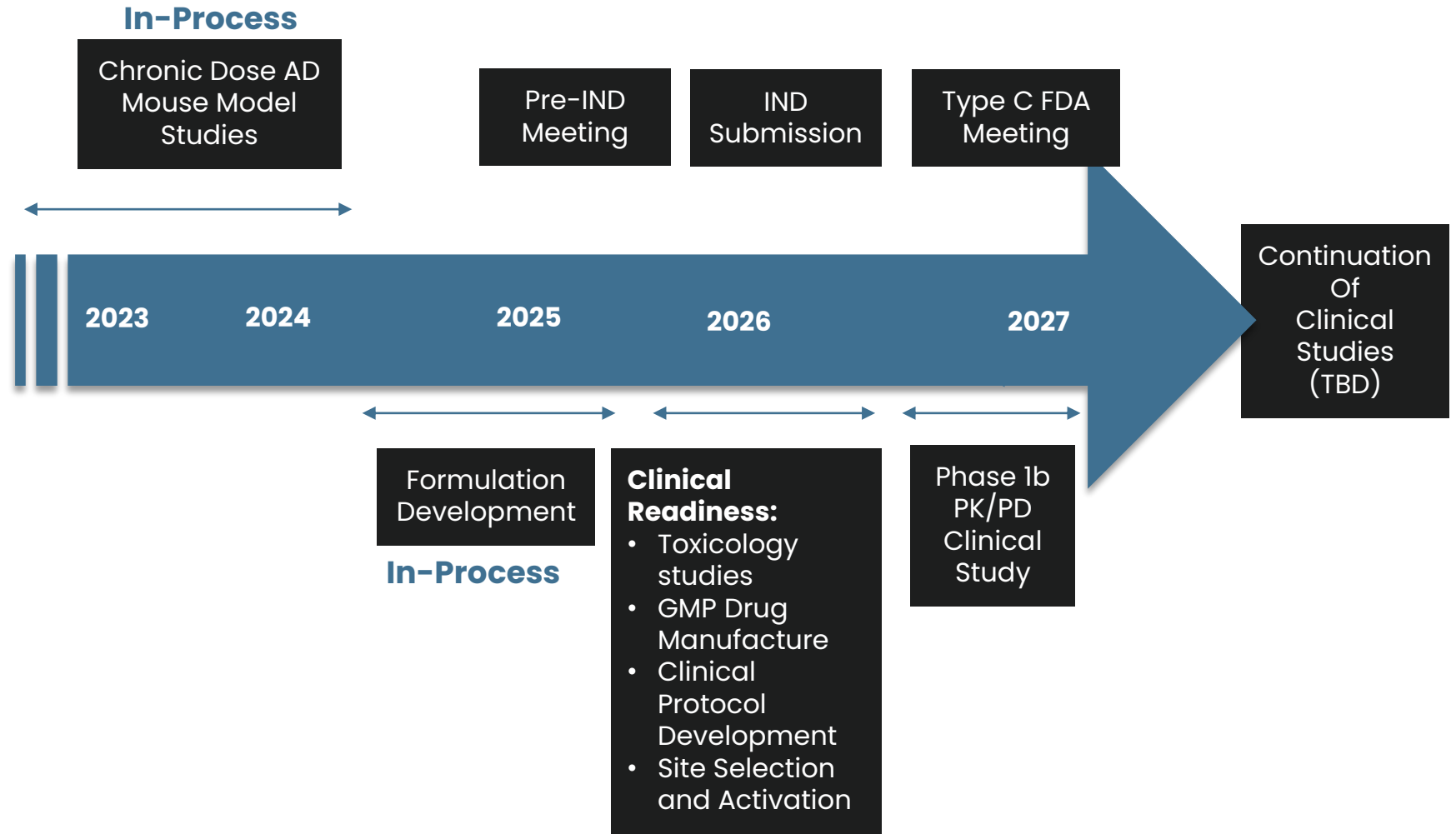
Preclinical Studies  
completed at WashU



**2025**

Pre-IND Meeting  
Submission

# HT-ALZ 505(b)(2) Development Pathway



Current estimated dates; pending FDA meetings for clinical studies.

