Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- adult patients with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy. (1.9)

Urothelial Carcinoma

- adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC. (1.10)
- adult patients with unresectable or metastatic urothelial carcinoma, as first-line treatment in combination with cisplatin and gemcitabine. (1.10)
- adult patients with locally advanced or metastatic urothelial carcinoma who:
    - have disease progression during or following platinum-containing chemotherapy.
    - have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. (1.10)

Colorectal Cancer

- adult and pediatric (12 years and older) patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in combination with ipilimumab. (1.11)
- adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. (1.11)

Hepatocellular Carcinoma (HCC)

- adult patients with unresectable or metastatic hepatocellular carcinoma (HCC), as a first-line treatment in combination with ipilimumab. (1.12)
- in combination with ipilimumab in adult patients with unresectable or metastatic HCC who have been previously treated with sorafenib. (1.12)

Esophageal Cancer

- adult patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neoadjuvant chemoradiotherapy (CRT). (1.13)
- adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy whose tumors express PD-L1 (≥1). (1.13)
- adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with ipilimumab whose tumors express PD-L1 (≥1). (1.13)
- adult patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy. (1.13)

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

- adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma whose tumors express PD-L1 (≥1) in combination with fluoropyrimidine- and platinum-containing chemotherapy. (1.14)

[a] This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

- Administer by intravenous infusion after dilution based upon recommended infusion rate for each indication. (2)
- Unresectable or metastatic melanoma
    - Adult and pediatric patients weighing 40 kg or greater: 240 mg every 2 weeks or 480 mg every 4 weeks. (2.2)
    - Pediatric patients weighing less than 40 kg: 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks. (2.2)
    - Adult and pediatric patients weighing 40 kg or greater: 1 mg/kg followed by ipilimumab 3 mg/kg on the same day every 3 weeks for 4 doses, then 240 mg every 2 weeks or 480 mg every 4

Core Risk Management Plan for Humira

AbbVie Inc. (AbbVie)

RMP version to be assessed as part of this application:

RMP Version Number: 16.2

Data lock point for this RMP: 31 December 2021

Date of final sign off: September 2024

Rationale for submitting an updated RMP:

Removed Long Term Safety Information in the Treatment of Children with Uveitis from Missing Information.

Reclassified Missing Information "Episodic treatment in Ps, UC and JIA" to "Episodic treatment in UC"

Summary of significant changes in the RMP: A summary of significant changes is included in RMP Annex 8.

INDICATIONS AND USAGE

KEYTRUDA is also indicated for the treatment of adult and pediatric patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after three or more prior lines of therapy.

Pt: Jane Doe

Dx: metastatic melanoma (C43.9)

Start Keytruda 200mg IV q3wks

– Dr. Smith