Libtayo® (cemiplimab-rwlc) – New indication

- On February 9, 2021, Sanofi and Regeneron announced the FDA approval of Libtayo (cemiplimab-rwlc), for the treatment of patients:
  - With locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom a HHI is not appropriate
  - With metastatic BCC (mBCC) previously treated with a HHI or for whom a HHI is not appropriate. The mBCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for the mBCC indication may be contingent upon verification and description of clinical benefit.

- Libtayo is also approved for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

- The approval of Libtayo for the new indications was based on an open-label study in 112 patients with advanced BCC who had progressed on HHI therapy, had not had an objective response after 9 months on HHI therapy, or were intolerant of prior HHI therapy. Patients received Libtayo for up to 93 weeks until disease progression, unacceptable toxicity, or completion of planned treatment. The major efficacy outcome measures were confirmed objective response rate (ORR) and duration of response (DOR).

  In patients with laBCC, the ORR was 29% (95% CI: 19, 40). The median DOR was not reached (95% CI: 2.1, 21.4+).
  In patients with mBCC, the ORR was 21% (95% CI: 8, 41). The median DOR was not reached (95% CI: 9.0, 23.0+).

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