CT·RS
Cell Therapies
Research & Services

[redacted]

European Medicine Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

11.07.2014

Withdrawal of Neofordex (dexamethasone) 40 mg tablets,
EMEA/H/C/002418

Dear [redacted]

We would like to inform you that Laboratoires CTRS has taken the decision to withdraw the application for Marketing Authorisation of Neofordex (dexamethasone) 40 mg tablets, intended to be used in adults for the treatment of symptomatic multiple myeloma in combination with other agents.

This decision was taken since additional data are required in order to address CHMP questions relating to pharmaceutical aspects of the Neofordex dossier. These data will not be available within the timeframe allowed in the Centralised Procedure.

Laboratoires CTRS will resubmit the dossier as soon as the data addressing the CHMP's questions are available.

Patients participating in on-going compassionate use programmes of Neofordex can continue treatment as per the applicable protocol.

Laboratoires CTRS agrees for this letter to be published on the European Medicines Agency website.

Yours sincerely,

[redacted]

Laboratoires CTRS

Laboratoires CTRS

Cc: [redacted]