

[13 Mar 2017]

## Direct Health Care Professional Communication

**HERCEPTIN (Trastuzumab): Reminder of importance of cardiac monitoring guidance during trastuzumab therapy to reduce the frequency and severity of left ventricular dysfunction and congestive heart failure (CHF).**

Dear Healthcare Professional,

F. Hoffmann-La Roche Ltd/Genentech Inc. Saudi Arabia would like to inform you of the following:

### **Summary**

The objective of this DHPC is to highlight the importance of the trastuzumab cardiac monitoring information and treatment algorithm as stated in the Herceptin (trastuzumab) SPC, in order to ensure appropriate management of left ventricular dysfunction and congestive heart failure (CHF).

This information is being sent in agreement with Saudi Food and Drug Authority (SFDA).

Key messages for prescribing oncologists and gynaeco-oncologists are highlighted below:

- Discontinue Herceptin treatment in patients receiving adjuvant therapy and withhold Herceptin in patients with metastatic disease for clinically significant decrease in left ventricular function.
- Cardiac assessments, as performed at baseline, should be repeated every 3 months during trastuzumab treatment.
- Please adhere to the stopping rules as detailed in the Herceptin (trastuzumab) SPC: Posology and method of administration, including cases when LVEF percentage drops  $\geq 10$  percent points from baseline AND to below 50%, trastuzumab treatment should be suspended and a repeat LVEF assessment performed within approximately 3 weeks.
- Trastuzumab and anthracyclines should not be given concurrently in combination in the metastatic breast cancer (MBC) setting and in the adjuvant breast cancer treatment setting. Refer to Herceptin SPC: Special warnings and precautions for use.
- Continue monitoring every 6 months following discontinuation of trastuzumab treatment until 24 months from the last administration of trastuzumab. In patients who receive anthracycline-containing chemotherapy, further monitoring is recommended, and should occur yearly up to 5 years from the last administration of trastuzumab, or longer if a continuous decrease of LVEF is observed.
- If symptomatic cardiac failure develops during trastuzumab therapy, it should be treated with standard medicinal products for CHF. Most patients who developed CHF or asymptomatic cardiac dysfunction in pivotal trials improved with standard CHF treatment consisting of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) and a beta-blocker.
- LVEF measurement continues to be the required method to monitor cardiac function; biomarkers may be a supportive tool for patients specifically at risk to experience CHF but cannot replace LVEF assessment by ECHO or MUGA.

- Heart failure may be moderate to severe and lead to death. In addition, caution should be exercised in treating patients with increased cardiac risk (e.g. hypertension, documented coronary artery disease, congestive heart failure, diastolic dysfunction, and older age).
- Prescribing physicians should highlight to other physicians responsible for the follow-up of a trastuzumab treatment patient that it is important to continue regular cardiac monitoring as per the Herceptin (trastuzumab) SPC.

### **Background for this Cardiac Monitoring Reminder**

Although there are no new cardiac safety risk signals with trastuzumab therapy, results from surveys have shown that adherence to cardiac monitoring could be improved to reduce the frequency and severity of left ventricular dysfunction and CHF in patients treated with trastuzumab therapy.

Cardiac risk of trastuzumab therapy has been shown to be reversible in some patients upon discontinuation of trastuzumab treatment, underscoring the importance of monitoring LVEF function of patients during trastuzumab treatment and after trastuzumab treatment discontinuation.

### **Further Information**

#### Therapeutic Indications:

As per the currently approved Herceptin (trastuzumab) SPC, Herceptin should only be used in patients with metastatic or early breast cancer and metastatic gastric cancer whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay.

#### ***Call for reporting***

As a reminder, there is a need to report any suspected adverse reactions suspected to be associated with the use of Herceptin to:

#### Roche Pharmacovigilance Department:

Telephone: +966 11 4545039

Email: [jeddah.drug\\_safety@roche.com](mailto:jeddah.drug_safety@roche.com)

Fax: +966 11 4545896

Or, report to SFDA:

The National Pharmacovigilance and Drug Safety Centre NPC:

Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)

Fax: +966112057662

Toll free phone: 8002490000

Online: <https://ade.sfda.gov.sa/>

#### ***Company contact point***

Should you have any questions regarding the use of Herceptin, please feel free to contact us at:

Telephone: +966 11 4545039

Fax: +966 11 4545896

Website: [www.roche.com](http://www.roche.com)

Sincerely,

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Qualified Person Responsible for Pharmacovigilance

