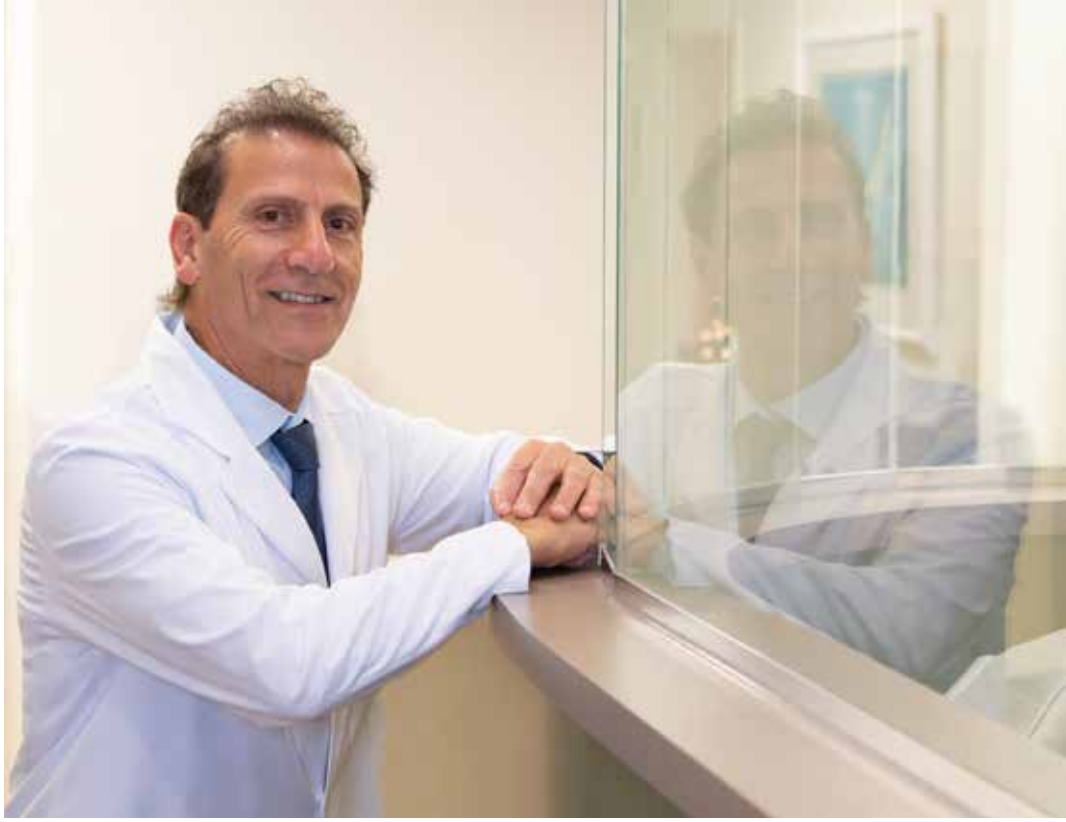
The Rising Appeal of Biosimilar Drugs

When we think of manufactured drugs, we usually picture mass-produced pills made with compounds under tightly controlled conditions.

A more recent trend is the use of biologic drugs that are grown in a lab from living sources – typically proteins from human genes or other living organisms – and are used to prevent, treat or cure a variety of diseases, including cancer. Although these "biologics" have been around for more than 100 years with the use of vaccines and insulin, their popularity has grown dramatically since the 1980s as they offer new options to target the immune system or other biological processes at the cellular level.

A new branch of biologic drugs known as biosimilar drugs has come along just within the past few years that further expands the choices doctors and patients have in treating various conditions. Like other biologics, biosimilar drugs come from cultures of living cells whose genes (DNA) can help treat or reverse a medical condition. Although few patients are familiar with biosimilars, the treatments are becoming an increasingly popular choice.

The U.S. Food and Drug Administration has already approved the use of 23 biosimilars, most of them in recent years, based on favorable studies of their effectiveness; some are not yet available commercially.



Two authorities on the subject, Melody Chang, RPh, MBA, BCOP and Dr. Jorge Ayub, were asked to shed some light on this growing field of medicine. Chang is a Board-certified oncology pharmacist and the director of pharmacy operations at Florida Cancer Specialists & Research Institute (FCS). Dr. Ayub is an FCS hematologist and oncologist based in New Port Richey, Florida.

What do you want people to know about biosimilar drugs?

Chang: Biosimilars are essential to oncology care. They are the top drug expenditures for most outpatient clinics. As more biosimilars come to market in the next several years, their use in oncology will play a very important role. There is also a greater need for education among key stakeholders – physicians, nurses, pharmacists, payers and patients – to ensure their appropriate use.

Ayub: Biosimilars are important because they offer patients more treatment options at a lower cost.

Cost is a big advantage. Are there other advantages?

Chang: In addition to cost savings and increasing patients' access to biologics, more biosimilar competition means more opportunities for quality improvement in the manufacturing process. This could impact medication safety in a positive way.

Ayub: Another main advantage is they provide increased access to this important family of drugs.

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How equivalent are they to the original, or name-brand, drug?

Ayub: The drugs are highly similar but not the same, and they produce equivalent results. There are no meaningful differences in clinical outcomes. The features that they share are very important and include the amino acids sequence and the mechanism of action. Before approval, they have to demonstrate no clinically meaningful differences between a biosimilar and the reference product in terms of safety, purity and potency.

Why can't they be called generic drugs?

Chang: Generic drugs are chemically synthesized, with small molecular weight and are completely identical. In contrast, like all biological products, biosimilars are produced by living cells or organisms. They are complex in structure and large in molecule, and thus are usually not fully characterized and definitely not identical.

Ayub: They are not the same compound as the brand name.

But they accomplish the same therapeutic and clinical results?

Chang: Until a biosimilar can be deemed "interchangeable" by the FDA, we cannot declare that they have the same therapeutic and clinical results in any given patient. We can only say that they will have no meaningful differences in the safety and efficacy of the clinical results.

Ayub: Biosimilar manufacturers have to collect data showing that they are comparable to the reference product.

Who should inquire about whether biosimilar drugs are a better option, patients or their doctors?

Ayub: The best individual to decide is the physician caring for the patient.

Chang: I agree that physicians are best equipped to help their patients understand the complexities of biosimilars and help them make decisions in their best interest.

When should patients rule out using a biosimilar drug?

Chang: If a patient has a sensitivity to a name-brand product, they should rule out using its biosimilar(s).

Ayub: If a patient doesn't feel comfortable using this option, then I wouldn't recommend it. +

Biosimilar Drugs Available at Florida Cancer Specialists

FCS currently administers several biosimilar drugs to treat various cancers or other disorders such as:

Cervical cancer; colorectal cancer; glioblastoma; NSCLC (non-small cell lung cancer); renal cell cancer

Anemia due to:
a) chronic kidney disease with or without hemodialysis
b) zidovudine
c) chemotherapy; reduction of red blood cell transfusions in surgery

HER2 (Human Epidermal Growth Factor Receptor 2) + breast cancer; HER2 + gastric or esophageal junction adenocarcinoma

To decrease infection/FN (febrile neutropenia) in patients receiving chemotherapy; reduce time to neutrophil recovery and duration of fever after acute myeloid leukemia induction/consolidation; reduce duration of neutropenia/febrile neutropenia in patients with non-myeloid diagnosis undergoing bone marrow transplantation; mobilization for peripheral stem cell collection; reduce incidence and duration of severe neutropenia