Background

- Cutaneous squamous cell carcinoma (CSCC) is the second most common skin cancer after melanoma.
- Most cases of CSCC are caused by sun exposure and skin damage; however, 1% to 5% of patients develop advanced disease, which is associated with poor prognosis.
- Cemiplimab was the first treatment approved by the US Food and Drug Administration (FDA) for the treatment of patients with locally advanced CSCC not amenable to surgery or radiation, or metastatic CSCC.
- In 2021, the FDA approved cemiplimab for the treatment of patients with locally advanced CSCC not amenable to surgery or radiation, or metastatic CSCC.

Methods

- Study design and data source:
  - This retrospective cohort study included all patients with advanced CSCC initiating cemiplimab monotherapy in the United States from 2011 to 2018 and in the nationwide de-identified Fairborn Health database.

- Study population:
  - The main study cohort included patients with advanced CSCC initiating cemiplimab monotherapy between September 2011 and September 2018 and was stratified by stage at index.
  - Clinical characteristics included age at index, years; primary location of CSCC, n (%); region, n (%); practice type, n (%); stage at index, n (%); ECOG performance status, n (%);
  - Additional inclusion and exclusion criteria were implemented as inclusion/exclusion criteria by design.

- Outcomes:
  - Time to next treatment (TTNT): Time from the initiation of a certain LOT to the date of first treatment by line of therapy (LOT).
  - Treatment pattern outcomes included the line setting of cemiplimab and type of therapy.

- Results:
  - In total, 622 patients were included in the main cohort and 240 patients in the trial-like cohort.
  - The main study cohort initiated cemiplimab monotherapy (index date: date of first dose), with ≥2 visits in the Flatiron Health network on or after January 1, 2011, and had metastatic CSCC.
  - The trial-like cohort included patients receiving cemiplimab on or after January 1, 2011.
  - A total of 622 patients were included in the main cohort and 240 patients in the trial-like cohort.
  - The main study cohort initiated cemiplimab monotherapy (index date: date of first dose), with ≥2 visits in the Flatiron Health network on or after January 1, 2011, and had metastatic CSCC.
  - The trial-like cohort included patients receiving cemiplimab on or after January 1, 2011.

- Conclusions:
  - This study, which included 622 patients with advanced CSCC initiating cemiplimab monotherapy in the United States from 2011 to 2018, and 240 patients in the trial-like cohort, provides insights into the real-world characteristics and outcomes of patients with advanced CSCC. The study highlights the importance of understanding the clinical and demographic factors influencing treatment outcomes and patient outcomes.