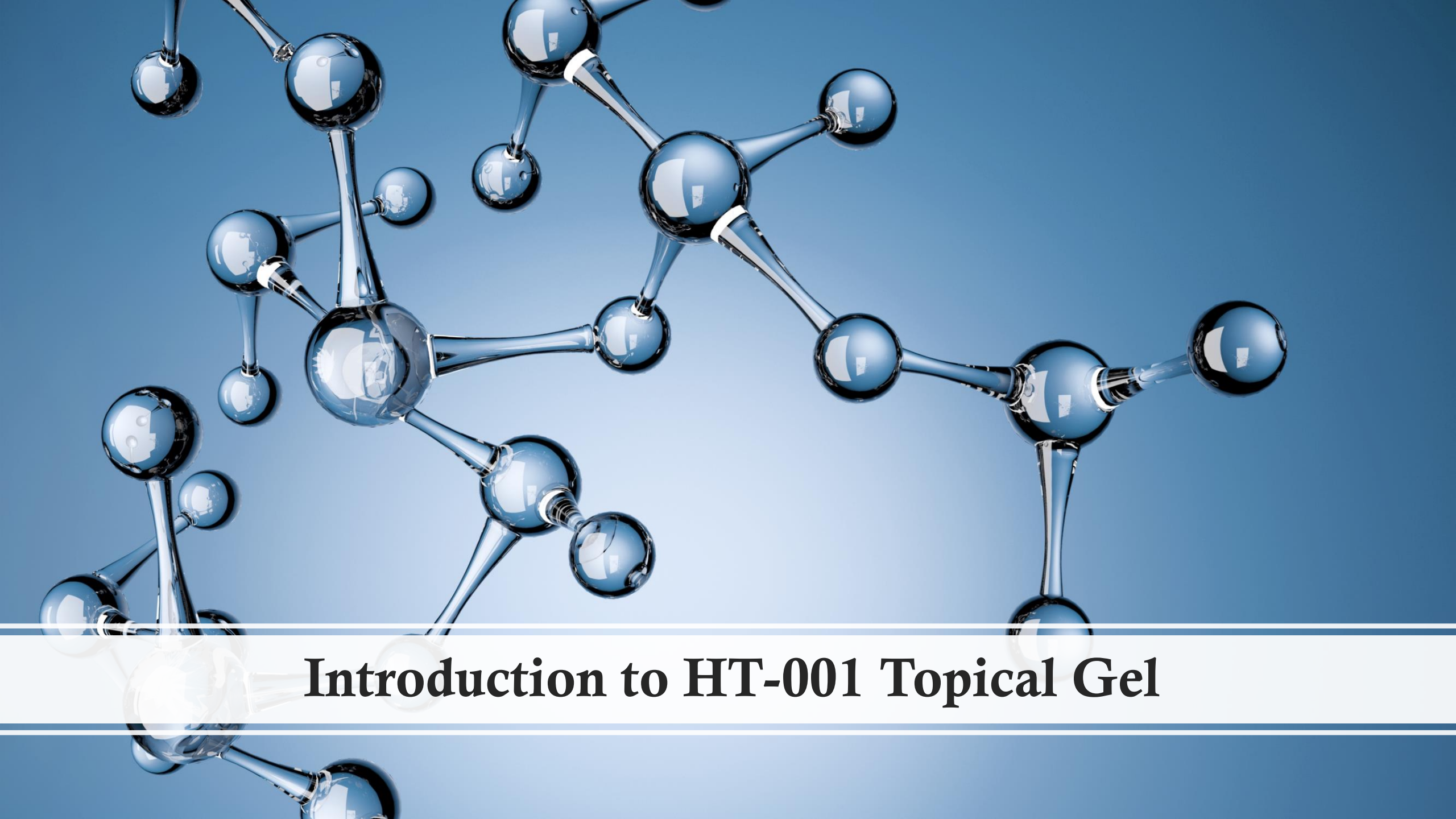

Introduction to HT-001 Topical Gel

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Introduction to HT-001 Topical Gel

- Novel Primary Indication
  - Treatment of mild to moderate cutaneous toxicities (skin, scalp, nails) associated with EGFR inhibitor cancer therapy
  - No other drugs approved for this indication
  - Qualifies as a "serious condition" to pursue FDA expedited programs (Fast Track, Breakthrough Designation, Priority Review)

- 505(b)(2) Regulatory Pathway

- Hoth has exclusive license from George Washington University for worldwide territory

Background: Cutaneous Toxicities Associated with EGFR Inhibitor Therapy

- Currently 11 EGFR inhibitor drugs are approved by FDA for the treatment of a variety of cancer types, including breast cancer, non-small cell lung cancer (NSCLC), pancreatic cancer, colorectal cancer, squamous-cell carcinoma of the head and neck, and medullary thyroid cancer

- Cutaneous toxicities are the most common side effect of EGFR inhibitor therapy
  - Most frequently occurring disorders include[1,2]:
    - **papulopustular (acneiform) rash (45 to 100%)**
    - **dry and itchy skin (12 to 16%)**
    - microbial infections (38 to 70%)
    - **nail changes (12% – 16%)**
    - **xerosis (7% – 35%)**
    - **pruritus (10% – 16%)**
    - alopecia (5% – 6%)

- EGFR therapy dose modification (10-50% reduction) has been reported to occur in up to 60% of cases and discontinuation of EGFR therapy in 32% of cases[3]

Background: HT-001 Mechanism of Action

- EGFR signaling is critical to maintain skin homeostasis; inhibition results in high influx of inflammatory cells and production of proinflammatory cytokines in the skin
- HT-001 is anticipated to inhibit recruitment and activation of immune cells, reducing inflammation

