Canadian Breast Cancer Network
Réseau canadien du cancer du sein

FACT SHEET

BIOSIMILARS FOR BREAST CANCER

Recently, there has been a lot of discussion around the use of "biosimilars" for cancer treatment. But for many patients, biosimilars are a new and unfamiliar term. What exactly does it mean to be treated with a biosimilar and how will these new therapies impact cancer treatment in Canada?

SIMILAR BUT DIFFERENT

Many treatments for cancer and other diseases are known as biologic drugs. These are therapies that come from living organisms or their cells and whose development process is complex and involving many stages. Biologic therapies tend to be large, complex molecules that cannot be chemically produced.

Biosimilar products on the other hand, are defined as drugs that are thought to be highly similar to a biologic drug that has already been approved for sale (also known as a reference product). Unlike generic drugs, which are chemically identical to an existing drug, biosimilars are similar to their reference products, but due to their large size and complexity are not actually identical.

BIOSIMILARS IN CANCER

Biosimilars have been used for the treatment of a number of diseases over the years. Health Canada has approved biosimilar treatments for arthritis, ankylosing spondylitis, psoriasis, ulcerative colitis and Crohn's disease. Currently the majority of biosimilars available for use in cancer are in the supportive care setting, but their use for cancer treatment is expected to increase over time.

The FDA in the United States has already approved two biosimilars for cancer treatment in 2017, including one for breast cancer, and it is expected that these treatments will be entering the Canadian market soon.

HOW ARE BIOSIMILARS REGULATED IN CANADA?

Health Canada has developed guidelines to promote the quality, safety and efficacy of biosimilars. Health Canada requires information from the biosimilar manufacturer that shows that the biosimilar treatment has comparable characteristics and efficacy as the original biologic drug. Health Canada looks at ensuring the similarity between the biosimilar and its reference treatment, so the type of data required for a biosimilar to be approved is different from the information needed for a new biologic treatment.

In certain circumstances, Health Canada may determine that a biosimilar is so close in

structure, safety and efficacy to the reference product, that they may approve a biosimilar for the treatment of multiple medical conditions or diseases, even if no clinical studies have been done. Health Canada can also reject the approval of a biosimilar for a specific condition or disease type, if they believe there are scientific and benefit/risk-based considerations. Health Canada also requires all manufacturers to submit a risk-management plan for any biologic, including biosimilars. Once a biosimilar is authorized, manufacturers are responsible for monitoring reported side effects, updating Health Canada with studies on new safety information, and requesting authorization for any changes in the manufacturing process, the dose regimen and the recommended usage of the drug.

WHAT DO PATIENTS NEED TO KNOW?

Since biosimilars are so new to the Canadian market, health providers and patient organizations have raised questions about how they will be used to treat patients:

Interchangeability:

There are concerns that with the availability of biosimilars, patients may have their current treatments switched over to a biosimilar without a physician or the patient's explicit knowledge. There are concerns that this type of substitution could impact a patient's health and further information is needed to guide the use of biosimilars in a patient's treatment plan.

Coverage:

Patients access their treatments through a number of different methods, including public provincial drug coverage and private insurance. There are concerns that the separate coverage plans across Canada may reimburse and cover treatments, including biosimilars, very differently. As a result, patients may have their treatment options limited to the criteria that is determined by their specific insurance plan. If a patient changes insurance providers, their treatment options may also be further restricted.

There is also lot of anticipation around what biosimilars may be able to offer patients in terms of treatment:

Affordability:

One of the most touted benefits of biosimilar treatments are the expected cost-savings they could offer to the Canadian health care system. Estimates range between 20-30 percent reductions in cost compared to the reference drug which could increase the accessibility of treatments for patients.

Availability:

It is hoped that biosimilar therapies could also offer greater availability than a reference product. For example, in situations where there is a shortage or high demand of a reference drug, biosimilar manufacturing could potentially help alleviate the scarcity of a treatment.

Greater choice in treatment:

The availability of safe and effective biosimilars could offer patients and healthcare providers with greater choice in treatment options and expand patient access to certain treatments.