CHEMGENEX
EUROPE S.A.S.

11 January 2011

Dr Eric Abadie
CHMP Chairman
European Medicines Agency
7, Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Subject: **Withdrawal of TEKINEX (omacetaxine mepesuccinate) 5mg, powder for solution for injection**
Marketing Authorisation Application: EMEA/H/C/001244

Dear Dr Abadie,

On behalf of ChemGenex Europe SAS (ChemGenex), I would like to inform you that, at this point of time, ChemGenex Europe SAS (ChemGenex) has taken the decision to withdraw the Marketing Authorisation Application (MAA) of TEKINEX (omacetaxine mepesuccinate) 5 mg, powder for solution for injection, which was intended to be used for the treatment of adults with Philadelphia chromosome positive chronic myeloid leukaemia (CML) who have the Bcr-Abl T315I kinase domain mutation and who are resistant to prior imatinib therapy.

The withdrawal is based on the following reasons:

- Following our discussions with the Rapporteur and Co-Rapporteur, ChemGenex has decided to combine data from its two pivotal studies, Study CML-202 and Study CML-203, and revise the proposed indication for TEKINEX to the treatment of adults with CML who have failed prior treatment with two or more currently approved tyrosine kinase inhibitors (TKIs).

- No further clinical studies are required to support the new indication; however, further data will need to be collected and analysed from participating clinical centers.
- ChemGenex will be unable to address the issues identified by the CHMP during the review of the MAA within the timeframe allowed by the centralised procedure.

In consideration of the amount of time required to respond to the issues raised by the CHMP, assemble the clinical data package supporting the new indication and in agreement with the Rapporteur and Co-Rapporteur, ChemGenex has decided to submit a new MAA for TEKINEX in the new indication. ChemGenex intends to submit a request for modification to the Pediatric Investigation Plan (PIP) for TEKINEX.

This new indication is in keeping with ChemGenex's global development plans for omacetaxine mepesuccinate which includes a parallel New Drug Application to be submitted in the United States.

Clinical trials with TEKINEX are currently ongoing with active patients.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

ChemGenex agrees for this letter to be published on the EMA website.

Sincerely,