Study to Investigate the Efficacy, Safety, and Tolerability of Topical HT-001 for the Treatment of Skin Toxicities Associated With Epidermal Growth Factor Receptor Inhibitors

NCT05639933

Status	RECRUITING
Phase	Phase 2
Sponsor	Hoth Therapeutics, Inc.
Enrollment	152 participants

Key Eligibility Criteria

Inclusion (9)

• Adult participant (ie, e 18 years of age at Screening/Baseline \[V1\]) prescribed an approved EGFRI to treat cancer (indication within the approved labeling for the EGFRI and/or on National Comprehensive Cancer Network guidelines or equivalent local standards).

• Approved EGFRIs include, but are not limited to: gefitinib, erlotinib, osimertinib, lapatinib, afatinib, dacomitinib, neratinib, vandetanib, lazertinib, cetuximab, panitumumab, necitumumab, pertuzumab, and amivantamab-vmjw.

• Administration of an EGFRI, in combination with other drugs, for treatment of cancer is acceptable as long as the other drug is identified in the approved label of the EGFRI (eg, erlotinib with gemcitabine) or part of the NCCN guidelines or equivalent local standards.

• Participant has developed a rash or symptoms of a rash (papular and/or pustular eruptions or cutaneous burning), as assessed by both Common Terminology Criteria for Adverse Events (CTCAE) grading and ARIGA scales (severity d 3) with overall involvement d 30% BSA.

• Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.

... and 4 more (see full listing online)

Exclusion (21)

• Participant has severe cutaneous toxicity (severity = 4 on the CTCAE grading and ARIGA scales) or cutaneous toxicity involvement that is \> 30% BSA, or other severe systemic toxicity (severity \> 3 on the CTCAE v5.0 scale) as a result of EGFRI therapy.

• Participant has any underlying physical or psychological medical condition that, in the opinion of the Investigator, would make it unlikely that the participant would comply with the protocol or complete the study per protocol.

• Participant has a history of other skin disorders (eg, atopic dermatitis, psoriasis, recurrent skin infections), or history of illness that, in the opinion of the Investigator, would confound results of the study or pose unwarranted risk in administering study drug to the participant.

• Participant has abnormal laboratory values at Screening/Baseline (V1):

• Absolute neutrophil count \< 1000/mm3 and WBC count \< 3000/mm3

... and 16 more (see full listing online)

Locations (12 total)

UCI Health - CIACC, Irvine, California, United States
UC Irvine - Chao Family Cancer Center, Orange, California, United States
Regis Clinical Research, Miami, Florida, United States
... and 9 more locations