Imjudo® (tremelimumab-actl) – New drug approval

- On October 24, 2022, AstraZeneca announced the FDA approval of Imjudo (tremelimumab-actl), in combination with Imfinzi® (durvalumab) for the treatment of adult patients with unresectable hepatocellular carcinoma (HCC).

- In the U.S., there are approximately 36,000 new liver cancer diagnoses each year. About 75% of all primary liver cancers in adults are HCC.

- Imjudo is a human monoclonal antibody that targets the activity of cytotoxic T-lymphocyte-associated protein 4 (CTLA-4). Imjudo blocks the activity of CTLA-4, contributing to T-cell activation, priming the immune response to cancer, and fostering cancer cell death.

- In addition, the drug label for Imfinzi was updated to include this new indication approval.

    — Imfinzi is also approved for non-small cell lung cancer, small cell lung cancer, and biliary tract cancer.

- The efficacy of Imjudo was established in HIMALAYA, a randomized, open-label study in patients with confirmed unresectable HCC who had not received prior systemic treatment for HCC. Patients were randomized to one of two investigational arms (Imjudo plus Imfinzi or Imfinzi) or sorafenib. The major outcome measure was overall survival (OS) between the Imjudo plus Imfinzi arm vs. the sorafenib arm. Additional outcomes were progression-free survival (PFS), objective response rate (ORR) and duration of response (DOR).

    — Median OS was 16.4 months and 13.8 months for Imjudo plus Imfinzi and sorafenib, respectively (hazard ratio [HR] 0.78, 95% CI: 0.66, 0.92; p = 0.0035).
    — Median PFS was 3.8 months and 4.1 months for Imjudo plus Imfinzi and sorafenib, respectively (HR 0.90, 95% CI: 0.77, 1.05).
    — The ORR was 20.1% (95% CI: 16.3, 24.4) and 5.1% (95% CI: 3.2, 7.8) for Imjudo plus Imfinzi and sorafenib, respectively.
    — The median DOR was 22.3 months (95% CI: 13.7, not reached) and 18.4 months (95% CI: 6.5, 26.0) for Imjudo plus Imfinzi and sorafenib, respectively.

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

- The most common adverse reactions (≥ 20%) with Imjudo use were rash, diarrhea, fatigue, pruritus, musculoskeletal pain, and abdominal pain.

- The most common laboratory abnormalities (≥ 40%) with Imjudo use were increased aspartate aminotransferase, increased alanine aminotransferase, decreased hemoglobin, decreased sodium, increased bilirubin, increased alkaline phosphatase, and decreased lymphocytes.

- The recommended dose of Imjudo in patients with a body weight of 30 kg and more is a single dose of Imjudo 300 mg intravenously followed by Imfinzi 1,500 mg at day 1 of cycle 1; and then continue Imfinzi 1,500 mg as a single agent every 4 weeks. For patients with a body weight of less than 30 kg, the recommended dose is a single dose of Imjudo 4 mg/kg followed by Imfinzi 20 mg/kg at day 1 of cycle 1; and then continue Imfinzi 4 mg/kg as a single agent every 4 weeks.

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    - After cycle 1 of combination therapy, Imfinzi should be administered as a single agent every 4 weeks until disease progression or unacceptable toxicity.

- AstraZeneca's launch plans for Imjudo are pending. Imjudo will be available as a 25 mg/1.25 mL and 300 mg/15 mL single-dose vial.

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