Unloxcyt™ (cosibelimab-ipdl) – New drug approval

- On December 13, 2024, Checkpoint Therapeutics announced the FDA approval of Unloxcyt (cosibelimab-ipdl), for the treatment of **adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC)** who are not candidates for curative surgery or curative radiation.

- cSCC is the **second most common type of skin cancer in the U.S.,** with an estimated annual incidence of approximately 1.8 million cases according to the Skin Cancer Foundation.

    — While most cases are localized tumors amenable to curative resection, each year approximately 40,000 cases become advanced and an estimated 15,000 people in the U.S. die from this disease.

- Unloxcyt is a programmed death ligand-1 (PD-L1) blocking antibody.

- The efficacy of Unloxcyt was established in CK-301-101, a multicohort, open-label study in patients with metastatic mCSCC (n = 78) or laCSCC (n = 31) who were not candidates for curative surgery or curative radiation. Patients received Unloxcyt until disease progression or unacceptable toxicity. The major efficacy outcomes were objective response rate (ORR) and duration of response (DOR).

    — **In the mCSCC population, the ORR was 47%** (95% CI: 36, 59) and the median DOR was not reached (range: 1.4+, 34.1+).
    — **In the laCSCC population, the ORR was 48%** (95% CI: 30, 67) and the median DOR was 7.7 months (range: 3.7+, 17.7).

- Warnings and precautions for Unloxcyt include severe and fatal immune-mediated adverse reactions; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplant; and embryo-fetal toxicity.

- The most common adverse reactions (≥ 10%) with Unloxcyt use were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

- The recommended dose of Unloxcyt is 1,200 mg administered as an **intravenous infusion over 60 minutes every 3 weeks** until disease progression or unacceptable toxicity.

- Checkpoint Therapeutics' launch plans for Unloxcyt are pending. Unloxcyt will be available as a 300 mg/5 mL (60 mg/mL) solution in a single-dose vial.