## Biolexa:

### Value Proposition

**Market Growth:** Atopic dermatitis market predicted to grow from \$6.4B in 2017 to \$18.3B by end of 2027\*

**Mechanism of Action:** Novel mixture of two previously approved compounds targeting the underlying Staphylococcus aureus infection hypothesize to potentiate Atopic Dermatitis (AD) or eczema flares – First compound prevents biofilm formation, which protects the underlying infection, allowing the second, an antibiotic, to more effectively treat the underlying infection.

**Addresses Unmet Need:** Non-corticosteroid treatment targeted for treatment of both pediatric and adult mild to moderate AD populations

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## Recent & Upcoming Milestones: BioLexa Lotion



**2021**

Phase 1b Cohort 1 with  
healthy subjects  
completed



**Dec 2021**

Phase 1b cohort in  
patients with mild to  
moderate atopic  
dermatitis initiated



**Sep 2022**

Open Label dosing  
portion of Phase 1b Study  
is completed

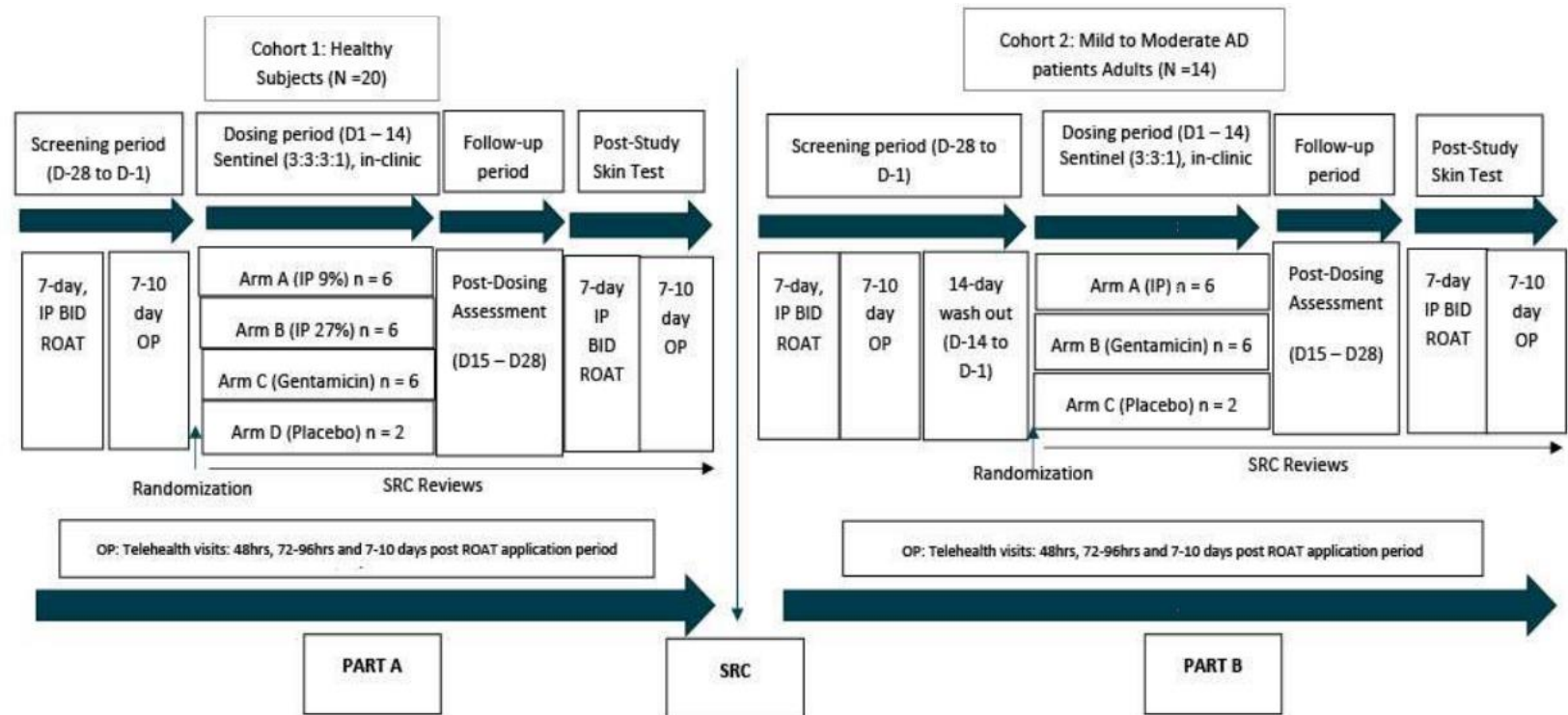


**2023**

Data Readout from Phase  
1b Clinical Study

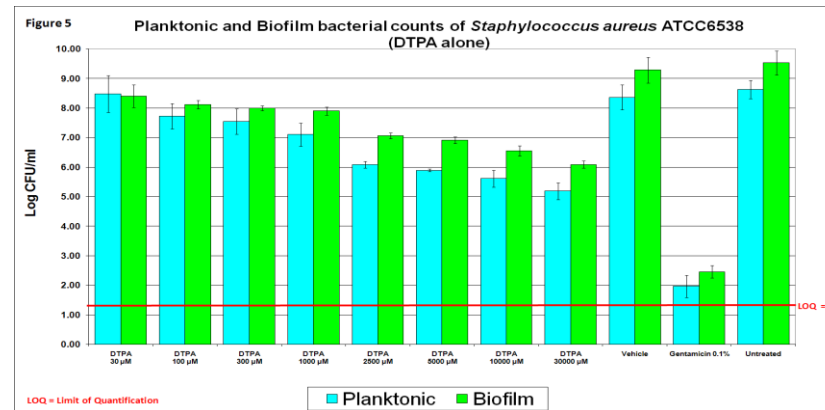
