[redacted]

14 September 2022

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

Subject: **Withdrawal of Hervelous (EMEA/H/C/005880), trastuzumab, 150 mg, powder for concentrate for solution for infusion**

Dear Dr. Harald Enzmann,

We would like to inform you that, at this point of time, Prestige Biopharma Belgium BVBA has taken the decision to withdraw the application for Marketing Authorisation of Hervelous, trastuzumab, 150 mg, powder for concentrate for solution for infusion, which was intended to be used for the treatment of adult patients with HER2-positive metastatic and early breast cancer, and metastatic gastric cancer.

This withdrawal is based on the view that CHMP considers that at this time, the data provided would not be sufficient to support a positive opinion on the marketing authorisation of Hervelous (trastuzumab).

There are no ongoing trials or compassionate use programs for Hervelous.

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

Prestige Biopharma would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC, and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

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

Yours sincerely,

[redacted]