Study of Afatinib in Advanced Cutaneous Squamous Cell Carcinoma

NCT05070403

Status	RECRUITING
Phase	Phase 2
Sponsor	H. Lee Moffitt Cancer Center and Research Institute
Enrollment	25 participants

Plain Language Summary

This trial is studying afatinib, a targeted oral medication, in people with advanced skin squamous cell carcinoma (a type of skin cancer) that cannot be removed by surgery or treated with radiation.

You may be eligible if...
- You are 18 or older
- You have advanced or metastatic cutaneous squamous cell carcinoma (skin cancer that has spread or cannot be surgically removed)
- You have already received immunotherapy (PD-1/PD-L1 drugs) unless you were not a candidate for it
- You have at least one measurable tumor
- Your blood counts, liver, and kidney function are within acceptable ranges

You may NOT be eligible if...
- You have not recovered from significant side effects of prior cancer treatments
- You received another systemic treatment, major surgery, or radiation within the past 2 weeks
- You are pregnant or unwilling to use contraception
- You are unable to provide tumor biopsy samples before and during treatment

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (16)

- Age e 18 years at the time of informed consent
- ECOG performance status d2
- Adequate bone marrow, organ function and laboratory parameters:
- ANC e 1.0 × 109/L;
- Hemoglobin e 8 g/dL;

... and 11 more (see full listing online)

Exclusion (6)

- In participants with known liver cirrhosis, those with severe (Child Pugh C) hepatic impairment will be excluded.
- Untreated, uncontrolled or symptomatic brain metastases or leptomeningeal carcinomatosis that are not stable or require corticosteroids,
- Participants with mixed histologies (eg, sarcomatoid, adenosquamous) will generally not be eligible, unless the predominant histology is invasive cuSCC.
- Participants with a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.
- Participants with known human immunodeficiency virus (HIV)-infection are eligible providing they are on effective anti-retroviral therapy and have undetectable viral load at their most recent viral load test and within 90 days prior to randomization. Participants

with a known history of hepatitis C virus (HCV) infection must have been treated and cured. Participants with HCV infection who are currently on treatment must have an undetectable HCV viral load prior to randomization.

... and 1 more (see full listing online)

Locations (1 total)

Moffitt Cancer Center, Tampa, Florida, United States