BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Lipomed GmbH submitted on 4 July 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) through the centralised procedure for LITAK, which was designated as an orphan medicinal product EU/3/01/055 on 18 September 2001.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur:	Dr. P. Arlett	Co-Rapporteur:	Dr. J. Ersbøll

Orphan Drugs:

Cladribine (subcutaneous use) was designated as an orphan medicinal product for the orphan indication: Treatment of indolent non-Hodgkin's lymphoma.

Licensing status:

LITAK has been approved in Switzerland (May 2000), Israel (January 2001), Cyprus (May 2001), Romania (December 2001), Bulgaria (February 2001), Slovakia (March 2003), Iran (November 2002), Iraq (May 2002), Syria (August 2002) for the treatment of indolent Non-Hodgkin's lymphoma, as follows: as first line treatment of hairy cell leukaemia, as second line treatment in recurrent or refractory grade I and II follicular lymphoma and indolent disseminated lymphomas (chronic lymphocytic leukaemia, small lymphocytic leukaemia, lymphoplasmacytic lymphoma).
In Europe cladribine, intended to be administered as an intravenous infusion, was first approved in Sweden in November 1993 for the treatment of hairy cell leukaemia. It is now available in all Member States of the Community except Ireland. In Austria, Finland, Portugal, Spain and the United Kingdom, the approved therapeutic indication also includes certain other lymphoid malignancies.

2 Steps taken for the assessment of the product

- The procedure started on 22 July 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 25 September 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 4 October 2002.
- During the meeting on 19-21 November 2002 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 22 November 2002.
- The company submitted the responses to the CPMP consolidated List of Questions on 11 April 2003.
- The (Co)Rapporteur circulated the joint Assessment Report on the company's responses to the List of Questions to all CPMP members on 21 May 2003.
- During the CPMP meeting on 24 - 26 June 2003 the CPMP adopted a List of Outstanding Issues to be addressed by the applicant in writing and if necessary during an oral explanation.
- The (Co)Rapporteur circulated the joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CPMP members on 18 September 2003.
- During the CPMP meeting on 23 – 25 September 2003, outstanding issues were addressed by the applicant during a hearing before the CPMP on 24 September 2003.

- During the meeting on 21 – 22 October 2003 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to LITAK on 22 October 2003.
- The European Commission returned the initial CPMP Opinion of October 2003 to the EMEA, requesting to reconsider this application according to a different legal basis.
- During the meeting on 20 - 21 January 2004 the CPMP, in the light of the overall data and justifications submitted and the scientific discussion within the Committee, issued a revised positive Opinion for granting a Marketing Authorisation to LITAK on 21 January 2004.