Mylan

Date: August 03, 2017

To:
Dr. Tomas Salmonson, PhD (CHMP Chair)
European Medicines Agency
30 Churchill Place
London E14 5EU
United Kingdon

Subject: Withdrawal of Ogivri, (trastuzumab), 150 mg/vial powder for concentrate for solution for infusion – EMEA/H/C/004346.

Dear Dr. Salmonson,

We would like to inform you that, at this point of time, Mylan S.A.S. has taken the decision to withdraw the application for Marketing Authorisation of Ogivri, (trastuzumab), 150 mg/vial powder for concentrate for solution for infusion, which was intended to be used for the treatment of adult patients with Metastatic Breast Cancer, Early Breast Cancer and Metastatic Gastric Cancer.

This withdrawal is based on the following reason:

- *cGMP clearance of the drug product manufacturing facility was not obtained within current clock-stop*

This withdrawal does not impact ongoing clinical studies. There are no compassionate use programs for this product.

Mylan remains committed to delivering this important medicine to patients and would like to sincerely thank the EMA as well the (Co-) Rapporteurs for their guidance, support and engagement in the review. Those efforts permitted us to work to effectively progress the application through the review process to date. We look forward to continuing this review with the Agency and intend to re-submit this application as soon as possible. We are also actively engaged with the drug product manufacturing facility to address the remaining observations in a holistic manner and ensure inspection readiness by October 2017 so that a positive opinion can be reached following re-submission.

We would like to reiterate that we reserve the right to make further submission at the earliest.

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

Yours Sincerely,