Guerbet

Date: 12th December 2007

Guerbet

Boîte postale 57400
95943 Roissy CdG Cedex France
Tél. : 33 (0)1 45 91 50 00
www.guerbet.com

Villepinte
Fax : (33-1) 45 91 51 99

Aulnay
Fax : 33 (0)1 45 91 51 23/51 91
Fax : 33 (0)1 45 91 76 03/51 11
Fax : 33 (0)1 45 91 76 91/76 01

Gonesse
Fax : 33 (0)1 45 91 76 76

Société Anonyme à Directoire
et Conseil de Surveillance
au capital de 11 875 976 €
Siège social :
15, rue des Vanesses
93420 Villepinte
308 491 521 RCS Bobigny
Siret 308 491 521 00057

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

Ref.: CHT/07_149

Subject: Withdrawal of Sinerem 20 mg/ml, superparamagnetic iron oxide nanoparticles stabilised with dextran and sodium citrate - EMEA/H/000801.

Dear CHMP Chairman,

For the withdrawal of initial marketing authorisation application.

I would like to inform you that, at this point of time, Guerbet has taken the decision to withdraw the application for Marketing Authorisation of Sinerem 20 mg/ml, superparamagnetic iron oxide nanoparticles stabilised with dextran and sodium citrate, which was intended to be used for the characterisation of lymph nodes visualised with MRI (Magnetic Resonance Imaging) in the evaluation of primary tumour spread in pelvic cancers.

This withdrawal is based on the following reason(s):
Despite potential benefit and acceptable safety profile, the CHMP considers that the pivotal study failed to statistically demonstrate the efficacy of Sinerem.

We inform the CHMP that Guerbet will continue to make Sinerem 20 mg/ml, superparamagnetic iron oxide nanoparticles stabilised with dextran and sodium citrate available for ongoing 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 this letter to be published on the EMEA website.

Yours sincerely,