Libtayo® (cemiplimab-rwlc) – New drug approval

- On September 28, 2018, the FDA announced the approval of Regeneron and Sanofi's Libtayo (cemiplimab-rwlc), for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

- CSCC is the second most common human cancer in the U.S. with an estimated annual incidence of approximately 700,000 cases. While the majority of patients with CSCC are cured with surgical resection, a small percentage of patients will develop advanced disease that no longer responds to local treatments including surgery and radiation.

    — Advanced CSCC may cause disfigurement at the site of the tumor and local complications such as bleeding or infection, or it may metastasize to local lymph nodes, distant tissues and organs and become life-threatening.

- Libtayo is a programmed death receptor-1 (PD-1) blocking antibody. By blocking this pathway, Libtayo may help the body's immune system fight the cancer cells.

- The efficacy of Libtayo was studied in two open-label clinical trials. A total of 108 patients were included in the efficacy evaluation. Patients received Libtayo 3 mg/kg intravenously every 2 weeks for up to 48 weeks in one study and up to 96 weeks in the second study. The primary endpoint was objective response rate (ORR).

    — The ORR was 47.2% (95% CI: 37.5, 57.1).
    — A total of 31 (61%) patients had a duration of response ≥ 6 months.

- Warnings and precautions of Libtayo include severe and fatal immune-mediated adverse reactions; infusion-related reactions; and embryo-fetal toxicity.

- The most common adverse reactions (≥ 20%) with Libtayo use were fatigue, rash, and diarrhea.

- The recommended dosage of Libtayo is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

- The wholesale acquisition cost (WAC) is $9,100 per three-week treatment cycle.

- Regeneron and Sanofi plan to launch Libtayo immediately. Libtayo is available as a 350 mg/7 mL (50 mg/mL) solution in a single-dose vial.

    — Libtayo will only be available through specialty pharmacy distributors and community oncology group purchasing organizations.