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Biosimilars in Oncology: Update Bulletin [Feb 2016]

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Abstracts

New KOL insights on the latest events that have the potential to shape the oncology biosimilars market. Topics covered include opinions about data from Sandoz's PROTECT 1 and PROTECT 2 studies which both compared the safety and efficacy of LA-EP2006 (a proposed pegfilgrastim biosimilar) to Amgen's Neulasta in patients with breast cancer; the regulatory filing of Celltrion's proposed rituximab biosimilar, CT-P10, to the European Medicines Agency (EMA), and the concerns KOLs have in relation to the potential for indication extrapolation from the rheumatology to oncology settings; the potential impact of The Centers for Medicare & Medicaid Services's (CMS) final rule on how it plans to reimburse for biosimilars covered under Medicare Part B in the US.

Key Questions Answered in this Update Bulletin:

Does the data from the PROTECT 1 and PROTECT 2 studies for Sandoz's LA-EP2006 (a proposed pegfilgrastim biosimilar) support its wider use in the oncology setting, and will payers or switching be the key driver of product utilisation?

Will Amgen's Neulasta OnPro kit slow down the adoption of pegfilgrastim biosimilars in the US, or will cost-effective biosimilars prompt payers to stop its reimbursement?

How concerned are KOLs that Celltrion's proposed rituximab biosimilar, CT-P10, could be awarded key oncology indications by extrapolation, and how could this effect product adoption?

Will the attraction of a cost-effective rituximab biosimilar prompt payers to stop the reimbursement of subcutaneous MabThera in Europe, or will the product's dosing and patient convenience benefits continue to support access?

Where will new biosimilar reimbursement rules have the most impact in the US;

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academic or community oncology clinics? Moreover, do KOLs believe that new CMS rules will drive down prices to unsustainable levels and cause the biosimilars market in the US to fail?

Update Bulletins include expert insight and analysis based on FirstWord analyst re-engagement with the KOLs after major events such as product approvals, key data releases and major conferences to deliver the most valuable insights with each update.

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