8 March 2013
EMA/CVMP/100985/2013
Committee for Medicinal Products for Veterinary Use

**Summary of opinion[1] (initial authorisation)**

# Oncept IL-2

## International non-proprietary name (INN): Feline interleukin-2 recombinant canarypox virus (vCP1338 virus)

On 7 March 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Oncept IL-2, lyophilisate and solvent for suspension for injection. The product is intended for immunotherapy to be used in addition to surgery and radiotherapy in cats with fibrosarcoma (2-5 cm diameter) without metastasis or lymph node involvement, to reduce the risk of relapse and increase the time to relapse (local recurrence or metastasis). The applicant for this veterinary medicinal product is MERIAL.

The active substance of Oncept IL-2 is feline interleukin-2 (IL-2) recombinant canarypox virus (vCP1338 virus), ATCvet code: QL03AX, belonging to antineoplastic and immunomodulating agents, other immunostimulants. Oncept IL-2 injected into the tumour bed delivers *in situ* a low dose of feline IL-2, which stimulates antitumour immunity while avoiding toxicity associated with systemic treatment. In a randomised clinical study Oncept IL-2 treated cats showed a significantly longer median time to relapse (above 730 days) compared to control cats (287 days) and Oncept IL-2 treatment significantly reduced the risk of relapse, from 6 months after the start of treatment, by approximately 56% after 1 year and 65% after 2 years.

The benefits of Oncept IL-2 are its reduction of the risk of relapse and its increase in the time to relapse (local recurrence or metastasis) when used in addition to surgery and radiotherapy. A moderate local reaction may occur (pain on palpation, swelling, scratching) that usually disappears spontaneously within 1 week at most.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Oncept IL-2 and therefore recommends the granting of the marketing authorisation.