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Pharmacovigilance in cancer medicine

Luis H Camacho
Center for Oncology and Blood Disorders, USA

Biologicals are critical in cancer medicine. Four of the top ten biological blockbusters worldwide are oncology drugs used for therapeutic or supportive care. The global market for biologic cancer therapies approximately totalled US$ 51.2 billion in 2014 and is expected to reach US$ 66.4 billion in 2019. Since the patents for most of these top-selling agents will expire by the year 2020, industry will turn to develop. In fact, manufacturing biosimilars is more cost and time effective than developing their reference products. However, the postmarketing safety monitoring is among many concerns surrounding the field of biosimilars in oncology. A PUBMED search for safety reports of the top three top cancer biologicals with upcoming patient expiration demonstrated only between two and eighteen publications since their FDA approval over one decade ago. Interestingly, while the toxicities observed during the development of bevacizumab were similar to the pre-marketing experience, a greater incidence of neutropenia was described with rituximab and a higher incidence of heart failure when in combination with adriamycin was described with the use of trastuzumab in their postmarketing vigilance. Greater efforts to educate patients and healthcare providers to report AEs as well as requesting periodical dissemination and publication of reports by sponsors will be determinant to ensure the post-marketing safety of these agents and gaining the trust of health care providers. Ultimately, the responsibility for identifying safety signals in postmarketing should be shared by healthcare providers, sponsors, and regulatory agencies in Europe and the US.

Biography

Luis H Camacho, MD, MPH received his MD degree from The Universidad Militar Nueva Granada in Bogota Colombia and Internal Medicine at The George Washington University in Washington DC. He was subsequently trained in Medical Oncology and Hematology at Memorial Sloan-Kettering in New York. He has dedicated his career to clinical investigation and drug development. He has over 150 peer reviewed publications including scientific abstracts, original articles, and book chapters. He serves the board of several regional and national societies and committees. This year, he has joined organizing committee of Euro Biosimilars 2016.

lhcamacho@cobd.us

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