9. APPENDICES

Patient information leaflet **Appendix A**

Sir, Madam,

You are currently receiving Vectibix® as part of the treatment for your disease.

Vectibix® is a drug developed and marketed by Amgen.

Amgen is currently carrying out a large-scale national study called POPEC aimed at assessing the incidence of dermatological toxicities induced by Vectibix® in patients and the way these toxicities are managed.

Information already present in your medical records will be collected; consequently no other examinations or blood tests will be necessary and there will be no change in the usual care given to you by your doctor.

The information that your doctor gives Amgen will be collected over a maximum period of 6 months. It will mainly concern demographic data (your age and gender), your general health, your medical history, a description of your disease and its history, along with the treatments that you are receiving, dermatological toxicities and any side effects following the start of treatment with Vectibix®, and some blood test results.

Your doctor will also ask you to complete a questionnaire with 11 questions designed to assess the impact of your skin problem on your life.

The data collected will remain confidential and will be protected by medical secrecy rules. It will be made anonymous and will then be used solely for the purposes of this study. To do this, the data collected will be computerised by Amgen or by a company assisting it for management of the study, in accordance with French data protection law No. 78-17 of 6 January 1978 (amended by law 2004-801 of 6 August 2004).

You are free to refuse to have your medical records used in this study.

You may contact your doctor at any time to gain access to your personal data and, in particular, the information contained in your medical records. You may also ask to correct your data at any time or object to it being processed, in which case the data concerning you will be deleted and not analysed.

For the requirements of the study, Amgen, or any company assisting it, may have access to your medical records and, with the cooperation of your doctor, collect personal data concerning you. The employees of Amgen and any companies assisting it will be bound by professional secrecy and required to keep your data confidential, subject to the penalties stipulated in article 226 - 13 of the French Code of Criminal Law.

In the context of quality controls aimed at verifying the accuracy and relevance of the data collected during the study, direct access to your medical records may be authorised subject to the requirements of medical secrecy.

You are free to refuse to take part in this study or to change your mind at any time. This decision will in no way affect the quality of neither your subsequent medical care, nor your relationship with your doctor.

In accordance with French law, this study was approved by the French consultative committee for the processing of information in the field of health research (CCTIRS) on 17 February 2011 and was authorised by the French Data Protection body (CNIL) on 15 April 2011.

Please do not hesitate to ask your doctor if you have any questions concerning this study.