# BioLexa Phase 1b Clinical Study Design

A Randomised, Double-Blind, Vehicle Controlled, Sequential Group Study to Determine the Safety, Tolerability, Pharmacokinetics and Efficacy of Twice Daily Application of Topical BioLexa™ in Adult Healthy Subjects and Patients with Mild to Moderate Atopic Dermatitis



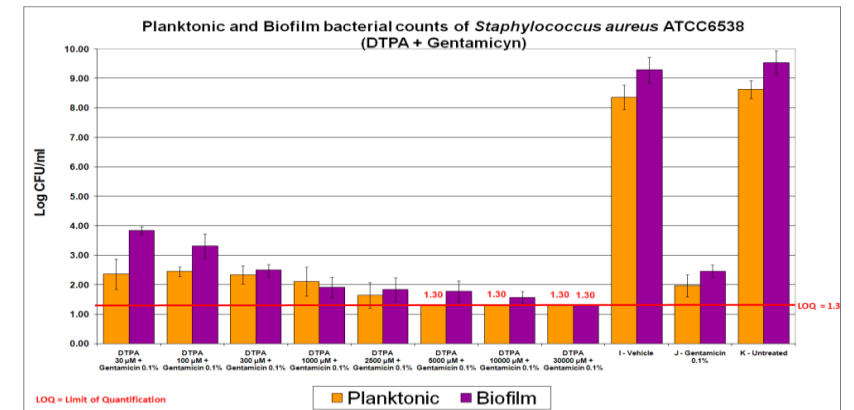
# BioLexa: Proof-of- Concept Results

This study concluded that the combination of gentamicin and Ca-DTPA is more effective to reduce bacteria growth and inhibit the formation of biofilms than each compound individually.



DTPA  
Alone

Gentamicin  
Alone



Combination Reduced Bacteria Below LOQ

Miller School of Medicine, of the University of Miami and University of Cincinnati - Determination of the effects of a novel antimicrobial agent used in conjunction with Gentamicin on *Staphylococcus aureus* using a porcine model: preliminary evaluations Jose Valdes, Joel Gil, Andrew Herr, Andrew Harding and Stephen Davis

Miller School of Medicine, of the University of Miami and University of Cincinnati - Determination of the effects of a novel antimicrobial agent used in conjunction with Gentamicin on *Staphylococcus aureus* using a porcine model: preliminary evaluations Jose Valdes, Joel Gil, Andrew Herr, Andrew Harding and Stephen Davis

