1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Bioenvision Limited submitted on 27 July 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Evoltra, which was designated as an orphan medicinal product on 5 February 2002 and 8 May 2003.

The legal basis for this application refers to Article 8.3(i) of Directive 2001/83/EC, as amended - complete and independent application.

The application submitted is a complete dossier composed of administrative information, complete quality data, non-clinical and clinical data based on the applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or study(ies).

Protocol Assistance:
The applicant did not seek Protocol Assistance at the CHMP.

Licensing status:
The US FDA authorised clofarabine on 28 December 2004.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Eric Abadie Co-Rapporteur: Barbara van Zwieten-Boot

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 27 July 2004.
- The procedure started on 16 August 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 26 October 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 29 October 2004.
- During the meeting on 13-15 December 2004, the CHMP 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 15 December 2004.
- A study related inspection of the laboratory that performed preclinical studies requiring GLP Compliance in connection with the application was conducted by the Dutch competent authority (VWA) and the French competent authority (AFSSAPS) between 1 and 3 February 2005. The studies were found to be compliant with the requirements of OECD GLP principles.
- AAI Development Services was inspected between 13 and 16 June 2005 by the UK competent authority (MHRA) in connection with the application and found to be in compliance with EU GMP.
- A clarification meeting on the CHMP List of Questions was held on 22 February 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 9 August 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 20 September 2005.
- During the CHMP meeting on 10-13 October 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted responses to the CHMP list of outstanding issues on 18 January 2006.
- The Rapporteurs circulated an updated Joint Assessment Report on the applicant's responses to the list of outstanding issues on 6 February 2006.
- During the meeting on 20-23 February 2006, the CHMP, 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 Evoltra on 23 February 2006. The applicant provided the letters of undertaking on the follow-up measures and specific obligations to be fulfilled post-authorisation on 22 and 23 February 2006.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 29 May 2006.