LES LABORATOIRES SERVIER

SERVIER

[redacted]

Suresnes, March 21st, 2014

[redacted]

Subject: **Withdrawal of an application for a type II variation**
PROTELOS® - EMEA/H/C/560/II/035
OSSEOR® - EMEA/H/C/561/II/031
(strontium ranelate 2g, granules for oral suspension)

Dear [redacted]

I would like to inform you that, at this point of time, Les Laboratoires Servier have taken the decision to withdraw the Type II variation application for Protelos®/Osseor®, submitted on 14 April 2012, for a new indication in the treatment of osteoarthritis (structure modifying drug).

This withdrawal is based on the fact that the data so far available are not sufficient to address CHMP's concerns on clinical data.

There are no consequences on the use of Protelos®/Osseor® in its approved indications in severe osteoporosis.

This withdrawal has no consequence on the-going trial which is a post-treatment follow-up with no study treatment administered.

The MAH reserves the right to make further submissions at a future date in this or other therapeutic indications.

I agree for this letter to be published on the EMA website.

Yours sincerely

[redacted]

Merci d'adresser toute correspondance au :
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