International Regulatory Affairs

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Vectibix: DHPC EU

Direct Healthcare Professional Communication on the association of panitumumab (Vectibix®) with life-threatening and fatal infectious complications of severe skin reactions including necrotising fasciitis.

Dear Healthcare Professional,

Summary

- **Severe skin reactions (grade 3) have been reported very commonly in patients treated with Vectibix**
- **Five cases of necrotising fasciitis, three fatal, have been reported in patients treated with Vectibix.**
- **Patients who have severe skin reactions or who develop worsening skin reactions whilst receiving Vectibix should be monitored for the development of inflammatory or infectious sequelae (including cellulitis, sepsis and necrotising fasciitis), and appropriate treatment promptly initiated.**
- **Withhold or discontinue Vectibix in the event of skin toxicity with severe or life threatening inflammatory or infectious complications.**

The information in this communication has been agreed with the European Medicines Agency.

Further information on the safety concern

Vectibix is indicated for the treatment of patients with wild-type *KRAS* metastatic colorectal cancer (mCRC):

- in first-line in combination with FOLFOX
- in second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine based chemotherapy (excluding irinotecan).
- as monotherapy after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

Severe skin reactions (grade 3) are known to very commonly occur with Vectibix use as monotherapy or in combination with chemotherapy.

These reactions include rare cases of skin necrosis (which is listed in the product information). In some instances, severe skin reactions to Vectibix have been followed by life-threatening infectious complications such as cellulitis, sepsis and necrotising fasciitis.

A review of clinical studies and post-marketing reports has identified five cases of necrotising fasciitis associated with Vectibix treatment. Three of the five cases of necrotising fasciitis were fatal and two were life-threatening.

All of the cases of necrotising fasciitis occurred in the setting of advanced metastatic disease and involved combination chemotherapy regimens associated with myelosuppression and/or impaired wound healing. Four of the five patients had been treated with Vectibix in combination with oxaliplatin-based chemotherapy (two patients had also received bevacizumab with this combination). One patient received Vectibix in combination with irinotecan-based chemotherapy.

The product information for Vectibix has been updated with information on the risk of necrotising fasciitis (see Annex).

Further advice for healthcare professionals

Vectibix treatment should be withheld or discontinued in the event of skin toxicity with severe or life-threatening inflammatory or infectious complications.

Reporting of suspected adverse reactions with the use of Vectibix

Any suspected adverse reactions with Vectibix should be reported to the Irish Medicines Board. The IMB can be contacted on (01) 676 4971. Suspected adverse reactions may also be reported to Amgen Europe B.V by contacting 1800 585 160 or +44 (0) 1223 436712

Communication information

Should you have any questions or require additional information regarding the use of Vectibix, please contact Amgen UK, Medical Information on +44 (0)1223 436712

Yours sincerely,

Dr Steven Bellamy MBChB
Medical Director, UK & Ireland

Annex: Revised copy of the Vectibix Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL).