אוגוסט 2019

AVASTIN®
אוווסטין

Bevacizumab 25mg/ml
Concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים שנעשו בעלון לרופא של התכשיר.
לתשומת ליבכם, בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויות הרשומות לתכשיר בישראל:

1. Avastin in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum.

2. Avastin in addition to platinum-based chemotherapy is indicated for first - line treatment of patients with unresectable advanced metastatic or recurrent non- small cell lung cancer other than predominantly squamous cell histology.

3. Avastin in combination with interferon alfa-2a is indicated for first line treatment of patients with advanced and /or metastatic renal cell cancer.

4. Avastin in combination with paclitaxel is indicated for first-line treatment of patients with metastatic breast cancer.

5. Avastin as a single agent, is indicated for the treatment of glioblastoma in patients with progressive disease following prior therapy.

6. Avastin, in combination with carboplatin and paclitaxel, is indicated for the front-line treatment of advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are at high risk for recurrence (residual disease after debulking).

7. Avastin, 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.

8. Avastin (Bevacizumab) 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.

9. Avastin (Bevacizumab) in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for treatment of patients with persistent, recurrent, or metastatic carcinoma of the cervix.

10. Bevacizumab, 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.

הסבר:
<u>טקסט עם קו תחתי</u> מציין טקסט שהוסף לעלון.
~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שאושר ע"י משרד הבריאות.
העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד 6391 , הוד השרון 4524079 טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

בת אל כהן
רוקחת ממונה

לביא עמי-עד
רוקח ממונה

בסעיף 5.1 Pharmacodynamic properties עודכן המידע הבא:

[…]

First-line treatment of non-squamous NSCLC with EGFR activating mutations in combination with erlotinib

JO25567
Study JO25567 was a randomized, open-label, multi-center Phase II study conducted in Japan to evaluate the efficacy and safety of Avastin used in addition to erlotinib in patients with non-squamous NSCLC with EGFR activating mutations (exon 19 deletion or exon 21 L858R mutation) who had not received prior systemic therapy for Stage IIIB/IV or recurrent disease. The primary endpoint was progression-free survival (PFS) based on independent review assessment.

Secondary endpoints included overall survival, response rate, disease control rate, duration of response, and safety.
EGFR mutation status was determined for each patient prior to patient screening and 154 patients were randomised to receive either erlotinib + Avastin (erlotinib 150 mg oral daily + Avastin [15 mg/kg IV every 3 weeks]) or erlotinib monotherapy (150 mg oral daily) until disease progression (PD) or unacceptable toxicity. In the absence of PD, discontinuation of one component of study treatment in the erlotinib + Avastin arm did not lead to discontinuation of the other component of study treatment as specified in the study protocol.

The efficacy results of the study are presented in Table 14.

Table 14 Efficacy results for study JO25567

	Erlotinib *N = 77#*	*Erlotinib + Avastin* *N = 75#*
PFS^ (months)		
Median	9.7	16.0
HR (95% CI)	0.54 (0.36; 0.79)	
p-value	0.0015	
Overall Response Rate		
Rate (n)	63.6% (49)	69.3% (52)
p-value	0.4951	
Overall Survival* (months)		
Median	47.4 ~~48.5~~	47.0 ~~48.4~~
HR (95% CI)	0.81 (0.53; 1.23) ~~0.91 (0.56; 1.46)~~	
p-value	0.3267 ~~0.6838~~	

A total of 154 patients (ECOG Performance Status 0 or 1) were randomized. However two of the randomized patients discontinued the study before receiving any study treatment
^ Blinded independent review (protocol-defined primary analysis)
* Exploratory analysis; final OS analysis at clinical cut off on 31 October 2017, approx. 59% of patients had died.
~~OS updated analysis at clinical cut-off on 28 October 2015, approx. 45% patient had died and OS is therefore considered immature.~~

CI, confidence interval; HR, Hazard ratio from unstratified Cox regression analysis; NR, not reached.

[…]