



Date: 23 July 2008

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

Subject: Withdrawal of Diractin, 22.9 mg/g, gel - EMEA/H/C/000865/

Dear Mr Abadie,

I would like to inform you that, at this point of time, IDEA AG has taken the decision to withdraw the application for Marketing Authorisation of Diractin, 22.9 mg, gel, which was intended to be used for "symptomatic treatment of inflammations and pain from osteoarthritis".

This withdrawal is based on the following reasons:

The efficacy of the drug for the proposed dose has not been sufficiently demonstrated. This was identified as a major clinical issue.

The withdrawal has no consequences for the ongoing clinical trials: IDEA AG is currently conducting two additional phase III clinical trials investigating the efficacy and safety of two dosages of the product for the treatment of osteoarthritis of the knee.

IDEA is reserving the right to make further submission(s) at any future date in this or other therapeutic indication(s).

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

Yours sincerely,

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