European Medicines Agency

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PUBLIC STATEMENT ON
CEA-SCAN (Arcitumomab)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 04 October 1996 the European Commission granted a marketing authorisation for the whole European Union to Immunomedics GmbH, for Cea-Scan (arcitumomab), for the following indication:

"CEA-Scan is indicated only in patients with histologically-demonstrated carcinoma of the colon or rectum for imaging of recurrence and/or metastases. CEA-Scan is employed, in the above mentioned patients, as an adjunct to standard non-invasive imaging techniques, such as ultrasonography or CT scan, in the following situations:

• Patients with evidence of recurrence and/or metastatic carcinoma of the colon or rectum, who are undergoing an evaluation for extent of disease, such as prior to surgical resection and/or other therapy.

• Patients with suspected recurrence and/or metastatic carcinoma of the colon or rectum in association with rising levels of carcinoembryonic antigen (CEA)."

CEA-Scan has been marketed in Austria, Belgium, Czech Republic, Cyprus, Finland, France , Germany, Greece, Hungary, Ireland, Italy, Luxemburg, Malta, the Netherlands, Poland, Portugal, Spain, Sweden and United Kingdom.

On 30 August 2005, the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for CEA-Scan for commercial reasons.

On 27 September 2005 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "CEA-Scan". Pursuant to this decision the European Public Assessment Report for CEA-Scan has been removed from the EMEA website.

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