Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse, Belgium

Dr Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

8 November 2019

Withdrawal of Type II variation EMEA/H/C/002697/II/0029 for Opsumit (macitentan)

Dear Dr Enzmann,

We would like to inform you that, at this point of time, Janssen-Cilag International NV has taken the decision to withdraw the application to extend the use of Opsumit in the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH) in adult patients of WHO FC II to III, to improve exercise capacity.

The sponsor has decided to withdraw the submission for the indication in patients with inoperable CTEPH based on the MERIT-1 study (MERIT-1/AC-055E201) following feedback from CHMP and from recent investigational site inspections. We fully intend to continue to generate additional data for macitentan in this indication to support a future filing.

The sponsor does not anticipate an impact on any other ongoing clinical trials with macitentan as monotherapy or in combination with other drugs; a full evaluation is ongoing.

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

Janssen-Cilag International NV would like to sincerely thank the CHMP (co-) Rapporteurs and the EMA for the time dedicated to review this application and the support provided during the procedure.

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

Yours sincerely,

[redacted]