NOVARTIS

Business Unit Oncology
Drug Regulatory Affairs

**Novartis Pharma AG**
WKL-490.4.24
CH-4002 Basel
Switzerland

Date: 18 October 2006

Dr David Brasseur
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

**Subject: Withdrawal of GLIVEC® (imatinib mesilate)**
**50 mg and 100 mg Capsule, hard**
**100 mg and 400 mg Film-coated tablet**
**Type II variation EMEA/H/C/00406/II/0034**

Dear Dr. Brasseur

I would like to inform you that Novartis Europharm Limited, at this point of time, has taken the decision to withdraw the application for the extension of GLIVEC indication in the treatment of the orphan disease "aggressive systemic mastocytosis".

This withdrawal is based on the following reasons:

- The CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance. The Committee acknowledged however the biological plausibility, the rarity of the disease and the limited therapeutic options. Novartis is committed to further define the benefit/risk ratio through an expanded access program utilizing European experts in the management of this rare disease.

This decision will not have consequences for patients enrolled in clinical trials or compassionate use programmes.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for such a letter to be published on the EMEA website.

On behalf of Novartis Europharm Limited