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

17 June 2008

Subject: Withdrawal of Spanidin (Gusperimus) 50 mg/ml, powder for solution for injection, EMEA/H/C000809

Dear Dr. Abadie,

I would like to inform you that, at this point of time, *Euro Nippon Kayaku GmbH* has taken the decision to withdraw the application for Marketing Authorisation of *Spanidin (Gusperimus) 50 mg/ml, powder for solution for injection*, which was intended to be used for

“therapy for induction of remission in adult patients suffering from clinically refractory Wegener’s granulomatosis (WG), where standard treatment with cyclophosphamide (CYC) plus glucocorticoids failed to induce or maintain remission. In addition, patients, who cannot tolerate to the standard treatment or have contraindications against CYC, are included in clinically refractory WG. Patients should have at least one major or three minor items on the disease activity score list of Birmingham Vasculitis Activity Score (BVAS) 2003”.

This withdrawal is based on the request by CHMP for an additional controlled study, which we are not able to provide within the timeframe allowed by the Centralised Procedure. 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,