יולי 2021

MVASI (Bevacizumab)

Powder for concentrate for solution for infusion

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא לתכשיר אמווסי.

בהודעה זו מצויינים השינויים העיקריים בלבד.

ההתוויות המאושרות:

MVASI in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum.
MVASI in addition to platinum - based chemotherapy is indicated for first - line treatment of adult patients with unresectable advanced metastatic or recurrent non- small cell lung cancer other than predominantly squamous cell histology.
MVASI in combination with interferon alfa-2a is indicated for first line treatment of adult patients with advanced and/or metastatic renal cell cancer.
MVASI in combination with paclitaxel is indicated for first-line treatment of adult patients with metastatic breast cancer.
MVASI as a single agent, is indicated for the treatment of glioblastoma in patients with progressive disease following prior therapy.
MVASI in combination with carboplatin and paclitaxel, is indicated for the front-line treatment of advanced (FIGO stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer in adult patients who are at high risk for recurrence (residual disease after debulking).
MVASI in combination with carboplatin and gemcitabine, is indicated for the treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents.
MVASI in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin is indicated for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents.
MVASI in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated, in patients who cannot receive platinum therapy, for treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.
MVASI, in combination with erlotinib, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations.

עדכונים מהותיים בעלון לרופא:

5.1 Pharmacodynamic properties

[…]

Malignant Glioma (WHO Grade IV) – Glioblastoma

Data from study AVF3708g

Epithelial ovarian, fallopian tube and primary peritoneal cancer

Front-line treatment of ovarian cancer

Data from studies GOG-0218, BO17707 (ICON7), AVF4095g, GOG-0213 and MO22224

[...]

Pediatric population
[...]

Soft tissue sarcoma
In a randomized phase II study (BO20924) a total of 154 patients aged ≥ 6 months to < 18 years with newly diagnosed metastatic rhabdomyosarcoma and non-rhabdomyosarcoma soft tissue sarcoma were treated with standard of care (Induction IVADO/IVA+/- local therapy followed by maintenance vinorelbine and cyclophosphamide) with or without bevacizumab (2.5 mg/kg/week) for a total duration of treatment of approximately 18 months. At the time of the final primary analysis, the primary endpoint of EFS by independent central review did not show a statistically significant difference between the two treatment arms, with HR of 0.93 (95% CI: 0.61, 1.41; p-value = 0.72). The difference in ORR per independent central review was 18% (CI: 0.6%, 35.3%) between the two treatment arms in the few patients who had evaluable tumor at baseline and had a confirmed response prior to receiving any local therapy: 27/75 patients (36.0%, 95% CI: 25.2%, 47.9%) in the chemo arm and 34/63 patients (54.0%, 95% CI: 40.9%, 66.6%) in the BV + chemo arm. The final overall survival (OS) analyses showed no significant clinical benefit from addition of bevacizumab to chemotherapy in this patient population.

6.6 Special precautions for disposal and other handling

MVASI should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared solution. A sterile needle and syringe should be used to prepare MVASI.