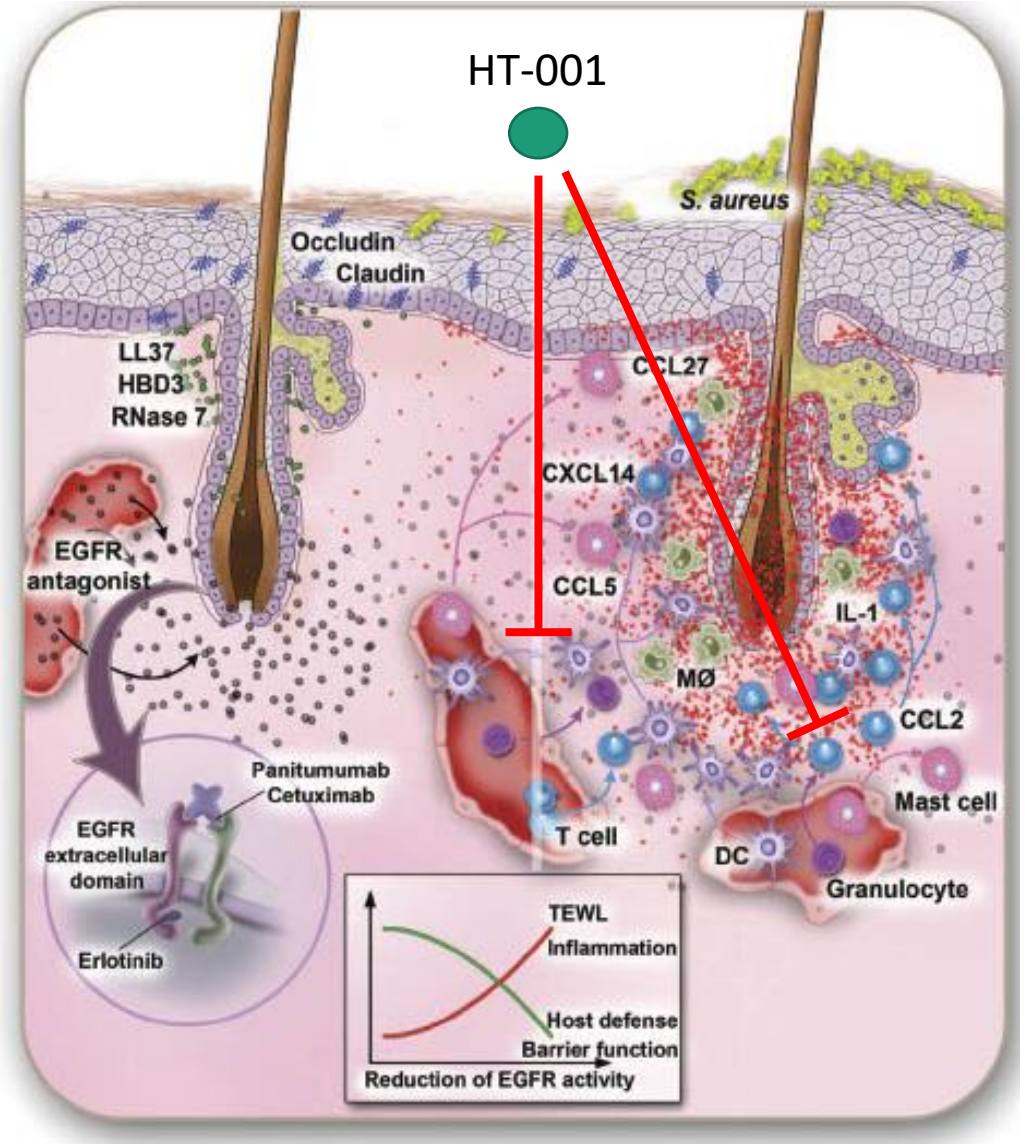
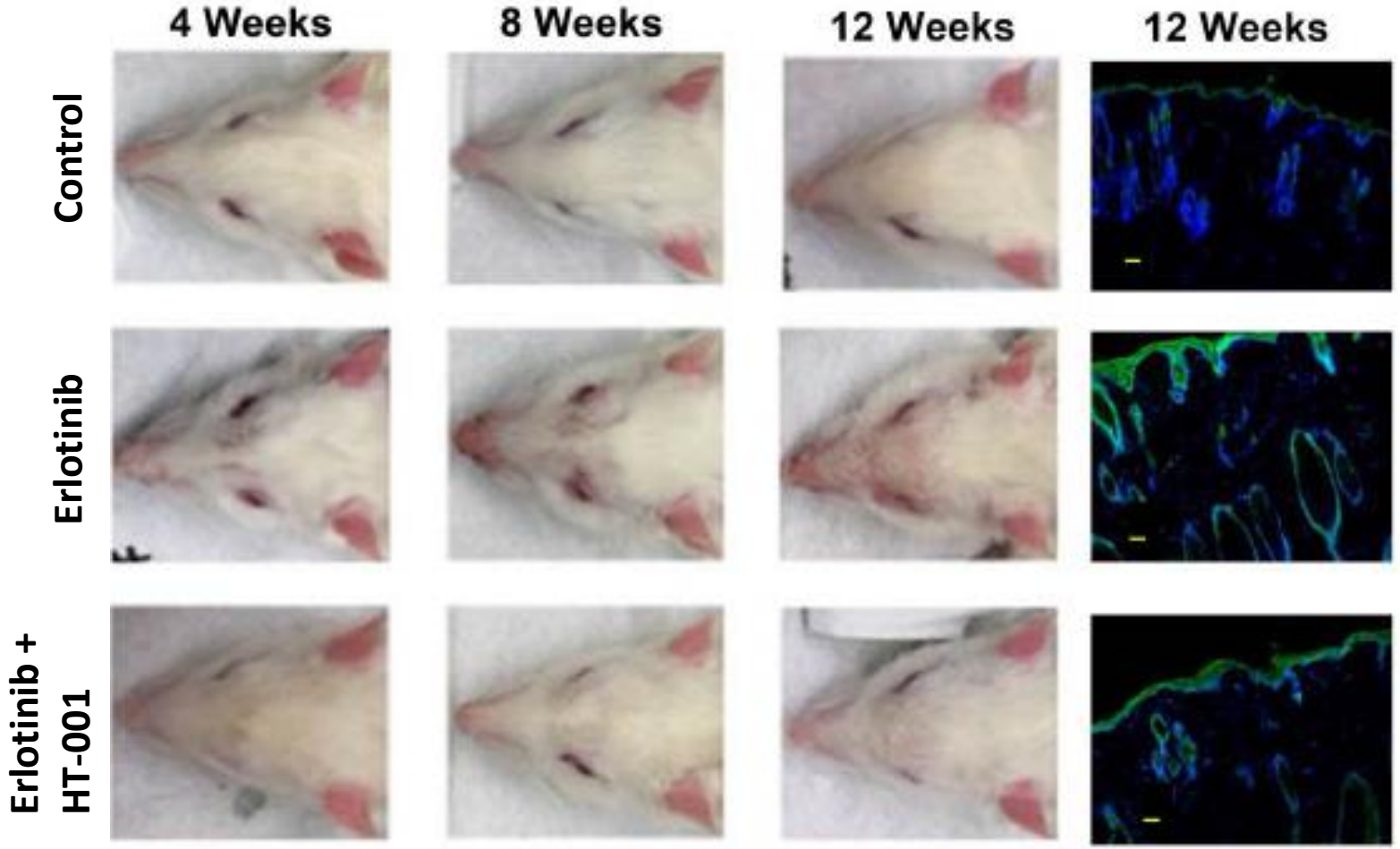


