LES LABORATOIRES SERVIER

[redacted]

March 17th, 2014
Ref.: 14.008/LSYA/acdu

Subject: **Withdrawal of an initial marketing authorization application**
DITELOS® - EMEA/H/C/2593
ISSARLOS® - EMEA/H/C/2756
(strontium ranelate 2g/colecalciferol 1000 IU, 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 application for Marketing Authorization of Ditelos®/Issarlos®, submitted on 4 May 2012, which was intended to be used in patients with osteoporosis at risk of vitamin D insufficiency.

This withdrawal is based on the fact that the Chemical and Pharmaceutical data so far available are not sufficient to address CHMP's concerns within the available timeframe.

There are currently no on-going clinical trials or compassionate use programme for this product. Therefore, there are no anticipated consequences of this withdrawal.

The MAH reserves the right to re-submit an application 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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