GASTRIC CANCER: HER2 TREATMENTS

A checklist addressing questions patients with gastric cancer may have about HER2 treatments

1. What are the treatment options for HER2 positive (HER2+) gastric cancer?

Current guidelines recommend a targeted therapy drug with an active substance called **trastuzumab** plus **chemotherapy** for patients with HER2+ gastric cancer. Following treatment with trastuzumab, another biological drug, **fam-trastuzumab deruxtecan** may be suggested.[1]

2. What is trastuzumab and how does it work?

Trastuzumab is classified as a **monoclonal antibody, biologic drug**. Trastuzumab works by attaching itself to the HER2 proteins on the cell surface. It stops the signaling responsible for cancer cells to grow, divide, and spread and encourages your body's immune cells to attack and destroy the cancer cells.

3. What is fam-trastuzumab deruxtecan and how does it work?

Fam-trastuzumab deruxtecan is classified as a **monoclonal antibody, biologic drug**; trastuzumab is conjugated or connected with a chemotherapy drug, creating an **antibody-drug conjugate (ADC)**. Fam-trastuzumab deruxtecan binds the trastuzumab antibody to the HER2 proteins on cancer cells, delivering chemotherapy directly into the cancer cells, to destroy them, while limiting damage to healthy cells. This approach may be considered after treatment with trastuzumab.

4. What are biologics?

Biological medicines, also called biologics, are big molecules that are produced in living cells or organisms. They have a complicated structure and are complex to manufacture. In digestive cancers, biologics are used as **immunotherapy** and **targeted therapy** treatments.

A biologic with an active substance not previously used to treat any disease is known as an originator. Originators are patented, and when the patent expires, usually after some 15–20 years, other new products with the same active substance can enter the market. These new products are known as biosimilars.

5. What are biosimilars?

A **biosimilar** is a biological medicine that has essentially the same active substance and the same indication as the originator.

Biosimilars are as **safe** and **effective** as the originators, they are assessed by the **European Medicines Agency (EMA)**, the EU body responsible for the evaluation and supervision of medicinal products, and are approved if they comply with the same strict regulatory requirements applied to all biological medicines. The EMA monitors the safety and efficacy of biosimilars before approval and then continuously.

When it comes to the treatment of advanced gastric cancer, the EMA initially approved the **biologic originator** with the active substance called **trastuzumab**. Currently, EMA has approved six trastuzumab biosimilars (as of November, 2022).

6. Are biosimilars the same as generics?

No. **Generics** have a simple structure and contain exact copies of chemically made active substances. Unlike generics, all biologics, including biosimilars, are made in living cells, so no two batches of any biologic are the same. This is normal and tightly controlled. Both biosimilars and generics are versions of brand-name products with the same efficacy and safety.

1. Lordick, F. *et al*. Gastric cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. *Annals of Oncology* (2022)

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7. What are the benefits of using a (trastuzumab) biosimilar?

There are no additional treatment benefits when using biosimilars compared to the originator. **Both are equally safe and effective.** Biosimilars have been proven to be advantageous to European health systems, hospitals, and ultimately the patient community, as they contribute to more **sustainable** and **affordable** healthcare systems.

The use of biosimilars offers the opportunity for:

- funding new, innovative treatments for patients, using released resources to improve patient support programs, hiring additional nurses in the hospital, or investing in new treatment and research
- helping reduce the waiting time to be treated
- more patients to have access to biological treatments

8. What are the downsides of biosimilars?

There are **no downsides** to using biosimilars.

9. What is switching?

A **change between two products** with the **same active substance** is called switching. For example, switching occurs if you have been treated with the originator and your physician proposes to replace the originator with a biosimilar. Switching does not result in treatment change.

The efficacy of a biosimilar is the same as that of the originator. Your treatment will continue to be the same in terms of **quality**, **safety**, and **efficacy**. After the switch, your disease progression and treatment efficacy will continue to be monitored as before. As with any biological treatment, you should always report any unexpected side effects.

10. Will I have any additional side effect(s)?

No. Biosimilars and originators cause the same **side effects**, all of which are included in the package insert description. As for any treatment, if you believe you are experiencing any additional side effect(s), you should contact and discuss this with your physician and/or your pharmacist.

Remember:

- ☐ **Use simple language when explaining medical terminology.**
- ☐ **Choose a private and quiet place for the discussion.**
- ☐ **Tailor your messages to the patient and consider specific factors when talking about biosimilars, such as the patient's age or cultural background.**
- ☐ **When describing biosimilars, emphasise that there are no differences compared to originators in terms of quality, safety, and efficacy. If the conversation leads to it, outline the benefits biosimilars offer to patients and the healthcare systems.**
- ☐ **Answer questions until the patient begins to understand how the treatment works. Encourage the patient and his/her family to ask additional questions.**
- ☐ **For any further questions, provide the patient with a healthcare professional's updated contact details.**
- ☐ **Provide the patient with reliable and trustworthy information/tools on biosimilars (e.g. DiCE's information booklet for patients with gastric cancer and the Biosimilar Medicines Information For Patients document by the European Commission).**

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