Figure adapted from Lichtenger 2013, et al

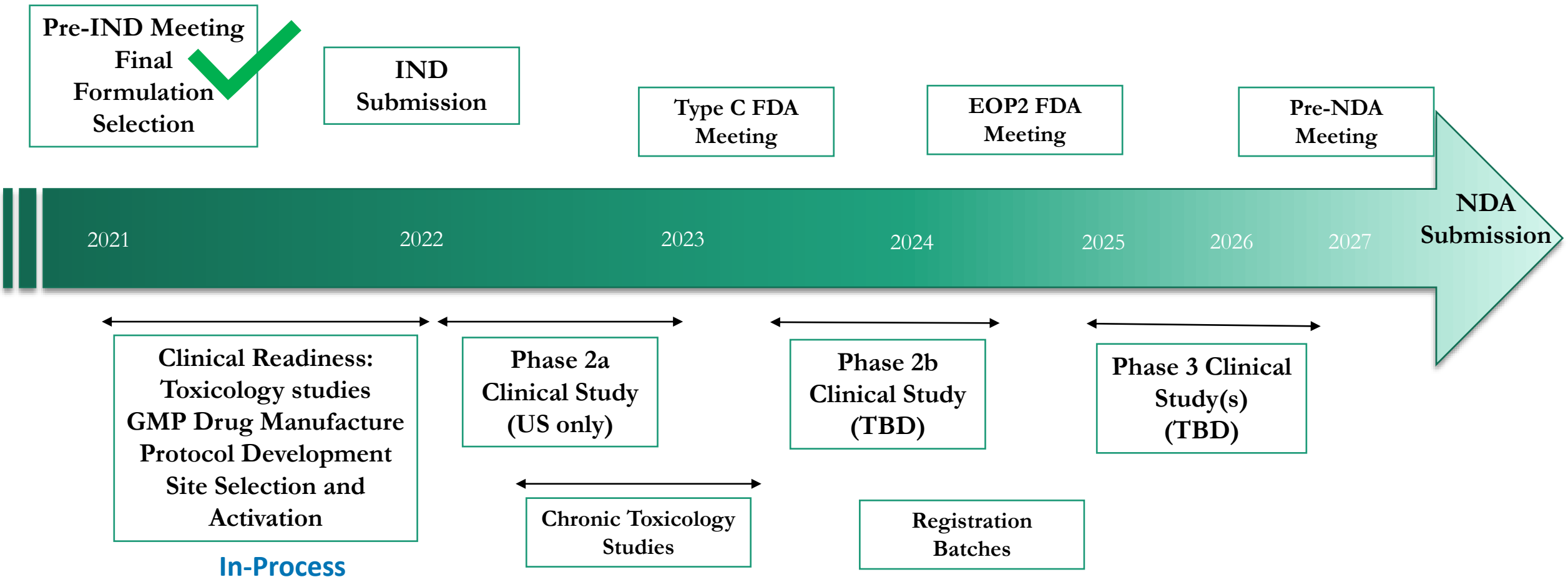
HT-001 Significantly Reduces EGFR Inhibitor-Induced Cutaneous Toxicity