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# Preclinical Development

 HOTH THERAPEUTICS

HT-004



## HT-004:

### Value Proposition

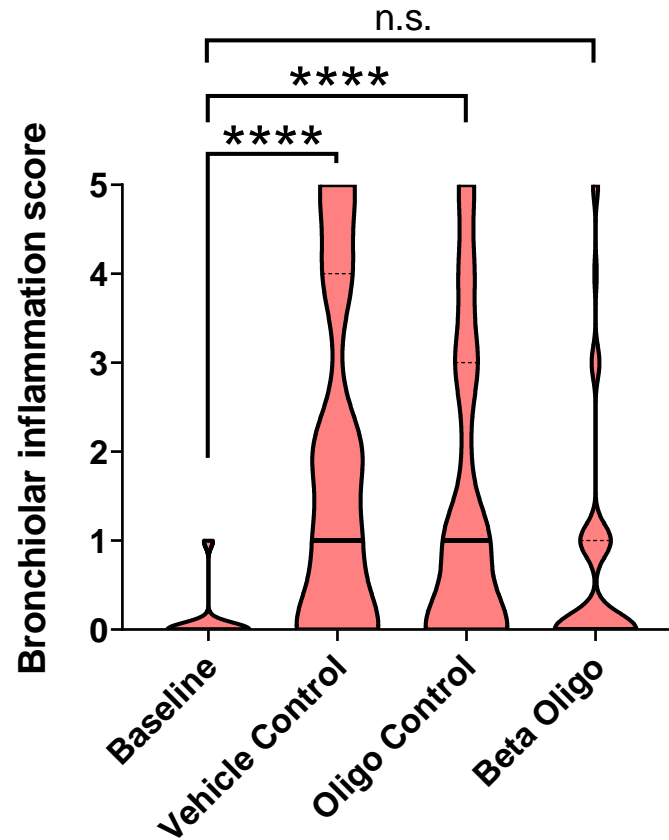
**Market Growth:** The global asthma therapeutics market reached a value of \$17.6B in 2020. The market is expected to reach a value of \$19.13B by 2026, expanding at a CAGR of 1.60% during 2021–2026.\*

**Mechanism of Action:** Target IgE receptor trafficking to prevent downstream inflammatory pathways

**Addresses Unmet Need:** New class of drug for maintenance treatment of asthma with potential for a better safety profile

\*Asthma Therapeutics Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2021–2026, imarc

## HT-004: Asthma & Allergic Inflammation



- Peribronchiolar Inflammation was reduced by inhalation of HT-004 that targets FcER1-beta alternative exon splicing.
- Ovalbumin inhalation induced airway-centric recruitment of inflammatory cells predominated by eosinophils admixed with lymphocytes, macrophages, and fewer mast cells.
- Inflammatory cell recruitment was minimal in lungs of mice lacking the ovalbumin-induced allergic airway disease and administered only PBS vehicle control.
- Inflammatory cell recruitment was moderate to marked resulting in expansion of peribronchiolar connective tissues by several cells thick in some areas for mice in control treatment groups with ovalbumin-induced allergic airway disease (vehicle control and oligo (non-target) control).
- Despite ovalbumin-induced allergic airway induction, lungs from mice receiving inhalation of HT-004 had reduced inflammatory cell recruitment around bronchioles.

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# Investment Highlights



## Programs in Clinical Stage of Development

- Addressing multi-billion-dollar unmet market opportunities across indications
- HT-001 – no approved product/competitor currently on the market, clinical trial currently enrolling
- HT-KIT – Pre-IND Meeting with FDA successful and IND-enabling tox studies and development underway in 2025

## Diverse and Robust Pipeline of Pre-Clinical Candidates


- Offers strong intellectual property portfolio, including exclusive licenses to patents and trademarks
- Multiple shots on goal with diversified portfolio and market
- Multiple assets have platform technology possibilities

## Clean Financials

- 13.2 million shares outstanding (as of June 6, 2025)
- Cash on hand is sufficient to take company through the clinical and pre-clinical programs currently in development

## Experienced Management, Board and Scientific Advisors

- Experienced management team, board of directors and scientific advisors with proven financial, capital markets and drug development experience

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**Thank  
You.**



## **Contact Information**

### **Investor Relations:**

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