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Rituximab and biosimilars: Equivalence and reciprocity

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Cancer is a debilitating disease affecting millions of people daily. Over the years cancer treatment has advanced in leaps and bounds. Antibodies are important breakthrough therapeutic agents for cancer. These agents, proteins produced by B lymphocytes of the immune system in response to antigens, bind to receptors on cell surfaces so that the antigen-antibody complexes can be recognized and destroyed by phagocytes. While each B cell synthesizes only one kind of antibody, an entire population of different types of B cells and their respective antibodies are produced in response to various antigens to which the organism had been exposed. However to be useful clinically, substantial amounts of a single antibody must be generated from a single ancestral B cell. These populations of antibodies produced by a specific population of B cells are the monoclonal antibodies that have become the cornerstone of treatment for cancer and many immunologic illnesses. The purpose of this report is to provide an overview of the clinical development of biosimilars in clinical oncology focusing on rituximab and like biosimilars.

Biography

Charles L. Bennett, M.D., Ph.D., M.P.P., is a hematologist and oncologist whose research focuses on preventing adverse drug events and improving drug safety. An international expert in his field, Bennett was recruited in Spring 2010 as the new endowed chair of the South Carolina Center for Economic Excellence (CoEE) in Medication Safety and Efficacy and the Josie M. Fletcher Professor of Pharmacy at the University of South Carolina (USC) campus of the South Carolina College of Pharmacy. The Medication Safety and Efficacy program which Bennett leads works to prevent adverse drug effects (ADEs) and to improve drug safety. The Center was created in 2005 to study the effects of prescription and over-the-counter medications, particularly on children and the elderly. Dr. Bennett, along with his team at the Medication Safety and Efficacy CoEE, will be developing technology that has high likelihood of commercialization, will look for ways to make drug information more consumer-friendly, and will create new training tools for health care providers.

His work has identified fatal side effects for 50 blockbuster pharmaceuticals and resulted in over 100,000 lives saved. The manufacturers include General Electric, AMGEN, Pfizer, Wyeth, Novartis, Roche, and Johnson and Johnson, the products life-time sales are > $100 billion, and savings resulting from these studies are >$10 billion. He has published 400 manuscripts in such journals as the New England Journal of Medicine, Lancet, JAMA, Annals of Internal Medicine, JAMA: Internal Medicine, Journal of Clinical Oncology, Blood, Urology, Journal of the National Cancer Institute, and the British Journal of Haematology.

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