Direct Healthcare Professional Communication

April 2023

Yervoy (Ipilimumab) Notification of Pack Deviation from Egypt Specific Pack to US Pack

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

Yervoy (Ipilimumab) 5mg/ml Injection, 50mg/10ml Vial was approved by the Egyptian Drug Authority on 3-June-2021 (Reg# EGY/BP/May 2021/0254/01).

Yervoy is approved in Egypt for the following indications:

- YERVOY is indicated for the treatment of unresectable or metastatic melanoma in adults and pediatric patients (12 years and older)
- YERVOY is indicated for the adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy
- YERVOY, in combination with nivolumab, is indicated for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma (RCC)
- YERVOY, in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations.

To facilitate early access of Yervoy to the cancer patients in Egypt, the Egyptian Drug Authority has granted an exceptional approval to import the US specific pack instead of the currently approved Egypt specific pack.

Further information on the safety concern and the recommendations:

We would like to bring to your attention that the Yervoy US pack (Batch no. ACB9876, Mfg Date: Aug 2022, Expiry Date: July 2025) includes the following indication that is not approved by the Egyptian Drug Authority

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470

- Yervoy in combination with nivolumab is indicated for the treatment of adult and pediatric patients 12 years of age and older with microsatellite instability high (MSI H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan.

- YERVOY, in combination with nivolumab, is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

- YERVOY, in combination with nivolumab, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

- YERVOY, in combination with nivolumab, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

We request you to kindly take the above information into consideration in your clinical practice and would recommend to only refer to the approved indications in Egypt listed in the attached package insert.

The YERVOY Egyptian packs (for the approved indications only) are expected to be available by July 2023.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470