Erlotinib-Induced Dermatological Effects in Rats are Rescued by Concurrent Treatment with HT-001

- Oral administration of 5.85 mg/kg/day erlotinib, with or without 1.15 mg/kg/day HT-001 for 12 weeks
- In comparison to erlotinib-only treatment, concomitant treatment with HT-001 showed:
  - Resolution of erlotinib-induced dermatitis and hair loss
  - Significant reduction in substance P
  - Significant reduction in neutrophil activity
  - Restoration of cardiac dysfunction

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



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

Success Factors

- Key partnerships established for clinical readiness for IND-opening, Phase 2a dose ranging clinical trial
  - Worldwide Clinical Trials – CRO for protocol development and study management
  - Camargo Pharmaceutical Services – CRO for IND preparation and submission
  - Charles River Laboratories – CRO for IND-enabling toxicology studies

- Pre-IND Meeting complete with positive outcomes
  - The proposed HT-001 formulation and drug substance specifications are reasonable
  - No significant changes to the planned IND-enabling toxicology program
  - The proposed indication for HT-001 across the entire class of EGFR inhibitors may be appropriate, pending appropriate data from phase 3 trials.
  - Detailed feedback for proposed IND-opening phase 2a study in patients receiving EGFR inhibitor therapy

- Drug product formulation selected and confirmed skin penetration and retention, stability, and preliminary proof of concept data to support no change to efficacy from prior studies

References

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3. Boone, S. L., Rademaker, A., Liu, D., Pfeiffer, C., Mauro, D.J., Lacouture, M.E. (2007). Impact and Management of Skin Toxicity Associated with Anti-Epidermal Growth Factor Receptor Therapy: Survey Results. Oncology 72(3-4):152-9.

THANK YOU

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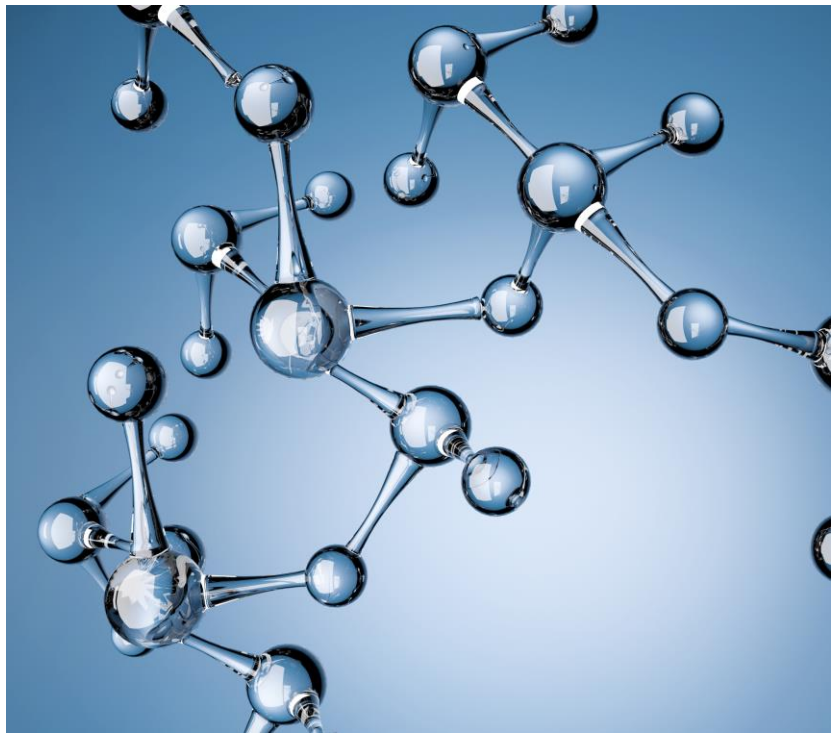

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