Nursing Roles

Clinical implications regarding trends, administration, and education for biosimilars in oncology practice

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BACKGROUND: With the advent of biosimilars into the U.S. healthcare market, knowledge deficits exist for nurses and patients regarding the regulatory approval process and key nursing considerations for each of these new medications.

OBJECTIVES: This article provides essential clinical information for oncology nurses who are directly involved in patient care who will be administering U.S. Food and Drug Administration (FDA)–approved biosimilars for oncologic use. Oncology nurses must be informed on their therapeutic uses, mechanisms of action, and administration considerations.

METHODS: An overview of biosimilars in the United States is given, and each FDA-approved oncology biosimilar medication is described in detail.

FINDINGS: Oncology biosimilars are safe and effective treatment options that may increase patient access, decrease healthcare costs through competition, and improve the lives of patients with certain malignancies. Nurses are in key roles in patient care to foster the transition from previously patented, branded, and expensive medications to biosimilars that can achieve the same desired effects for a lower cost.

KEYWORDS
oncology; biosimilars; nursing; clinical implications

DIGITAL OBJECT IDENTIFIER
10.1188/18.CJON.S1.21-26

ALTHOUGH 12 BIOSIMILARS ARE APPROVED by the U.S. Food and Drug Administration (FDA) for mostly autoimmune, treatment-related side effects and other chronic disease indications, only six have been approved for oncologic use in the United States as of September 2018 (Panesar, 2016; FDA, 2018). The current article will discuss clinical implications on trends, administration, and education for the first three oncologic biosimilars approved by the FDA: filgrastim-sndz (Zarxio®), trastuzumab-dkst (Ogivri™), and bevacizumab-awwb (Mvasi™). Although approved, trastuzumab-dkst and bevacizumab-awwb will not be available in the U.S. market because of patent issues with the reference biologics until June or July 2019, respectively.

Overview of Filgrastim-sndz (Zarxio®)

Granulocyte–colony-stimulating factor (G-CSF) is a glycoprotein that stimulates the bone marrow to produce granulocytes and stem cells that go through a process of development, differentiation, and maturation and are then released into the bloodstream (Panopoulos & Watowich, 2008). Granulocytes include neutrophils (the most abundant), eosinophils, basophils, and mast cells. Once in the bloodstream, these cells have important immune functions to protect and survey the blood and body for foreign invaders (e.g., bacteria, parasites), promote inflammation, and eliminate these threats through phagocytosis. G-CSFs stimulate neutrophil progenitors by binding to specific cell-surface receptors that, in turn, stimulate growth, differentiation, and commitment of neutrophils with a resultant increase in circulating blood concentrations that ward off potential infections and potentially sepsis (Singh, Newman, & Seed, 2015).

Filgrastim (Neupogen®) is a recombinant human G-CSF that is synthesized using *Escherichia coli*, whose structure varies slightly from the natural glycoprotein and requires daily subcutaneous injections or dosing. Pegfilgrastim (Neulasta®) is another commercially available form of recombinant human G-CSF that has a much longer half-life, which allows the benefit and ease of once-a-cycle subcutaneous injection or dosing. Filgrastim-sndz (Zarxio) is the biosimilar medication mimicking the effects of filgrastim, or recombinant human G-CSF. Filgrastim-sndz was FDA-approved as a biosimilar on March 6, 2015, for patients with nonmyeloid cancers who receive myelosuppressive chemotherapy to decrease the incidence of infection, as manifested by febrile neutropenia (Sandoz, Inc., 2015) and is available in the U.S. market.

Filgrastim-sndz injection is a sterile, clear, colorless to slightly yellow, preservative-free liquid. Filgrastim-sndz is dosed at 5 mcg/kg per day