Janssen Biologics B.V.

Einsteinweg 101, 2333 CB Leiden
PO Box 251, 2300 AG Leiden
The Netherlands

Date: 12 May 2014

Dr. Tomas Salmonson, CHMP Chairman

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

Subject: Withdrawal of Simponi (golimumab), 12.5 mg/ml, concentrate for solution for infusion, intravenous use - **EMEA/H/C/992/X/047**

Dear Dr. Salmonson,

We would like to inform you that, at this point of time, Janssen Biologics B.V. has taken the decision to withdraw the extension application for a change to the marketing authorisation for Simponi to add a new strength, new pharmaceutical form and new route of administration (Simponi 12.5 mg/ml, concentrate for solution for infusion, intravenous use) in the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate.

The Rapporteur assessment report indicates that further data are required which Janssen Biologics BV is not able to provide at the current time and therefore has decided to withdraw the EU application.

The withdrawal of this application of the intravenous formulation of Simponi in the EU has no impact on the use of Simponi subcutaneous or intravenous formulations in approved indications worldwide and has no consequences on ongoing clinical trials.

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 EMA website.

Yours sincerely,

[redacted]

Senior Director, EMEA-TA Lead Immunology
Global Regulatory Affairs
Janssen Biologics B.V.

[redacted] tel www.janssen-biologics.nl Chamber of Commerce Den Haag 28041872