DOR *BioPharma*

22 May 2008

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

Subject: **Withdrawal of orBec®, beclomethasone dipropionate, 1 mg, Tablet and Gastro-resistant tablet**
Marketing Authorisation Application Number: EMEA/H/C/803

Dear Dr. Abadie,

I would like to inform you that DOR Biopharma UK, Ltd. (DOR) wishes to withdraw the application for the Marketing Authorisation of orBec®, beclomethasone dipropionate, 1 mg, Tablet and Gastro-resistant tablet, which was intended to be used for the treatment of the orphan disease gastrointestinal Graft-versus-Host-Disease (GI GvHD).

The basis for the withdrawal is the fact that the additional clinical data requested by the CHMP to support the application cannot be provided within the timeframe of the current application procedure.

DOR intends to provide orBec® to in-need patients upon physician request via compassionate use during conduct of the confirmatory trial.

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,

DOR BioPharma UK, Ltd.

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