## BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The applicant Pfizer Limited submitted on 30 August 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for SUTENT, which was designated as an orphan medicinal product EU/3/05/267 and EU/3/05/268 on 10 March 2005.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:

Rapporteur: **Pasqualino Rossi** Co-Rapporteur: **Jens Ersbøll**

**Orphan Drugs:**

SUTENTwas designated as an orphan medicinal product in the following indications: treatment of malignant gastrointestinal stromal tumour (GIST) and renal cell carcinoma.

**Scientific Advice:**
The applicant did not seek scientific advice the CHMP.

**Licensing status:**
The product was not licensed in any country at the time of submission of the application.

### 2. Steps taken for the assessment of the product

- The procedure started on 28 September 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 12 December 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 14 December 2005.
- The CHMP adopted a report on similarity of SUTENT with authorised orphan medicinal products for the same therapeutic indication on 14 December 2005.
- During the meeting on 23-26 January 2006, the CHMP agreed on the consolidated List of Questions to be sent to the applicant, and questions for the CHMP Scientific Advisory Group (SAG) for Oncology. The final consolidated List of Questions was sent to the applicant on 3 February 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions and questions for the CHMP Scientific Advisory Group (SAG) for Oncology on 21 February 2006 and 2 March 2006. The applicant submitted additional responses to the CHMP consolidated List of Questions on 5 April 2006.
- During a meeting of a SAG-Oncology on 9 March 2006, experts were convened to address questions raised by the CHMP. The Applicant presented the Applicant’s views on the questions related to SUTENT. Answers and comments were given by the group.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 27 March 2006. The Rapporteurs circulated an addendum to the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 10 April 2006.
- During the meeting on 24-27 April 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 conditional Marketing Authorisation to SUTENTon 27 April 2006. The applicant provided the letter of undertaking on the specific obligation and follow-up measures to be fulfilled post-authorisation on 26 April 2006.
- The CHMP opinions were forward, in all official languages of the European Union, to the European Commission, which adopted the corresponding decision on 19 July 2006.