Janssen-Cilag International NV
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26 October 2017

Dr. Tomas Salmonson
Chair of Committee for Medicinal Products for Human Use
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Subject: Withdrawal of Plivensia (sirukumab), 50 mg, solution for injection, pre-filled syringe and pre-filled pen - **EMEA/H/C/004165/0000**

Dear Dr. Salmonson

We would like to inform you that, at this point of time, Janssen-Cilag International NV has taken the decision to withdraw the application for Marketing Authorisation of Plivensia (sirukumab), 50 mg, solution for injection, pre-filled syringe and pre-filled pen, which was intended to be used for the treatment of moderately to severely active rheumatoid arthritis in adult patients.

This withdrawal is based on the following reason:

The Company made a global strategic decision to prioritize other assets in our portfolio, given the need for additional clinical data that would result in significant delays to patient access to sirukumab in parts of the world, and the availability of other treatments targeting the IL-6 pathway.

The ongoing global long-term extension study in rheumatoid arthritis will be discontinued.

We reserve the right to make further submissions at a future date in other therapeutic indication(s).

Janssen would like to sincerely thank the (Co)-Rapporteurs and all Assessors, the EMA, as well as the PRAC and CHMP members for the time dedicated to reviewing this application and the valuable support and guidance provided during the procedure.

We agree for this letter to be published on the EMA website.

Yours sincerely,